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Sustaining the implementation of evidence-based interventions in clinical and community settings

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Published in
Frontiers in Health Services

ISSN 1664-8714
ISBN 978-2-83252-125-0
DOI 10.3389/978-2-83252-125-0

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Sustaining the implementation of evidence-based interventions in clinical and community settings

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Citation

Nathan, N., Hailemariam, M., Hall, A., Shelton, R. C., Laur, C., eds. (2023). *Sustaining the implementation of evidence-based interventions in clinical and community Settings*. Lausanne: Frontiers Media SA. doi: 10.3389/978-2-83252-125-0

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frontiers | Frontiers in Health Services

TYPE Editorial
PUBLISHED 24 March 2023
DOI 10.3389/frhs.2023.1176023

OPEN ACCESS

EDITED AND REVIEWED BY
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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 28 February 2023
ACCEPTED 09 March 2023
PUBLISHED 24 March 2023

CITATION
Nathan N, Shelton RC, Laur CV, Hailemariam M and Hall A (2023) Editorial: Sustaining the implementation of evidence-based interventions in clinical and community settings.
Front. Health Serv. 3:1176023.
doi: 10.3389/frhs.2023.1176023

Editorial: Sustaining the implementation of evidence-based interventions in clinical and community settings

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KEYWORDS

sustainability, sustainment, future direction, community settings, clinical settings, sustainability strategies, measurement

Editorial on the Research Topic
Sustaining the implementation of evidence-based interventions in clinical and community settings

Introduction

For the last few decades, the science of how best to implement effective Evidence Based Interventions (EBIs) has become an important focus in health services research (1). Accordingly, we have seen significant improvements in the adoption and implementation of EBIs in both clinical and community settings, leading to improvements in health outcomes and healthcare delivery (2, 3). For example, a review by Cassidy et al. of 41 studies found that multi-strategy interventions were effective at implementing guidelines in nursing which had positive effects on patient health status outcomes (3).

The public health impact of such EBIs and their equitable delivery and impact is however dependent upon how well and for how long they are implemented (4). For example, modelling of Australian government obesity targets suggests it will require the sustained implementation of a number of effective EBIs for at least a decade to achieve these targets (5). However, evidence from systematic reviews suggest that only 23% of public health and clinical interventions are sustained two years after initial implementation resulting in reduced health benefit (6). This has led sustainability to be identified as "one of the most significant translational research problems of our time" (7). As less than 1% of research in the last decade has focused on sustainability (6, 8), this Research Topic set out to encourage research that has explored the issue of sustainability (sustained impact and delivery of EBIs over time) across a diverse range of settings and health topics. Collectively, these 14 papers offer some key insights into the

challenges, possible solutions, and future research needed within the field of sustainability science including:

1. *Design for sustainment from the outset.*

A common theme within this Research Topic was the importance of planning for sustainability from the start of implementation efforts. Two important pre-implementation steps identified were: (i) involving key knowledge users early in the planning process to ensure that they value and have a sense of ownership over the intervention; and (ii) integrating the EBI into existing systems and structures within the organisation.

For example, the study by Swindle et al. found in a survey of Early Care and Education Directors who had implemented a nutrition intervention that continued use of the program was associated with (i) their perception that the EBI was better than alternative programs and (ii) the EBI was integrated into centre schedules and routines. In our paper (Nathan et al.), published in this Research Topic, we propose a compilation of strategies that could be considered to support sustainability, highlighting that many should be considered at earlier phases of the implementation process, rather than planning for and instigating sustainability during the sustainability phase only. Despite the importance of planning early for sustainability it does not yet seem to be common practice, as shown in the review by Engelhart et al. where planning for sustainability was often not addressed or was deficient. If we are to successfully sustain EBI delivery post-active implementation, we need to work towards actively planning for sustainability as early as possible.

2. *Engaged and supportive leadership team is essential for sustainability*

Several studies included in this Research Topic identified the vital role leadership support plays in the sustainability of EBIs, including those by Nadalin Penno et al., Agulnik et al. Love et al. and McLoughlin et al. Demonstrable support from organisational leadership seems particularly pertinent for successful sustainability of EBIs. Ways leadership can actively engage and demonstrate their support for EBI sustainment were identified in the study by Agulnik et al. and included strategies such as: provision of physical resources (e.g., financial support, equipment), active support for implementation (e.g., ensure staff are trained in the EBI or ratify institutional policies for the EBI) or publicly endorsing the EBI (e.g., acknowledging staff for their work or attending team meetings). Future efforts to sustain EBIs should endeavour to actively engage organisational leaders early, and may consider encouraging leadership to employ such strategies to demonstrate their support for EBI sustainment.

3. *Ongoing access to education and training is needed to sustain EBI implementation*

Training is a common implementation strategy used to enhance the knowledge and skills of clinicians, or those working in community settings, to effectively implement EBIs. Systematic reviews of the sustainability of EBIs have however consistently found that staff turnover is a key determinant to EBI sustainment (9, 10). High staff turnover can significantly impact an organisations ability to continue to deliver an EBI, as there is a loss of corporate knowledge when trained staff leave, while new staff may have limited understanding of the need for the EBI or competence to effectively deliver it. Implementation researchers and practitioners may therefore need to consider how, after once active implementation support has ceased, new staff to the organisation will be trained to deliver the intervention with enough fidelity to ensure sustained delivery and impact. The importance of staff training to sustainability was identified by multiple studies in this Research Topic, including those conducted by: Rakhra et al. Siegal et al. Love et al. and McLoughlin et al. Strategies that may be effective include incorporating training into orientation processes for new staff and offering booster sessions for existing staff, employing low cost training modalities i.e., online training, creating handover manuals or forming communities of practice within and between organisations (10, 11).

4. *Routine monitoring of EBI delivery can facilitate sustainability*

Monitoring the continued and equitable delivery of an EBI once the implementation phase has ended is crucial for sustainability (12), although not yet common practice. This highlights a current limitation of the field to routinely monitor and report EBI delivery to facilitate sustainability. Whilst we know that most EBI implementation attenuates over time (13), little is known as to when or how quickly such reductions occur. Routine monitoring of EBI implementation would enable agencies to identify when and what kind of support may be needed in order to ensure that the EBI continues to be delivered over time, and reaches a diverse range of settings and populations. Central to any monitoring system is the use of valid and reliable measures (13).

However, inconsistencies in how sustainability is defined and measured seems to be a significant limitation in the field. For example, the review by Engelhart et al. found that the variation in the definitions and methods used to measure sustainability impacted the ability to gather high quality and generalizable information on the sustainability of breastfeeding interventions in low- and middle-income countries. To ensure accurate monitoring and understanding of sustainability, it is imperative the field moves towards developing and using valid, reliable and standardised measures of sustainability (14). A recent comprehensive review by Hall et al. evaluated various measures of sustainability and sustainability determinants relevant to clinical and community settings (13). Efforts like these may help guide those developing monitoring systems in their selection of robust, pragmatic measures.

Conclusion

Failure to sustain implementation of effective EBIs wastes the considerable health system investment required to achieve initial implementation, often results in organisations regressing to pre-implementation levels, and reduces partners trust and willingness to engage in future initiatives (1). Therefore, as policy-makers, practitioners and researchers we have a responsibility to ensure that we think carefully about the EBIs we select for implementation and then how (if at all) we plan to support its

ongoing implementation before we invest scarce public health dollars into its implementation. Encouragingly, this Research Topic suggests that work is being done across contexts and health issues to answer pressing issues in the field. Collectively, the included studies highlights some important future directions that those working in the field may consider for research and practice, in particular: identify, describe and rigorously test the effectiveness of sustainability strategies in clinical and community settings, determine methods or processes for establishing monitoring systems and describe how existing or new measures or tools are applied in sustainability research.

Author contributions

NN lead the drafting of the manuscript with all authors contributing equally. All authors contributed to the article and approved the submitted version.

Funding

This project is funded through the NHMRC as part of NN's Medical Research Future Fund (MRFF) Investigator Grant (GS2000053). Funding was also provided through NHMRC (APP1153479) National Centre of Implementation Science. The contents are the responsibility of the authors and do not reflect the views of the NHMRC. The funders had no role in the study design, conduct of the study, analysis, or dissemination of findings.

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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ORIGINAL RESEARCH
published: 28 April 2022
doi: 10.3389/frhs.2022.881639

Evaluation of a Large-Scale School Wellness Intervention Through the Consolidated Framework for Implementation Research (CFIR): Implications for Dissemination and Sustainability

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OPEN ACCESS

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Specialty section:
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

Received: 22 February 2022
Accepted: 06 April 2022
Published: 28 April 2022

Citation:
McLoughlin GM, Sweeney R, Liechty L, Lee JA, Rosenkranz RR and Welk GJ (2022) Evaluation of a Large-Scale School Wellness Intervention Through the Consolidated Framework for Implementation Research (CFIR): Implications for Dissemination and Sustainability. Front. Health Serv. 2:881639. doi: 10.3389/frhs.2022.881639

Background: Numerous studies have tested school-based interventions promoting healthy behaviors in youth, but few have integrated dissemination and implementation (D&I) frameworks. Using D&I frameworks can inform if and how an evidence-based intervention is implemented and maintained and provide strategies to address contextual barriers. Such application is necessary to understand how and why interventions are sustained over time. We evaluated a school wellness initiative called SWITCH® (School Wellness Integration Targeting Child Health) to (1) assess implementation outcomes of adoption, fidelity, and penetration, (2) discern implementation determinants through the Consolidated Framework for Implementation Research (CFIR), and (3) examine differences among inexperienced and experienced schools and influential factors to sustainment.

Methods: A total of 52 schools from Iowa, United States enrolled in the 2019–2020 iteration of SWITCH (22 inexperienced; 30 experienced). The CFIR guided the adaptation of mixed methods data collection and analysis protocols for school settings. Specific attention was focused on (1) fidelity to core elements; (2) adoption of best practices; and (3) penetration of behavior change practices. Determinants were investigated through in-depth qualitative interviews and readiness surveys with implementation leaders. A systematic process was used to score CFIR domains (between −2 and +2) indicating positive or negative influence. Independent *t*-tests were conducted to capture differences between samples, followed by a cross-case analysis to compare determinants data. Inductive coding yielded themes related to sustainment of SWITCH beyond formal implementation support.

Results: Experienced schools had higher scores on fidelity/compliance ($t = -1.86$ $p = 0.07$) and adoption ($t = -2.03$ $p = 0.04$). CFIR determinants of innovation source, culture, relative priority, and leadership engagement were positive implementation determinants, whereas tension for change and networks and communications were negative determinants. Distinguishing factors between experienced and inexperienced schools were Readiness for Implementation and Self-efficacy (experienced significantly higher; $p < 0.05$). Strategies to enhance sustainability were increasing student awareness/advocacy, keeping it simple, and integrating into school culture.

Conclusions: Findings provide specific insights related to SWITCH implementation and sustainability but more generalized insights about the type of support needed to help schools implement and sustain school wellness programming. Tailoring implementation support to both inexperienced and experienced settings will ultimately enhance dissemination and sustainability of evidence-based interventions.

Keywords: dissemination, implementation, sustainability, children, health promotion, obesity prevention, school wellness

INTRODUCTION

School-based health promotion interventions have been shown to have a positive impact on promoting student physical activity and nutrition behaviors (1–5); however, systematic application of dissemination and implementation science (D&I) frameworks are needed to advance the gap between research and practice (6, 7). Furthermore, despite the promise of comprehensive programs, limited research exists to illustrate steps to sustain programs over time (8, 9). Particular emphasis is needed to evaluate strategies aimed at building capacity in school systems since programming is a shared responsibility. Without guidance on how to sustain interventions, school leaders are likely to abandon programming over time, leading to diminished impacts on children's health and well-being.

The present paper reports on the capacity-building process employed in a school wellness initiative called SWITCH® (School Wellness Integration Targeting Child Health). The initiative was built on the foundation of an evidence-based obesity prevention program called Switch that worked through schools to help students "*switch what they do, view, and chew*" (10–12). Through a United States Department of Agriculture (USDA) grant, emphasis shifted to building capacity in schools to independently coordinate and sustain school wellness programming based on Switch. Formalized D&I strategies were critical in facilitating the transition from an evidence-based program (i.e., Switch) to an evidence-based process (i.e., SWITCH) for sustaining health promotion in schools. Schools self-enroll in a cyclical training (Fall) and implementation (Spring) process which prepares them to develop a comprehensive approach to student health promotion (physical activity, screen time, nutrition behaviors). The process is aimed at helping schools to meet mandates such as the USDA final rule, which tasks schools with developing and evaluating school wellness programs and policies (13, 14).

Foundational research by our team documented the feasibility of training school leaders (15), the acceptability of educational modules for classroom, physical education, and lunchroom settings (16–18) and the validity of school readiness and wellness environment assessment tools (19, 20). Subsequent studies evaluated alternative implementation strategies (21), the levels of engagement by 4-H leaders (county-level Extension officers who facilitate local-level implementation) assisting in programming (22) and the factors that influenced implementation and scale-up (13). This most recent evaluation focused on capacity-building and highlighted changes in organizational readiness, reflecting prior literature and warranting its inclusion in subsequent evaluation (23–26). Guided by D&I principles, SWITCH programming has transitioned to be fully managed and coordinated by leaders within the state 4-H network who lead local-level programs and initiatives (https://www.iowaswitch.org/). The established infrastructure provides an ideal model to understand the factors influencing implementation and sustainability of school wellness programming.

The Consolidated Framework for Implementation Research (CFIR) (27, 28), referred to as a *determinants framework* in the D&I literature, offers specific advantages for a more comprehensive analyses of factors influencing implementation of SWITCH. Specifically, CFIR comprises 39 constructs housed within six key domains: Intervention Characteristics (factors within the intervention itself such as cost and complexity); Outer Setting (factors external to the implementation setting such as policy); Inner Setting (factors within organization such as networks, culture); Readiness for Implementation (organizational and individual capacity for implementation); Characteristics of Individuals (implementation leaders' confidence and motivations to implement); and Implementation Process (practices that facilitate implementation such as planning and executing). Such framework has been used predominantly in healthcare settings to investigate determinants of implementation (28–31), with growing application to

school and community settings (32, 33). The CFIR website (www.CFIRguide.org) provides comprehensive resources for researchers conducting qualitative and mixed methods evaluation to ground their analysis through systematic coding of interview/qualitative data to facilitate interpretation (31). The CFIR constructs guided several recent mixed method studies on the 2018–2019 iteration of SWITCH (13); however, it was not possible to fully integrate the interview and implementation outcome data and this hindered our ability to understand determinants that linked to specific implementation outcomes.

The present study on the 2019–2020 iteration of SWITCH employs an integrated mixed methods analysis, based on CFIR coding methods (23), to better understand the factors that influence implementation and sustainability of school wellness programming. The CFIR methodology has documented utility for clinical research (23, 28, 31), but this is one of the first systematic applications of CFIR mixed methods analysis methods for evaluating programming in community / school settings. The study builds directly on our past work (13) by seeking to understand the factors that explain variability in implementation effectiveness between experienced and inexperienced schools. Readiness for implementation has been identified as a barrier to *sustaining* evidence-based interventions in schools (9); but few studies have directly examined the relationships between implementation determinants (such as readiness) and outcomes in school-based health promotion research (34, 35). Addressing this gap was the main goal of the 2019–2020 iteration of SWITCH. Accordingly, this study had three primary aims:

1) To assess implementation outcomes of adoption, fidelity, and penetration of SWITCH.
2) To discern implementation determinants grounded in the CFIR through a deductive approach.
3) To examine the differences in outcomes and determinants among new and experienced schools, and influential factors to sustainment of SWITCH.

Results of this study will provide critical information which may help inform implementation strategies for scale-up and sustainability in school-based interventions.

MATERIALS AND METHODS

A mixed methods implementation study grounded in the CFIR was conducted to evaluate key outcomes, determinants, and nuanced relationships between these factors among new and experienced schools in the 2019–2020 cycle of SWITCH. Evaluation approaches followed recommended data collection and analytic methodologies of CFIR, developed by Damschroder and colleagues (27, 31). To our knowledge, this is one of the first documented adaptations of the CFIR mixed methods protocols with the goal of understanding relationships between implementation determinants and outcomes within a school health promotion context.

Participants and Procedures

A total of 52 schools enrolled in the 2019–2020 iteration of SWITCH (30 had prior experience and 22 had no previous exposure). Demographic information for these schools is shown in **Table 1**. The cyclical training (fall) and implementation (spring) process of SWITCH across the academic year facilitates a continuous quality improvement process (36), whereby feedback from schools and implementation outcome data drive modifications to the program each year. More information about the training process can be found in **Additional File 1**, our previously published article (13), and the program website (https://www.iowaswitch.org/). Briefly, schools were asked to form a wellness team which comprised three members of staff across different school settings (e.g., classroom teachers, physical education, food service, other teachers, administration, counselors, nurses, etc.) and to register prior to the beginning of the academic year. Following registration, schools were asked to attend a total of four webinars and an in-person conference during the fall semester, as well as complete several pre-program audit tools. The implementation phase spanned a 12-week period from January–April of 2020, but due to the coronavirus (COVID-19) outbreak, schools were forced to close in Iowa on March 13th thus forcing a transition to virtual communications/implementation after week 8 of the program. It was not possible to capture final outcome data, but schools completed the midpoint evaluation of school implementation. Below we outline data sources for implementation outcomes and determinants, and the steps taken to rigorously analyze these data.

Measurement of Implementation Outcomes: Adoption, Fidelity, and Penetration

The field of D&I offers many frameworks and theories to help researchers and practitioners discern why evidence-based practices are or are not implemented in routine care. Regarding *implementation outcomes* frameworks, the framework by Proctor and colleagues (37) conceptualized several distinctive outcomes that are important to include within implementation evaluations: (1) acceptability (the degree to which an innovation is a perceived good fit); (2) adoption (intent to implement); (3) appropriateness (degree of compatibility within setting); (4) cost (to implement, value for money); (5) feasibility (possibility of successful implementation); (6) fidelity/compliance (executed as intended); (7) penetration (reach within setting); and 8) sustainability (long-term impact). For the purpose of this study, we chose to examine the determinants of adoption, fidelity, and penetration among schools enrolled in SWITCH due to the heavily integrated implementation practices needed to create systems change in the school setting.

Adoption is operationalized by Proctor and colleagues (37) as "intention, initial decision, or action to try or employ an innovation or evidence-based practice" (p. 69). Thus, we measured adoption through implementation surveys at the 6-week mark, examining uptake of best practices in various settings (use of curricular modules, posters, reinforced themes through discussion and tracking). Each best practice was scored as 0 (not at all implemented), 2 (somewhat implemented), and 3 (fully

TABLE 1 | School demographic information for the 2019–2020 Cohort.

	Free/reduced meals (%)		Racial/ethnic minority (%)		Enrollment		Experience (years)	
	Mean	***SD***	**Mean**	***SD***	**Mean**	***SD***	**Mean**	***SD***
Total ($n = 52$)	49.1	19.0	15.4	18.6	226.3	180.1	1.8	0.8
Inexperienced ($n = 22$)	50.7	21.9	20.0	21.5	224.6	200.5	NA	NA
Experienced ($n = 30$)	48.0	17.2	12.1	15.9	227.5	168.0	2.47	0.57

Free/reduced meals, percentage of students eligible for free/reduced meals; experience, years of experience in the program including present year (range 1–4). NA, not applicable.

implemented) and a summed score was generated based on the average of each component, to give possible range of 0–9.

Fidelity relates to "the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers" (p. 69) (37). The quality elements of SWITCH comprise; wellness team meeting (ideally at least once per week); using SWITCH website to promote student behavior tracking; engaging parents and other stakeholders; and integration of SWITCH modules/posters across the school setting. Fidelity therefore was calculated by using a summed score of quality elements which were scored the same way as best practices, giving a possible range of 0–12.

Finally, penetration is defined as the "integration of a practice within a service setting and its subsystems" (p.70) (37). This was calculated by determining the number of participants who used or interacted with an evidence-based practice, divided by the total number of participants eligible or within the sample. Since the behavioral tracking and goal setting interface is an integral component for students (38), it provides a good indicator of how many students are actively engaged in SWITCH within each school, thus providing data on penetration. We used data from SWITCH behavior tracking across weeks 1–8 (to account for COVID-19-related school closures). These data are presented as a decimal score (range 0–1.0, translated to 0–100%).

IMPLEMENTATION DETERMINANTS

Organizational Readiness

The School Wellness Readiness Assessment (SWRA) tool (20) was used to assess baseline readiness for implementation. Developed in line with the theory of organizational readiness for change (26, 39) and community capacity-building frameworks (40), the SWRA captures the unique, complex structure and specific settings within schools that impact student health, including classrooms, physical education, and lunchroom settings, and the broader school leadership and cultural context.

The SWRA includes questions across four subscales designed to assess setting-specific and school-wide wellness readiness: classroom readiness, physical education (PE) readiness, food services readiness, and school readiness. The SWRA items were assessed using a 5-point scale (strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree scale, coded as 0, 1, 2, 3, and 4, respectively). A copy of the SWRA is provided in **Additional File 2**. Wellness teams completed the 40-item SWRA through the program website. Scores for each of the subscales were calculated by averaging together the item responses in each section with higher scores representing higher states of readiness in specific settings and schools.

Qualitative Interviews Grounded in CFIR

Following procedures developed by Damschroder and colleagues (28, 31, 41), an interview guide was developed which aimed to understand the influence of each CFIR domain on implementation of SWITCH (see **Additional File 3**). Each school's wellness team was invited to participate and we asked as many people as possible to attend the interviews (usually 3 per team). Questions were open-ended; examples included, "What is your perception of the quality of the modules, posters, and other SWITCH materials that were provided?" (Innovation Characteristics – Design Quality and Packaging) and "How do you think your school culture affected the implementation of SWITCH programming?" (Inner Setting – Implementation Climate). Interviews were conducted by a qualitative and survey methodologist to ensure impartiality in responses from school wellness teams. To address issues of sustainability, interviewers asked "Think of the changes you have made in your school setting. To what degree do you think these changes are sustainable?" and then prompted participants to expand on their responses with examples. The goal was to encourage candid responses so time limits were not imposed on these conversations. This ensured in-depth understanding of each context and implementation climate.

Of the 52 schools enrolled in SWITCH, 45 (87% of sample) completed interviews. Of these 45, 17 were new and 28 were experienced. Each school that participated had between 1 and 3 members of their school wellness team present. **Table 2** shows representation of the various school staff positions within school wellness teams and those who were present in interviews; classroom and physical education teachers were included in most wellness teams and were most present on interviews, followed by food service and principals. Interviews lasted between 31 and 63 min, were conducted through video conferencing software (i.e., Zoom), and transcribed verbatim.

Qualitative Data Coding and Case Memos

The structure of the interview guide facilitated a predominantly deductive data analysis approach, in that each of the questions corresponded to a construct within each of the framework domains (31). However, we remained open, such that any themes that emerged through inductive approaches were included in our analyses; such combination of deductive and inductive coding integrates data-driven codes with theory-driven ones (42). For

TABLE 2 | Representation of various staff members in the total sample, then split by experience level.

School staff role	# Represented in total sample $N = 52$ schools		# Represented in inexperienced schools $n = 22$		# Represented in experienced schools $n = 30$	
	Wellness teams	Interview $n = 45$	Wellness teams	Interview $n = 17$	Wellness teams	Interview $n = 28$
Classroom teacher	59	21	22	7	37	14
Counselor	5	2	5	2	0	0
Food service/nutrition	17	3	7	2	10	1
Instructional coach	5	3	2	1	3	2
Nurse	15	4	3	0	12	4
Paraprofessional	1	0	0	0	1	0
Physical education	32	13	13	3	19	10
Principal	19	7	10	4	9	3
Superintendent	1	0	0	0	1	0
Other	9	2	4	1	5	1

Sample size in top row refers to total number of schools in each group; numbers in cells represent the total representation of specific roles on lead wellness teams and present in interviews. Total numbers can exceed the number of schools due to size of wellness teams.

example, for the interview questions that addresses sustainability (additional files), we coded data from these responses deductively where they aligned with relevant constructs of CFIR but also inductively to provide critical information to the research team on what factors influence sustainment.

First, the lead and second author met to develop a coding consensus document (**Additional File 4**), which described each CFIR construct and anticipated potential responses and themes that would emerge through the data. Applying the CFIR systematic coding approach facilitated the assignment of numerical scoring to the qualitative data, such that if a particular construct was deemed to have a positive influence on implementation based on interview responses, a score of +1 or +2 was assigned for that construct. Conversely, if a construct was deemed to be a negative influence, a score of −1 or −2 was given. If it was not clear whether a positive/negative influence manifested, a score of 0 was given; a score of "X" was used for mixed results (see **Additional File 5** for details on CFIR rating rules) (31).

Second, to establish inter-rater reliability, the two coders selected five transcripts and created independent case memos using the CFIR memo templates (41). Scores were compared and a percent agreement score was calculated; if the overall agreement score was <80%, the coders met to ensure consensus before coding another set of five transcripts. Once ≥80% agreement was met, the second author coded the remaining transcripts, before a randomly selected set of five transcripts was reviewed by the lead author. All coding was completed in memo documents (see **Additional File 6**). Finally, to facilitate content analysis and interpretation of trends in interview data, all memos were entered in to NVivo qualitative analysis software and coded into respective nodes, following the CFIR codebook template (41). To prepare the quantified CFIR data for merging into the larger dataset, each school ID was aligned with the scores for each construct and domain of the model. Any X scores (implying a mixed/uncertain rating) were converted to 0 for the purpose of analysis. Any scores without a score remained blank so as not to misguide subsequent analyses.

DATA ANALYSIS

Aims 1 and 2: Evaluate Outcomes and Determinants

All school demographic, implementation outcome, and quantified implementation determinant data from the coded CFIR interviews were merged using SAS software (Version 9.4, Cary NC) to facilitate descriptive and inferential analyses. First, descriptive tests were conducted to obtain means (and SD) for all implementation outcome and determinant data, then split by experience level (0 = inexperienced; 1 = experienced). Following recommendations from Damschroder et al. (23) Pearson bivariate correlations were run to establish correlations between implementation outcomes and determinants to examine associations and to understand potential influences of implementation for schools that experienced greater success. All tests were run in SAS software (Cary, NC), and α significance was assumed as $p < 0.05$; correlations with $p < 0.10$ were also highlighted due to the novel nature of this work. Based on such associations, salient quotes from interview transcripts were extracted to provide rich contextual details on determinants.

Aim 3: Investigate Nuanced Determinants for New and Experience Schools

To investigate distinguishing factors among inexperienced and experienced schools, an in-depth cross-case analysis was conducted based on prior evaluations through the CFIR in other settings (30, 31, 43, 44). Cross-case analysis provides a broad scope for researchers to systematically compare multiple "cases" (i.e., schools) and is a derivative of Qualitative Comparative Analysis (QCA) (45, 46). We pursued a combination of exploratory analysis and cross-case analysis to investigate the distinguishing factors between experienced and inexperienced

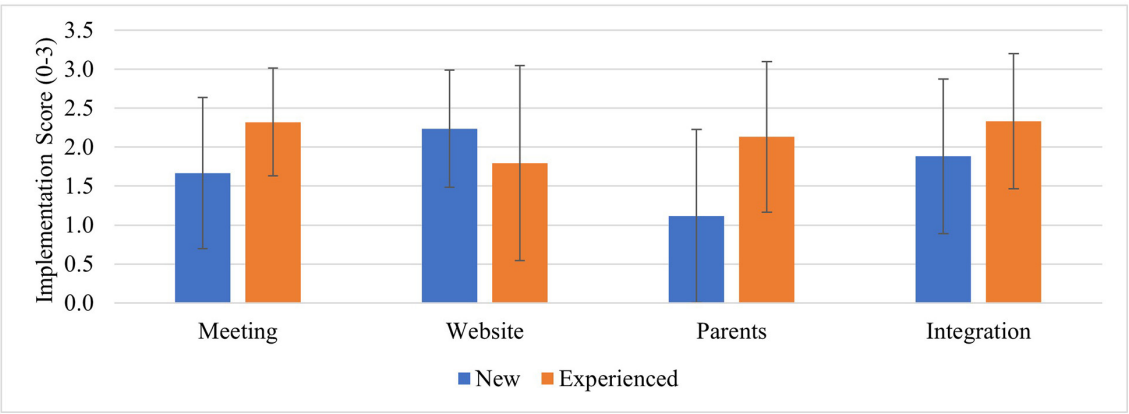

FIGURE 1 | Fidelity to SWITCH quality elements (Mean, SD) by experience level. Checkpoint surveys conducted at week 6; Implementation fidelity scores 96 0, not implemented at all, 2, somewhat implemented, 3, implemented fully; meeting, school wellness team meeting; website, setting up classrooms and student tracking in the website; parents, parent outreach activity; integration, implementing educational modules/resources across each of the SWITCH settings.

schools. Given that our sample size afforded exploratory inferential testing, we first conducted independent *t*-tests to examine differences in mean scores for each CFIR construct between the two samples (α significance was assumed as $p < 0.05$). In addition, we sought constructs which had >0.5 difference in mean score between the two samples, to highlight other distinguishing factors which may influence implementation (31). Subsequently, the research team explored qualitative extracts using NVivo as a means to contextualize findings from correlation analyses. Such an approach allowed for deeper contextual understanding of implementation practices which triangulate implementation determinants and outcomes (13).

To establish credibility, dependability, and trustworthiness, three key steps were taken in the analyses (47, 48). First, although the coding methods applied a deductive process, the lead researcher regularly conducted peer debriefing with other members of the research team to minimize potential bias and assumptive coding. Second, the mixed methods design facilitated methods triangulation throughout analysis procedures which ensured that distinguishing factors gleaned through cross-case analysis were properly contextualized and refuted if not enough substantive evidence existed (49). Finally, the use of coding memos provided the researchers with a method of maintaining an audit trail while coding, in which they took rigorous notes. This was exceptionally useful when establishing inter-rater reliability.

RESULTS

Aim 1: Implementation Outcomes

Schools reported strong fidelity (mean score 7.6 ± 2.91); however, this varied by schools and by item. Experienced schools reported better fidelity overall except for using the SWITCH website (see **Figure 1**). Parent outreach was the lowest implemented practice; outreach activities mostly entailed sending newsletters that were provided by the SWITCH team (70%); experienced schools reported more parent outreach practices than inexperienced schools. The most common method of school-wide integration was sending emails to the staff to inform them of the program and activities (88%) followed by using posters to promote SWITCH themes in different settings (73%). For adoption (5.53 ± 2.17), experienced schools reported significantly higher rates according to independent samples *t*-tests ($t = -2.03$, $p = 0.04$). This difference was consistent across use of modules, posters, and tracking/reinforcing themes. The highest implemented practice was classroom tracking followed by tracking in physical education setting (see **Additional File 7**).

Regarding penetration, behavioral tracking data demonstrate that inexperienced and experienced schools were approximately equal in terms of tracking rates between week 1 and week 7; 43 ± 29% of students in inexperienced schools and 46 ± 32% of experienced schools tracked each week (mean score 0.448, or 45%). Tracking naturally dropped due to COVID-19-related school closures but it is noteworthy that rates were essentially 0% for inexperienced schools but 25% for experienced schools. This indicates that the experienced schools were more likely to retain tracking rates to a greater extent than inexperienced schools. Only data from the first 8 weeks are used for the related correlation analyses.

Aim 2: Implementation Determinants

The process of converting qualitative interview data to numerical scores through CFIR protocols facilitated our ability to detect factors that were influential to SWITCH implementation outcomes. However, analysis of Cronbach's alpha revealed that none of the CFIR domains had acceptable internal consistency (all < 0.40). We therefore felt it important to show variability in the data as opposed to means and SD of global domains. **Figure 2** displays scores from each domain as dual-sided histograms to facilitate examination of variability, separated by experience level (discussed below). From examination it appears that for all schools, factors within the Outer Setting and Implementation

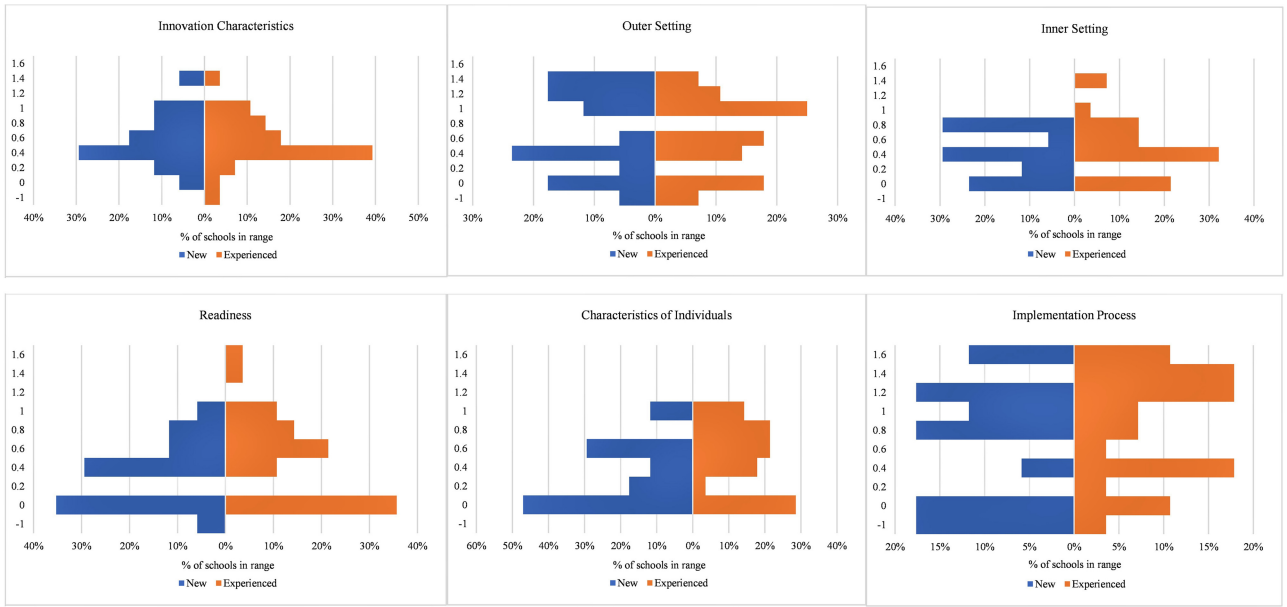

FIGURE 2 | Dual-sided histogram of CFIR domain scores, by experience level. Graph shows percentage of schools falling in specific ranges for global domain score (Y axis): −1 to −0.5; −0.5 to 0; 0 to 0.2; 0.21 to 0.4; 0.41 to 0.6; 0.61 to 0.8; 0.81 to 1.0; 1.01 to 1.2; 1.21 to 1.4; 1.41 to 1.

Process domains were most positively ranked, but high variability must be noted.

Table 3 displays all means ± SD for CFIR construct data. In terms of positive influential factors, data reveal that the most positive scores from coding of interview data were Readiness for Implementation – Leadership Engagement (i.e., building administration involvement/support; mean = 1.22 ± 1.02), Individual Characteristics – Knowledge and Beliefs about the Intervention (i.e., school wellness teams' perceptions of SWITCH; 1.51 ± 0.51), and Implementation Process – External Stakeholders (i.e., county 4-H Extension officer support; 1.42 ± 1.12). Regarding negative influences, lowest scores were assigned to Inner Setting – Relative Priority (i.e., priority given to SWITCH over other programs; −0.31 ± 1.26), Readiness for Implementation – Available Resources (i.e., time, personnel, equipment; −0.96 ± 0.88), and challenges in Implementation Process - Key Stakeholders (i.e., engaging parents; −0.22 ± 1.31).

Table 4 illustrates the results from exploratory Pearson bivariate correlation analyses for the whole sample. Almost all associations were positive, except Inner Setting-Networks and Communications ($r = -0.28$; $p = 0.07$) and Tension for Change ($r = 0.27$; $p = 0.09$), both negatively correlated with Adoption. Tension for Change was also negatively associated with Penetration ($r = -0.33$; $p = 0.02$). Salient interview extracts which relate to implementation outcomes are available in **Additional File 8** and provide context for the whole sample. **Figure 3** displays findings from the SWRA tool to assess baseline readiness/capacity. For the overall sample, a significant correlation was found between classroom readiness and adoption ($r = 0.366$, $p = 0.02$). This illustrates that schools that reported greater classroom capacity were also using modules, tracking, and using posters more often than schools with lower classroom capacity. For the inexperienced schools, overall school capacity was positively correlated to adoption, indicating that organization-level readiness was associated with use of best practices across the school ($r = 0.513$, $p = 0.04$). The lack of relationship between other capacity indicators and implementation outcomes is potentially due to the lack of variability in the capacity means. School and Class capacity had the largest range in scores (2 or 2.25 to 5) compared to PE and lunch capacity (between 3 and 5).

Aim 3: Differences in Outcomes and Determinants Among New and Experienced Schools, and Influential Factors to Sustainment of SWITCH

Cross-case analyses facilitated understanding of distinguishing implementation determinants between inexperienced and experienced schools. For inexperienced schools, the highest ranked positive determinant was Leadership Engagement (Inner Setting-Readiness for Implementation), suggesting that school administration support was an important contributing factor. For experienced schools, the highest ranked positive determinant was Engaging-Innovation Participants (Implementation Process), indicating that student involvement and advocacy was helpful for success. **Table 3** highlights the differences in mean scores between the two samples and distinguishing factors according to independent samples *t*-tests and large differences in means not detected through inferential testing. The two constructs which were statistically different were Readiness for Implementation (Inner Setting)

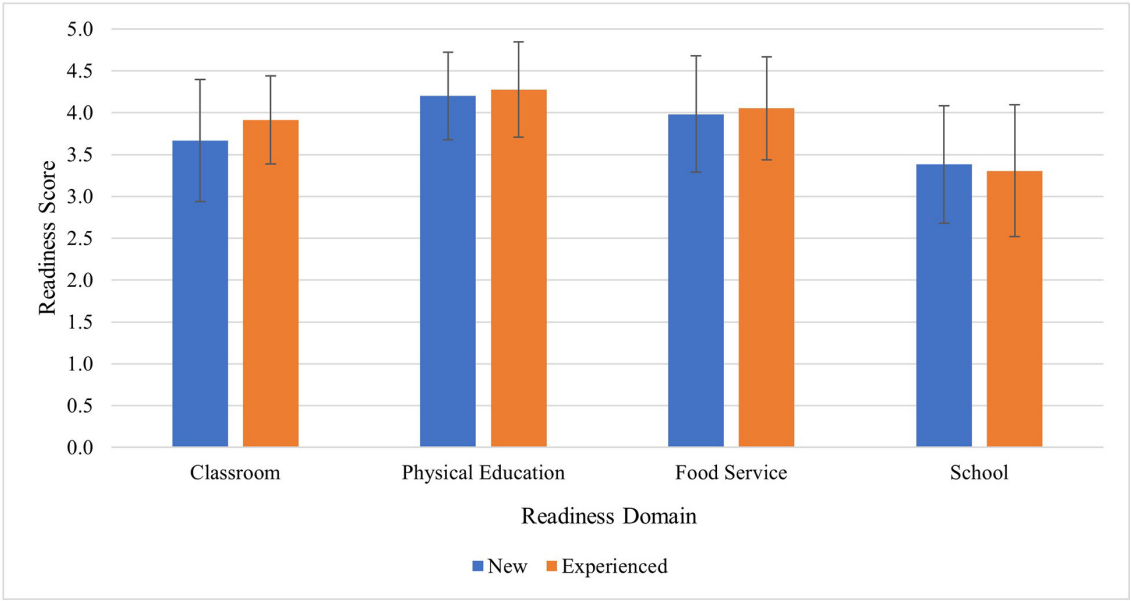

FIGURE 3 | Baseline readiness scores (mean, SD) from the SWRA tool. Raw scores ranged from 1–5 (higher score, stronger readiness/organizational capacity), then separated into new and experienced schools.

and Self-efficacy (Characteristics of Individuals); experienced schools had positive and significantly higher means in these constructs indicating they were positive determinants to implementation. Other distinguishing constructs which had large score differences were Cosmopolitanism (Outer Setting), Peer Pressure (Outer Setting), Compatibility (Inner Setting), Engaging (Implementation Process), and Innovation Participants (Implementation Process). Experienced schools had higher means except for Peer Pressure, which was higher for inexperienced schools.

Table 5 highlights the distinguishing constructs which separated the two samples based on deductive coding, with salient interview extracts from school participants. Extracts were chosen to represent some of the diverging quotations from the two distinct subsamples and reflect the ways in which they experienced implementation facilitators and barriers according to each CFIR construct. An example from the Readiness for Implementation highlights a difference for inexperienced schools, "From the first meeting it sounded like it was just maybe teaching a couple of lessons, and [team member] was going to be doing most of it, but we quickly found out that, that really wasn't the case" and experienced schools, "I think our core team does really well at keeping these things planned, and sticking together, and letting administration know what we're doing, and getting the okay." Another example from the Engaging construct highlights one perspective: "I don't feel we communicated well-enough to allow, or to educate the teachers on the importance of this program" (inexperienced). This is contrasted with an experienced school team member who said, "We had more success getting kids connected to their parents this year, compared to last year." These differences highlight nuanced barriers/facilitators among the two samples.

Finally, results from inductive coding with regard to sustainability revealed three overarching themes: (1) The importance of student awareness; (2) Keeping it simple; and (3) Integrating within school culture. **Additional File 9** shows salient quotes from interviews related to these themes, with quotes separated by experience level. For the first theme, when wellness team members were asked if they felt their changes were sustainable, many pointed to the impact SWITCH has had on students as a key reason why the program would be maintained in their setting. One inexperienced school member said, "the kids have now become aware of [how] they can change what they do, view, and chew… And maybe next year when they see us in the hallway, it'll click and [they will] remember that kind of stuff."

Many school wellness team members emphasized that while they could not implement all parts of SWITCH as much as they wanted to, they mentioned specific practices that seemed simple and granular which could be sustained. For example, one experienced school member said, "We've tried to do one thing at a time, to see if it was going to work. Changing the milk, we can do that. We do that all the time, now. And the brain breaks in the classroom, that's sustainable." This indicates that the wellness teams are thinking more about the discrete practices/policies they have in place as opposed to the comprehensive nature of the program, which may be too overwhelming. Finally, participants discussed how they "really see this as it's just part of our culture" (inexperienced school) when discussing this question. One experienced school member explicitly discussed how they

TABLE 3 | CFIR coding results by school experience and distinguishing factors.

CFIR Domain	Construct	Inexperienced		Experienced		Total			t	Cohen's *d*	*p*
		Mean	*SD*	Mean	*SD*	Mean	*SD*	*>0.5 difference*			
Intervention characteristics	Innovation source	0.41	0.71	0.21	0.57	0.29	0.63				
	Evidence strength and quality	1.06	0.90	0.79	0.88	0.89	0.88				
	Relative advantage	0.12	0.49	0.11	0.42	0.11	0.44				
	Adaptability	0.71	0.69	0.96	0.88	0.87	0.81				
	Trialability	0.00	0.00	0.07	0.66	0.04	0.52				
	Complexity (reverse)	0.06	1.03	0.43	0.92	0.29	0.97				
	Design quality	0.71	0.85	0.25	1.27	0.42	1.14				
	Cost (reverse)	0.41	0.51	0.64	0.87	0.56	0.76				
Outer setting	Student needs and resources	0.41	0.71	0.75	0.84	0.62	0.81				
	Cosmopolitanism	0.53	1.23	0.93	1.18	0.78	1.20	*			
	Peer pressure	0.71	1.05	0.25	0.70	0.42	0.87	*			
	External policy and incentives	1.06	1.14	0.68	0.94	0.82	1.03				
Inner setting	Structural characteristics	0.00	1.00	0.39	1.23	0.24	1.15				
	Networks communications	0.53	1.37	0.43	1.26	0.47	1.29				
	Tension for change	0.29	0.59	0.32	0.61	0.31	0.60				
	Relative priority	−0.41	0.94	−0.25	1.43	−0.31	1.26				
	Culture	0.88	0.86	0.82	0.94	0.84	0.90				
	Compatibility	0.76	1.15	1.32	0.67	1.11	0.91	*			
	Organizational incentives and rewards	0.00	0.00	0.07	0.26	0.04	0.21				
	Goals and feedback	0.53	0.80	0.43	0.57	0.47	0.66				
Readiness for implementation	Readiness for implementation	−0.12	1.22	0.89	0.74	0.51	1.06	**	−3.09	1.003	.005
	Learning climate	−0.12	0.33	0.14	0.52	0.04	0.47				
	Leadership engagement	1.35	1.06	1.14	1.01	1.22	1.02				
	Available resources	−1.24	0.83	−0.79	0.88	−0.96	0.88				
	Access to Knowledge and Information	0.65	1.46	0.36	1.16	0.47	1.27				
Individual characteristics	Knowledge and beliefs about intervention	1.35	0.49	1.61	0.50	1.51	0.51				
	Self-efficacy	−0.24	1.35	0.61	0.92	0.29	1.16	**	−2.50	0.731	0.01
	Individual stage of change	−0.06	0.24	−0.07	0.54	−0.07	0.45				
	Individual identification with organization	0.00	0.00	−0.07	0.66	−0.04	0.52				
	Other personal attributes	0.41	1.12	0.25	1.08	0.31	1.08				
Implementation process	Planning	0.29	1.05	0.21	1.42	0.24	1.28				
	Implementation leaders	0.88	1.11	0.79	0.74	0.82	0.89				
	Engaging	0.47	1.50	1.00	1.15	0.80	1.31	*			
	Opinion leader	0.24	1.39	0.54	1.07	0.42	1.20				
	Champions	0.94	0.90	1.07	1.02	1.02	0.97				
	External change agents	1.24	1.15	1.54	1.10	1.42	1.12				
	Key stakeholders	−0.47	1.18	−0.07	1.39	−0.22	1.31				
	Innovation participants	1.24	1.09	1.75	0.44	1.56	0.78	*			
	Executing	0.59	1.12	0.86	1.01	0.76	1.05				
	Reflecting and evaluating	0.12	0.33	0.25	0.65	0.20	0.55				

*CFIR, Consolidated Framework for Implementation Research; reverse, items reverse coded; all items scored on a range from −2 to +2; * Distinctively different (>0.5 score difference); ** Statistically significantly different; for all definitions, please see coding consensus document- additional files.*
Cohen's d calculation: https://www.socscistatistics.com/effectsize/default3.aspx.

are planning to keep SWITCH going despite common challenges of staff turnover which are pervasive in schools:

> I think everything we did is only going to be able to be built on. We've documented everything we did so if anything happened to any of us it's ready to go for the next group of people. And our district has worked really hard over the last couple of years with trauma informed care and social/emotional learning, so SWITCH ties into that with activity breaks, things like that. I foresee that that's just become common practice for our teachers.

TABLE 4 | Correlation analyses among determinants and outcomes.

CFIR Domain	Construct	All schools ($n = 47$)		
		Penetration	Fidelity	Adoption
Intervention characteristics	Innovation source	0.05	0.43**	−0.110
	Evidence strength and quality	−0.03	0.13	0.09
	Relative advantage	0.02	−0.04	−0.04
	Adaptability	0.15	0.03	−0.05
	Trialability	0.05	0.26	−0.11
	Complexity (reverse)	0.07	0.32**	0.08
	Design Quality	0	0.02	0.09
	Cost (reverse)	0.22	0.08	0.49**
Outer setting	Student needs and resources	0.26*	−0.04	0.19
	Cosmopolitanism	0.2	0.26*	0.05
	Peer pressure	0.09	−0.03	0.08
	External policy and incentives	0.05	0.22	−0.25
Inner setting	Structural characteristics	0.14	0.22	−0.02
	Networks communications	0.03	0.17	−0.28*
	Culture	0.39**	0.48**	0.27*
	Tension for change	−0.33**	−0.16	−0.27*
	Compatibility	−0.1	0.02	−0.06
	Relative priority	0.31**	0.34**	0.12
	Organizational incentives and rewards	0.31**	0.18	0.01
	Goals and feedback	0.05	0	−0.24
Readiness for implementation	Learning climate	0.11	0.31**	0.34**
	Readiness for implementation	0.06	0.21	−0.03
	Leadership engagement	0.31**	0.44**	0.42**
	Available resources	0.28*	0.32**	0.01
	Access to knowledge and information	−0.19	−0.2	−0.133
Individual characteristics	Knowledge and beliefs about intervention	0.01	0.18	0.21
	Self-efficacy	0.05	0.33**	−0.01
	Individual stage of change	−0.02	0.16	0.47**
	Individual identification with organization	0.35**	0.13	−0.07
	Other personal attributes	0.08	0.33**	−0.14
Implementation process	Planning	0.18	0.50**	0.27*
	Engaging	0.23	0.54**	0.2
	Opinion leader	0.05	0.59**	0.19
	Implementation leaders (SWT)	0.033	0.2	0.37**
	Champions	0.21	0.42**	0.32**
	External change agents	0.08	0.31*	−0.19
	Key stakeholders	−0.06	0.15	−0.06
	Innovation participants	0.2	0.44**	0.11
	Executing	0.38**	0.40**	0.02
	Reflecting and evaluating	0.12	0.33**	0.39**

*NA, not applicable due to lack of data to run correlations; *, $p < 0.1$; **, $p < 0.05$.*

This quote emphasizes the work that wellness teams have carried out to fully embed SWITCH within their systems so that it is compatible for their schools.

DISCUSSION

The aims of this study were to assess implementation outcomes of adoption, fidelity, and penetration of SWITCH to identify the factors that may influence sustainability. Grounded by CFIR, we discerned implementation determinants through a deductive approach and specifically examined the differences in outcomes and determinants among new and experienced schools. The use of CFIR as a guiding framework is novel in the school wellness setting, specifically the use of the framework systematic data analysis procedures, which facilitated a deep contextual understanding of relationships between

TABLE 5 | Distinguishing constructs between inexperienced and experienced schools.

Construct	Inexperienced	Experienced
Readiness for implementation**	"From the first meeting it sounded like it was just maybe teaching a couple of lessons, and [team member] was going to be doing most of it, but we quickly found out that, that really wasn't the case, but it worked out well, though. After we got over that initial shock of, 'oh my gosh, it's a lot more work' but it did go well"	"I think our core team does really well at keeping these things planned, and sticking together, and letting administration know what we're doing, and getting the okay. But then going about and implementing it and getting the help we need to go it from the parents' community, just doing it that way"
Self-efficacy**	"It was mostly just me and [other teacher]. They were on board, but yeah, again, just, it was brand new to us, so we didn't know how to incorporate everyone else into it just fully yet"	"I had 100% confidence in my teachers, because we sat down the year before and chose to do it again. Like I said, I feel that they did the best that they could with the amount of time that they had to be able to implement additional curriculum into their already busy curriculum"
Cosmopolitanism	"I didn't do a good job of reaching out to the community to see if there was anyone interested in helping us"	"We did the Iowa Farm-to-School local food day this past school year. And we were able to get apples and cider from [local orchard], and then we got fresh leaf lettuce and vegetables from our own greenhouse here. And so, we were able to explain that to the kids, and [4-H officer] actually came in and helped during that"
Peer pressure	"So knowing kind of the ins and outs and how [SWITCH] should look from another previous school that had success with it, really helped us just kind of get going and get it running at our school"	"We used to put a lot of things of what our school did to share our ideas, and we didn't [in the community of practice] but we did on our school Facebook page and shared a lot in that way. So, this year I didn't feel like I knew what a lot of schools had done"
Compatibility	"Our biggest hurdle was finding time for sixth, seventh, and eighth grade classroom activities just because our schedule just didn't work out very well. We ended up having all six, seventh and eighth graders on Mondays for Switch. We're a really tiny school, but that's still about 50 kids, which is a large group in a gym trying to teach"	"I guess I just keep going back to our kickoff that and with the teachers came up with on that and how it directly coincided with SWITCH and they were phenomenal. I think that they had the opportunity to do it something within their classroom I think they would do it"
Engaging	"I don't feel we communicated well enough to allow, or to educate the teachers on the importance of this program. In that regard, I need to do a better job next year along with whoever's helping in this"	"We had more success getting kids connected to their parents this year, compared to last year. We only had two connected last year, and I was one of them. And I think we ended up with about 25 parents connected to kids, which doesn't sound like a lot… that's still something that we want to improve upon so they know what the kids are doing so they can then support it at home"

*Orange, distinctively lower score; Green, distinctively higher score; ** Significantly different.*

implementation determinants and outcomes. Thus, a key innovation is the adaptation of a framework predominantly intended for healthcare settings (i.e., CFIR) to the school setting, marking an important advancement in the field of implementation science.

Aim 1: Assess Implementation Outcomes

The SWITCH program represents a capacity-building process which allows school wellness teams to develop and sustain comprehensive programs of their own which in turn are more sustainable over time. The moderate-high rates of Penetration also correspond with self-reported Adoption of program best practices across the school setting. Implementation data from adoption, fidelity, and penetration measures highlight the differences between experienced and experienced schools, a result that aligns with preliminary findings from prior evaluations (13). However, the finding that all schools struggled to engage parents despite increased efforts in the 2020 academic year reflects a wealth of prior research documenting this lack of engagement problem (8, 50, 51). Outreach practices of sending communications (emails/newsletters) and holding events for parental engagement were the most frequently reported, reflecting similar trends with school nutrition program promotion (52). Such findings stress the need to view implementation outcomes as incrementally changing constructs that must be studied over time. This finding is consistent with generalized recommendations for continuous quality improvement models (37, 53).

Aim 2: Assess Determinants of Implementation

The finding that Cosmopolitanism was higher in experienced schools, but Peer Pressure was lower than inexperienced schools, provides valuable information for how to support implementation efforts. Having links to other schools and organizations was viewed as a positive determinant of fidelity; interview data yielded some reasons for this, such as implementation support for delivering lessons and additional program materials and equipment, which may have further pushed a culture of health in school buildings. Although some initial research has demonstrated the positive role of external networks and support (54, 55), very little is known about the effectiveness of implementation strategies which provide targeted support from this domain. Accordingly, a potential implementation strategy for future work with schools may be to provide a local network of support, bringing together other sectors such as food retail and community centers, ultimately enhancing the culture of health in the community (56, 57).

Aim 3: Differences Between New and Experienced Schools

For inexperienced schools, Leadership Engagement was the highest rated positive determinant of implementation. This is noteworthy since lack of support or involvement from school administration is a frequently reported barrier in school-based interventions (58–61). In SWITCH, administrators were able to be a part of the wellness team and attend conferences and trainings which likely enhanced their exposure to—and awareness of—school wellness programming. For all schools, Available Resources was the most negatively ranked determinant, indicating this was the biggest challenge for implementation. Examples from interviews highlighted the role of personnel time, equipment availability, and funding as supports for implementation. Therefore, an implementation strategy for inexperienced schools may be a cost-matching initiative through local county 4-H extension or through collaborating with community stakeholders, as described above and recommended through findings of Waltz et al. (62). County extension offices have been encouraged to support SWITCH programming in their county, so this finding supports the importance of this practice. Engagement of Extension in this way also enhances cross-sector collaborations to build more sustainable school and community health programming (57).

As expected, the Readiness for Implementation domain and findings from the SRWA assessment highlight the importance of capacity-building programs for systems change (9). Both Readiness for Implementation and Self-Efficacy were significantly higher for experienced schools than inexperienced, bolstering findings from the SWRA. This is not surprising, as items from the SWRA relate to Self-Efficacy in the individual and organizational psychological domains, such as "staff members at all levels share a belief that they can implement school wellness programs effectively." Thus, implementation strategies to bolster capacity for implementation may be most appropriate. Within the D&I literature, the Expert Recommendations for Implementing Change (ERIC) research provides groundwork for selecting implementation strategies based on reported implementation challenges through models such as CFIR, facilitating tailored implementation support (62–64). For example, a CFIR-ERIC matching protocol conducted by Waltz et al. (62) and adapted by Cook et al. for school settings (65) highlighted that for Readiness for Implementation barriers, experts recommended "Assess for readiness and identify barriers and facilitators" as potential implementation strategies. In SWITCH, a core wellness team of at least three school staff members are trained over the course of a semester and complete the SWRA tool and School Wellness Environment Profile assessment, thus these strategies are already key components of the intervention model. Input from school stakeholders is often absent from the literature on implementation strategies, and a next step may be to include them in mapping procedures to advance the field.

The Implementation Process domain revealed that experienced schools ranked Engaging-general and Engaging-Innovation Participants distinctively higher than inexperienced schools, indicating these were more positively related to implementation. Related to innovation participants, youth advocacy in school wellness and health promotion has been demonstrated as an effective strategy for implementation and student health outcomes (66–68) and some studies are emerging regarding how student advocacy groups can be studied through a D&I lens (69). Engaging – Key Stakeholders was seen as a negative implementation determinant for all schools. Parents have been reported as the most difficult stakeholder group to engage in school-wide initiatives, and in previous cycles of SWITCH (13, 32, 50); however, some schools reported that when they did hold an event at school or at another academic-related event (i.e., parent-teacher conference), parents showed great interest. Thus, more research is needed to identify effective ways for engaging parents in school wellness, ideally with parents as the primary participants, to identify potential implementation strategies.

Finally, the inductive coding pertaining to sustainability revealed three primary themes which illustrate the strategies schools sought to maintain elements of SWITCH. A recent review highlights that most articles reporting facilitators/barriers to sustainment of interventions in schools cite factors from the Inner Setting as key determinants (9). Findings from the current study provide potential strategies that could be applied to mitigate barriers to sustainability, specifically (1) promoting student awareness and engagement, (2) focusing on a small number of key elements, and (3) integrating programming within school culture. These strategies were mentioned by participants as next steps for their wellness environment as formal implementation concluded, and all relate to potential barriers within the Inner Setting domain. However, it must be acknowledged that we were not able to test formalized strategies to enhance sustainability. Thus, a logical next step in this area may be to operationalize "sustainment" and to test the relative effectiveness of different strategies to enhance the sustainability of capacity-building interventions such as SWITCH. The present study provides insights into this development by identifying barriers and facilitators of adoption, fidelity and penetration.

LIMITATIONS

There are some limitations that could influence interpretations from this type of evaluation. First, and most important, the COVID-19 pandemic led to school closures which prevented completion of the 12-week implementation cycle. Thus, it is not clear whether the documented differences between inexperienced and experienced schools would have persisted or varied. Further, to prevent overburdening school staff, we refrained from collecting checkpoint survey data once schools closed and began remote learning, which may have limited understanding of fidelity and adoption within schools. Finally, we acknowledge potential limitations of applying CFIR constructs and coding methods non-healthcare settings. Our study was one of the first to employ CFIR in school settings using

a fully integrated mixed methods procedure. Therefore, the CFIR constructs/methods and their applications to school and community-based settings may need to evolve over time as replication of these methods occur. Ongoing work with SWITCH has utilized these findings, but the results provide generalizable insights about factors that influence the scale up and sustainment of interventions in other community-based settings (70). The process and systematic approach to the use of CFIR in the analyses also provide a guide for other school-based researchers seeking to utilize D&I methods to evaluate programming.

CONCLUSIONS

The present study highlighted various determinants that influenced implementation and sustainability of SWITCH. The study added novel insights which can be tested and applied in other studies in school and community settings. Specifically, we documented that inexperienced schools face greater challenges and need tailored support, findings which indirectly document the gains in capacity built through previous iterations of SWITCH. The mixed methods approach used in the study was particularly important in understanding the factors influencing implementation and the greater challenges faced by inexperienced schools.

An advantage of CFIR in the project is that it provides a systematic method for enhancing the rigor and quality of implementation evaluations. Replication of the methods in other school-based projects would enable more effective comparisons. The adoption of "common measures" for implementation determinants and outcomes is already evident in other lines of research (70–73). Similar standardization efforts in school-based research would enhance generalizability and transferability of qualitative findings to other contexts and geographic locations. It is clear that what gets measured often is what gets achieved. By standardizing methods and measures, there is greater potential for enhancing implementation and sustainability of school-based interventions through incremental evaluation.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Institutional Review Board (#14–651) at Iowa State University. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

GM and GW led the mixed methods design and evaluation components. RS and GM led the qualitative analysis procedures. RS and LL facilitated survey and interview data collection procedures. GM analyzed survey data and developed measures for school capacity. RR and JL provided feedback on analysis and interpretation of qualitative data. All authors contributed to the development of the research study and provided ongoing feedback throughout the implementation evaluation process and read and approved the final manuscript.

FUNDING

USDA NIFA grant: 2015–68001-23242. The USDA was not involved in the design of the study and collection, analysis, and interpretation of data or writing of the manuscript.

ACKNOWLEDGMENTS

The authors wish to thank the School Wellness Teams (SWT) that participated in the intervention, led programming, and provided their feedback. We also wish to thank individuals who served on the broader evaluation team for the SWITCH grant and contributed to early conceptualization: David A. Dewaltowski, Spyridoula Vazou, Lorraine Lanningham-Foster, and Douglas Gentile.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.881639/full#supplementary-material

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ORIGINAL RESEARCH
published: 13 June 2022
doi: 10.3389/frhs.2022.883072

A Slippery Slope When Using an Evidence-Based Intervention Out of Context. How Professionals Perceive and Navigate the Fidelity-Adaptation Dilemma—A Qualitative Study

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OPEN ACCESS

Edited by:
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Reviewed by:
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University of Zurich, Switzerland

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Specialty section:
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

Received: 24 February 2022
Accepted: 11 May 2022
Published: 13 June 2022

Citation:
Zetterlund J, von Thiele Schwarz U, Hasson H and Neher M (2022) A Slippery Slope When Using an Evidence-Based Intervention Out of Context. How Professionals Perceive and Navigate the Fidelity-Adaptation Dilemma—A Qualitative Study. Front. Health Serv. 2:883072. doi: 10.3389/frhs.2022.883072

Introduction: Adaptations are often necessary to effectively translate evidence-based interventions (EBI) between contexts, but compliance with the EBIs' core components is still important, which is referred to as the fidelity–adaptation dilemma. In the sustainment phase of implementation, it is the professionals delivering the EBIs who are tasked with the decision-making regarding adaptations, but the currently used models and frameworks mostly focus on the initial phases of implementation. To better understand and guide professionals in using EBIs, there is a need to explore professionals' perceptions of the fidelity–adaptation dilemma. The aim of this study is consequently to explore how professionals perceive and navigate the fidelity–adaptation dilemma when using an EBI out of context.

Materials and Methods: Semi-structured interviews were held with 19 psychologists working in primary care. The interviews concerned EBIs in general and Cool Kids, an evidence-based parenting education program designed for children with anxiety that is now used for children with lower levels of anxiety in another setting. The data were analyzed using an inductive content analysis method.

Results: The analysis resulted in two themes: *My standpoint regarding fidelity and adaptation is clear* and *Managing fidelity and adaptations is complicated*. The first theme summarizes the professionals' perceptions of confidence for either favoring fidelity or adaptations, as well as reasons for why they made adaptations. For the second theme, the professionals expressed concern about sometimes meeting difficulties with the dilemma when following their original inclination and having second thoughts about the impact the adaptations have in practice.

Conclusion: The professionals generally had strong preferences regarding fidelity and adaptations, but neither preference prevented them from facing difficulties with

the dilemma. The results point to a need for better information about possible adaptations from developers but also better support and guidance for professionals when implementing EBIs to ensure quality implementation and facilitate implementation. The results of this study can inform the design of support for professionals in managing the dilemma.

Keywords: evidence-based intervention, health care provider, attitude, adaptation, fidelity, parenting education, primary care, Cool Kids

INTRODUCTION

It is often complicated to implement interventions that have been proven effective in research, here referred to as evidence-based interventions (EBIs). Models and frameworks are therefore available to facilitate the process and support decision-making regarding adaptations during implementation (1–4). However, the extra resources and guidelines that are present during the initial phases of implementation are often withdrawn when the EBI enters the sustainment phase and is used in practice. Nevertheless, the sustainment phase is still important, as it plays a role in implementation and extensively affects the outcome quality of an EBI (5, 6).

Sustainability is dynamic, and the focus in the sustainment phase should be on the continuous work to find a fit between an intervention and the context since it is always changing (7). According to the dynamic sustainment framework, the concept of sustainability involves ongoing learning and problem solving (7). This dynamic view on sustainability highlights the complexity of implementation and there is, therefore, an ongoing need to work continuously and actively with fidelity and adaptation when implementing an EBI.

An issue that remains to be solved when EBIs are used in the sustainment phase is, therefore, to what extent an EBI needs to adhere to its original plan and whether purposeful adaptations based on restraints and possibilities in the non-research setting, the natural context (8), are acceptable or even desirable. This is commonly referred to as the fidelity–adaptation dilemma (5, 7–10). The definition of adaptation is often defined as any planned, proactive adjustment in the original method to improve the method's fit and effectiveness in the given context (1, 3, 11). Furthermore, context in this matter is referred to as everything that can influence the effectiveness of an EBI that is not part of the intervention (12). Adaptations are often necessary, for example, for an EBI to be effectively translated from one context to another (1, 8, 10), and high fidelity is uncommon (11). Studies report that 44–88% of EBI users make adaptations to the EBI they are working with (1, 3, 13). Common adaptations include the procedure, content, dosage, and target group of the EBI (1, 3, 8, 10). Adaptations have been suggested to be appropriate as long as the core components of an intervention are implemented with high fidelity and the adaptations are aligned with the intervention's goals (8). However, adaptations that are carefully planned and monitored (3, 7) are sometimes not differentiated from adaptations that occur less systematically and without planning (14). These types of adaptations can increase the risk of the intervention becoming ineffective or unsafe (7, 15). Further, even if adaptations are made to improve the intervention's effectiveness, feasibility, and fit, they can still be reactive or affect the EBI's core components (16). Adaptations are therefore sometimes also referred to as any kind of modification that is made, reactive or proactive, planned or unplanned (8). This definition is the one used in this study to allow for the exploration of all types of modifications as they are perceived by professionals, regardless of their timing, or intention.

The responsibility for handling the fidelity–adaptation dilemma and making important and complicated fidelity and adaptation decisions when delivering EBIs in the sustainment phase often lies with the professionals using the EBI in the natural context (5). In many instances, EBIs are recommended by a government body or other external actors without guidelines to the professionals on how to adapt the EBI to fit the new context. This is often due to a lack of knowledge of what to recommend; for example, only one-third of published EBIs in medical care have an adequate description of how to implement them in a natural context (17, 18). This is problematic and can result in a process other than the rational, structured approaches described in most of the available models and frameworks (1–4). Furthermore, the professional delivering the EBI plays one of the most important roles in the implementation (19), and the decisions these professionals have to make related to the dilemma and the dynamic situation they are in can affect not only themselves negatively but also the outcome. Prior research has, for example, illustrated how professionals' characteristics impact how they deal with fidelity and adaptations (5), which indicates that the delivery of EBIs is likely to differ from professional to professional.

Having to deal with the hard decisions and contradictory demands associated with the dilemma can potentially function as a cognitive and ethical stressor among professionals (5, 20, 21). There is a recognized need to further investigate and develop the sustainment phase (22–25). More precisely, there is a need to provide better practical tools to professionals for managing the fidelity–adaptation dilemma (3): first, to facilitate better clinical outcomes, but also to minimize potential stressors among professionals. To do this, more knowledge is needed about the fidelity–adaptation dilemma. There is a research gap regarding how professionals perceive this dilemma, how they manage it, and how they reason about its implications in the sustainment phase (5, 23, 26). Consequently, the aim of this study is to explore how professionals perceive and navigate the fidelity–adaptation dilemma. This was done in the context of an evidence-based

parent education program for children with anxiety (Cool Kids), delivered by psychologists but used in a different context and with a different target population than the program was originally designed for.

MATERIALS AND METHODS

The study is a qualitative study with semi-structured interviews with psychologists working in primary care in Sweden.

Case and Study Setting

This study focused on Cool Kids (27), an evidence-based manualized intervention developed in Australia, which was designed to help children being treated for severe anxiety within specialist psychiatric care. It is based on cognitive behavioral therapy and focuses on teaching 7–12 year-old children and their parents how to manage the child's anxiety. The Cool Kids program is group-based and consists of ten 2-h sessions running over a minimum of 10 weeks, and it has been shown to decrease anxiety levels (28). Children and parents receive the intervention in separate groups running in parallel, each led by one group leader with education in psychology.

In 2017, an academic primary care center with a regional commission to disseminate guidance and knowledge about the implementation of evidence-based psychological therapies in primary care recommended their primary care units to use Cool Kids. However, in this case, no specific guidance was given to psychologists working in the primary care units on how to adapt the manual for primary care or children with indications of mental illness, both of which differed from the original treatment as far as the context and target group, respectively. Any situation promoting a decision about fidelity and adaptation was therefore managed by the units and individual professionals.

Participant Selection

Eligible participants were all primary care psychologists experienced with Cool Kids, henceforth referred to as "professionals." All primary care units that received the recommendation to use Cool Kids by the academic primary care center were contacted ($n = 38$). The inclusion process is illustrated in **Figure 1**. All psychologists ($n = 28$) in the 13 units that reported that they currently or had previously worked with Cool Kids were invited to participate. Of these, nine psychologists declined to participate because they had never worked with the program, having a busy work schedule, or being on leave of absence. The total sample consisted of 15 women and 4 men between 26 and 65 years old (mean age 39 years). The included professionals had delivered Cool Kids at least once. The professionals varied in their education level; some were newly graduated psychologists (M.Sc. in psychology) and some had doctoral degrees.

Data Collection

Semi-structured face-to-face interviews were conducted in 2017 by one of two research assistants experienced in interviewing and using EBIs in clinical practice. Fourteen professionals were interviewed individually. Two group interviews (one with two and one with three professionals) were held at the request of the professionals who preferred to be interviewed together with the person(s) they worked with. The interviews lasted 40 min on average (range 26–52 min) and were held in an undisturbed location at the professionals' workplaces. Before the interviews started, the researcher informed the professionals about their involvement in the study, as detailed later in this section.

The interview guide was developed using the dynamic sustainment framework as guidance. This framework acknowledges the continuous work to find a fit between the intervention and the context, which emphasizes that the work with fidelity and adaptation are always present and something to actively address when working with an intervention (7). The questions focused on fidelity, adaptation, and the combination of the two, with the goal of addressing the unexplored aim of this study. The questions explored how the professionals perceived and navigated fidelity, adaptation, and the fidelity–adaptation dilemma, both when using Cool Kids specifically and in general. The interview guide also included questions about whether they had encountered difficulties or obstacles regarding fidelity and adaptations when working with Cool Kids. Examples of questions include: "What are your perceptions of fidelity and adaptations related to Cool Kids?"; "How do you generally address fidelity and adaptations when implementing an evidence-based intervention?" and "Have you experienced difficult trade-offs related to fidelity and adaptations of Cool Kids—if so, tell me more about it." The interview guide was iteratively refined through pilot testing with both EBI experts and professionals experienced with Cool Kids.

The planning and reporting of this study are in accordance with the Helsinki Declaration, as revised in 2013. The Swedish Ethical Review Authority reviewed the study protocol, concluded that ethical approval was not needed, and provided a statement that they did not have any ethical objections regarding the study (D no. 2017/729-31/5).

All professionals were given oral and written information about the study and a description of what participation entailed, as well as how they could later access the results. The professionals were assured that the researchers would safeguard personal data, that their participation in the study was voluntary and that participation could be withdrawn at any time without reasons given. They were also asked to provide written informed consent before the interviews began.

Data Analysis

All interviews, the unit of analysis, were audio-recorded, transcribed into text, and analyzed in several steps using inductive content analysis (29). This approach was chosen because the aim of this study was to explore a rather unknown area, and inductive content analysis can provide descriptive insight and increase knowledge about this unexplored phenomenon. With content analysis, it is possible to reduce data to concepts that describe the researched phenomenon—in this case, describing the professionals' perceptions and navigation of the fidelity–adaptation dilemma—by creating categories and subcategories using collections of codes that share a commonality

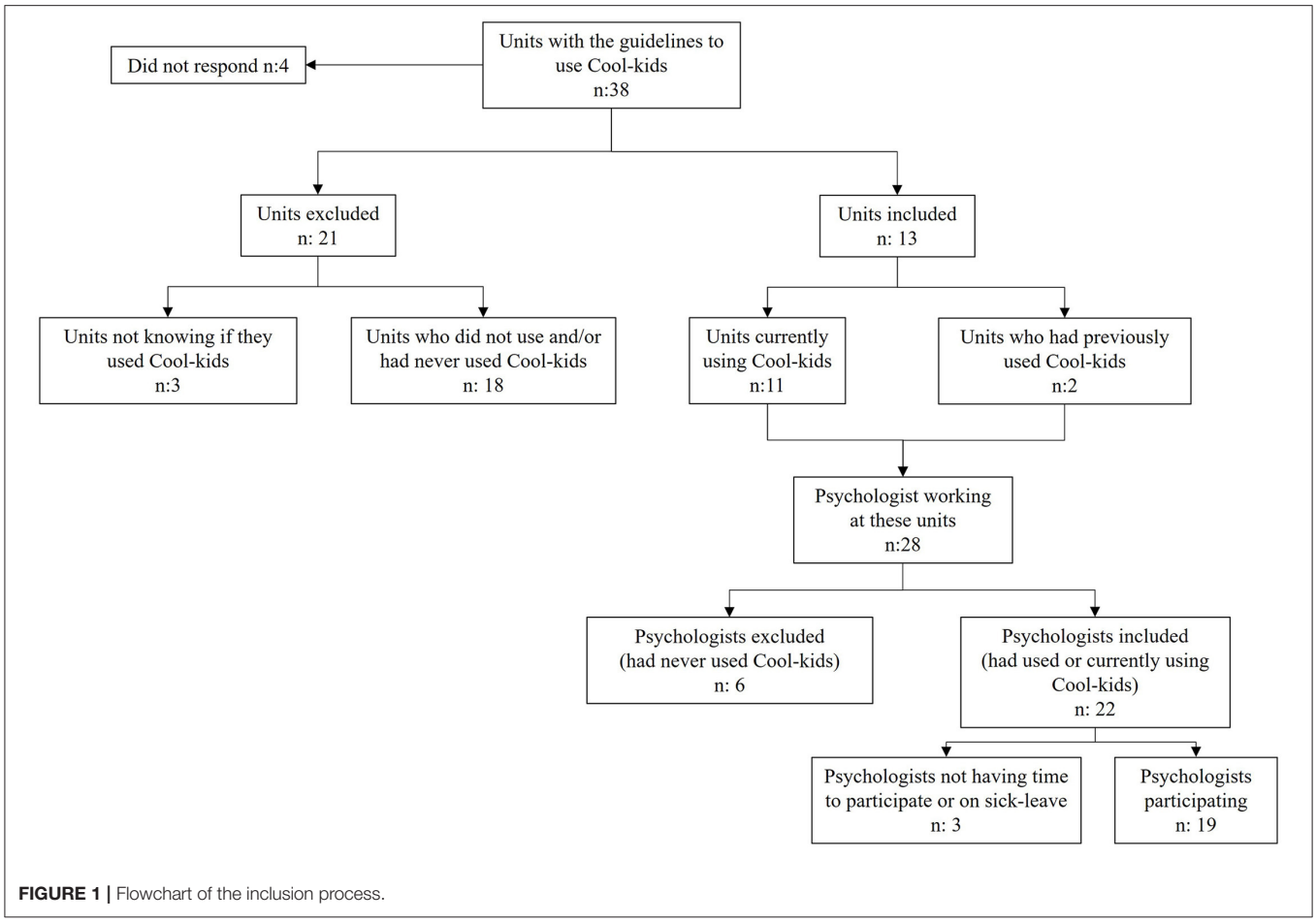

FIGURE 1 | Flowchart of the inclusion process.

and themes using collections of categories that are linked through underlying meaning (30).

The themes, categories, and sub-categories were created by condensation and abstraction. This is the process in which the data are shortened from full text into meaning units of words, sentences, or paragraphs containing aspects related to each other through their content or context and codes that label the meaning units. These meaning units and codes are then abstracted into categories, sub-categories, and themes. This process was conducted as follows: To get an overall picture of the content, all the interviews were read and reread by the first author (JZ), while the other authors read a random selection of interviews. The interview data were then uploaded onto NVivo 12 (31), and an initial analysis in which the data were tentatively organized, abstracted, and condensed into meaning units and codes was performed by JZ. The various codes were then compared based on similarities and differences and sorted into categories, sub-categories, and themes. A number of interviews were read and independently coded by another author (MN), and JZ and MN discussed their separate analyses to refine the results. The preliminary results were then discussed by all the authors to achieve a shared understanding of the content, and the final themes, categories, and sub-categories were given titles. Quotes from the interviews were also chosen to illustrate the content of the categories and sub-categories and were translated from Swedish into English. The data are available from the corresponding author upon reasonable request.

RESULTS

The analysis resulted in two themes: *My standpoint regarding fidelity and adaptation is clear* and *Managing fidelity and adaptation is complicated.* The first theme summarizes the professionals' perceptions of confidence for either favoring fidelity or adaptations, as well as the reasons why they made adaptations. The second theme made it clear that the professionals sometimes, regardless of their preference for either fidelity or adaptations, lacked confidence and encountered difficulties in handling fidelity, adaptations, and the conflict between the two. This theme summarizes how the fidelity–adaptation dilemma affected the professionals. The two themes, together with their categories and sub-categories, are presented and summarized in **Table 1**.

My Standpoint Regarding Fidelity and Adaptation Is Clear

This theme captures the professionals' preferences of confidence in either favor fidelity or adaptations, as well as the reasons

TABLE 1 | Professionals' perceptions of the fidelity–adaptation dilemma—the result of the analysis in themes, categories, and sub-categories.

Theme	Category	Sub-Category
My standpoint regarding fidelity and adaptation is clear	I am certain of my general inclination	The right thing to do is to deliver with fidelity
		Adapting is the right thing for me
	I make adaptations	Delivering with fidelity is impossible
		Delivering with fidelity is not worth it
		Some adaptations do not count
Managing fidelity and adaptation is complicated	It is difficult to manage fidelity and adaptation	It is hard to make adaptations, and it is hard to deliver with fidelity
		Managing trade-offs causes concerns
	What have I done and what has it become?	Adaptations cause uncertainty about the effect
		Adaptations make labeling the EBI confusing

why adaptations occur. These perceptions of feeling certain were summarized in two categories: *I am certain of my general inclination* and *I make adaptations.*

I Am Certain of My General Inclination

It was clear that the professionals had strong preferences for what they thought should be done when working with an EBI generally and with Cool Kids specifically. These different standpoints are presented in two sub-categories: *The right thing to do is to deliver with fidelity* and *Adapting is the right thing for me.*

The Right Thing to Do Is to Deliver With Fidelity

The professionals talked about the perception that adhering to the original plan or manual of an EBI was the right thing to do. They indicated that adherence should always be the guiding principle. The perception was also that if an intervention was supposed to be evidence-based, or called evidence-based, you should follow the manual step by step as closely as possible.

> My attitude is that you should try to follow the manual as much as possible. (Interview 3)

Adapting Is the Right Thing for Me

The second sub-category summarizes a perception that directly contrasts the first: following a manual step by step was not the way to work for these professionals. EBIs were perceived as good for research but not necessarily effective in practice. An EBI could serve as a guide, but when the professionals practiced their work, they had to follow what they believed in. They stated that instead of following a manual like Cool Kids strictly, they wanted to do their own thing and do what felt was right and what they were comfortable with as professionals—and that was not to follow a manual to the letter. The perception was that everyone is different, not only patients but also professionals. Each professional may have had a different teaching style, which resulted in different adaptations that fit them and their patients better. As professionals, they also perceived that they knew what helped and what did not and that they had knowledge that a manual did not have. The perceptions were that almost anyone could follow a manual like Cool Kids, but to treat a patient, you also need knowledge beyond what a manual can provide. This perception compelled them to remove parts that they did not believe in or were not consistent with or add things they thought were important or something they wanted to share their expertise in.

> I do not believe in one-size-fits-all. I want to be able to work a little more freely with the manual so that it suits me as well. How I want to work, what I want to teach, and like, how I want to progress my work. Some parts of a manual can also be parts that I think are more or less good. And if I do not believe in some parts, some sections, then maybe I do not include it because then I believe that I cannot deliver it in a good way. I have to start with how I want to work as a psychologist and how I see things. (Interview 10)

I Make Adaptations

Regardless of whether the professionals believed in or favored delivering with fidelity or making adaptations, they also perceived that there were situations in which adaptations were justified. These perceptions are divided into three sub-categories*: Delivering with fidelity is impossible*, *Delivering with fidelity is not worth it* and *Some adaptations do not count.*

Delivering With Fidelity Is Impossible

The participants indicated that even when professionals wanted to follow the original manual, it was sometimes perceived as an impossible task. Specific working contexts or conditions may require adaptations to be able to deliver the intervention; for example, there could be a limited number of professionals available or a limited amount of space or rooms to gather the participating parents and children, making it impossible to have parents and children in two parallel groups. The professionals also perceived that it was not possible to fully deliver with fidelity because you had a person in front of you for whom you had to adapt the intervention. The perception was that one format does not fit everyone, maybe not even anyone, and you have to make adaptations to make it fit the patient's needs. This could be due, for instance, to a child having two separate diagnoses, making it impossible to treat the patient in a group situation.

> So, if I had not made the adjustments, I would not have been able to work with it at all because it is meant to be done with two [group leaders]. (Interview 11)

Delivering With Fidelity Is Not Worth It

Another reason for making adaptations was because fidelity took too much effort and "cost" too much compared to what could be gained from following an original intervention plan, which made adaptations the way to go. This could be due to economic costs but also to the fact that the waiting list for care got longer if you followed the original intervention. This made professionals step away from the original manual and instead make adaptations; to deliver with fidelity came at a cost that was too high.

> I mean, it demands... then maybe it demands two, at least two people. And then you start counting on how many visits are lost. Then perhaps, in the end, the conclusion is that it is not worth it because we must prioritize the patients we already have. (Interview 14)

Some Adaptations Do Not Count

Some adaptations were not perceived as adaptations or were justified or minimized when professionals talked about them. In contrast to the adaptations that were perceived as unavoidable, these adaptations were dismissed as negligible and too insignificant to even be counted as adaptations. From this, it was perceived as possible to retain the perception of delivering with fidelity even though adaptations were made, for example, if adaptations were based on the theory of the program or if parts were only added from other EBIs. Adaptations that were perceived as small or that were not believed to affect the outcome did not count, either. Adaptations were also justified if the professionals knew or believed that others had made the same adaptations. Professionals expressed that they perceived adaptations to sometimes be justified based on the reasoning that the adapted intervention would benefit their patients more than the original intervention as described in the manual.

> No, but I still feel like I have followed it quite… quite closely. It is just that I have shortened… Has it been like a minor problem [with the patient], then I have done only three [sessions] [instead of ten sessions]… Actually… I think I have followed the manual, except that I had individual contacts [Instead of group sessions]. (Interview 11)

Managing Fidelity and Adaptations Is Complicated

In contrast with the clear position the professionals tended to have regarding favoring fidelity or adaptation, more reflective and conflicted perceptions emerged when talking about experiences and consequences of fidelity, adaptation, and the fidelity–adaptation dilemma. These difficulties and questions were perceived by the professionals regardless of their standpoint toward fidelity and adaptation and were divided into two categories: *It is difficult to manage fidelity and adaptation* and *What have I done and what has it become?*

It Is Difficult to Manage Fidelity and Adaptation

The professionals expressed a complicated and difficult relationship with both adaptation and fidelity, and they underlined that both delivering with fidelity and making adaptations were riddled with challenges, illustrating the ethical and moral distress that followed. These challenges are summarized in two sub-categories: *It is hard to make adaptations and it is hard to deliver with fidelity* and *Managing trade-offs causes concerns.*

It Is Hard to Make Adaptations and It Is Hard to Deliver With Fidelity

The professionals expressed that working with EBIs and making adaptations, whether forced or not, was difficult. They expressed anxiety about drifting too far away from or losing the original intervention with their adaptations, regardless of why the adaptations were made. They also perceived that they had to make difficult trade-offs because they did not want to ruin the intervention by making the "wrong" adaptations. Participants expressed feelings of concern about continually making adaptations without being mindful of the adaptations and forgetting to reflect on what they actually did. They also perceived that they had professional autonomy in their work, which was a good thing, but at the same time, they missed guidelines and support for how to work. They wished they had support on how to relate to fidelity and adaptations and how to stick to the core components of the intervention. The professionals expressed that they worked in a context that did not give them time to reflect on Cool Kids and the adaptations they had to or wanted to make, which could be exhausting and challenging. They also expressed that they were sometimes forced into a structure that was already set and they had to make the adaptations in an EBI that was already routine in that workplace, which felt wrong.

> But I do believe that I am doing it wrong… I do not want to ruin the material or do something that it is not intended to do. But I have still seen… I think that the benefit has been… or that it has still been better that I use the material and make the adaptations that I need. But if it is difficult to make adaptations, the trade-offs? Yes, it is because the children are different. (Interview 9)

Managing Trade-Offs Causes Concerns

The professionals perceived a conflict between wanting one thing and having to be pragmatic and do another. They expressed psychological stress when trying to deliver with fidelity but were unable to do so. They thought it was stressful to work with an intervention when they wanted the best for their patients but could not deliver the intervention as it was meant to be delivered. They also had the feeling that what they were doing was wrong when making adaptations they did not want to make, but the option was that or doing nothing at all.

Another concern was that everyone made different adaptations, which could result in unequal care. They expressed concern that the care the patients received was dependent on where they lived and who was treating them. They also thought

that both fidelity and adaptations had their pros and cons and that the patients they met were helped by different things. Some patients were helped by fidelity, a strict approach to a manual like Cool Kids, and some were helped by more adaptability. They felt that, on the group level, balancing fidelity and adaptation could be problematic and difficult, and they were apprehensive about providing unequal care. There was also a desire for guidance on how to work with the interventions in the future.

> We wish that we got some guidelines on how to use the method because we want everyone in the first line [primary care] to do the same thing: the care you get should not depend on where you live. Ideally, we would like a first-line-adapted Cool Kids treatment, but now it does not exist, and now we have done adaptations ourselves because we feel that we have to... (Interview 8)

What Have I Done and What Has It Become?

The last category of the *Managing fidelity and adaptation is complicated* theme describes the professionals' perceptions of ambiguity after having made adaptations to Cool Kids and EBIs in general.

Adaptations Cause Uncertainty About the Effect

The professionals perceived that it was hard to know how the adaptations they made altered the effectiveness of the EBI. They hoped or had a sense that the outcome was good but noted that they had no way of knowing if any improvement was due to the method or if it was the person delivering the intervention that had made a difference.

> Right. And it is difficult to know… It may well be that the outcome would have been the same with ten sessions as with seven, but it is… it is not possible to know… it is difficult to say anything about, of course, but my feeling is that it would not have been better with ten [sessions]. (Interview 16)

Adaptations Make Labeling the EBI Confusing

Finally, the professionals were uncertain how the adaptations affected the core of the program and wondered if they could still call it Cool Kids. Could they write in the electronic health record that they worked with Cool Kids, even after adaptations? Was it still an EBI when adaptations were made? They perceived that they could see results from the "new" intervention after the adaptations but was it still evidence-based? Thus, there was ambiguity regarding the implications of adaptations for both the effectiveness and integrity of the intervention.

> It feels like… is this evidence now, or is it mostly something that I have like… you may have started working evidence-based, and then it tends to be adapted more and more… you put your own thoughts on the whole thing too, do you understand? And then you get a little bit away from it. And then I do not know how to think about evidence… should it be very square-like and exactly the same? Or can it be a little more fluid? That is something I think about sometimes… when does it go from being evidence-based to becoming a little more [the psychologist's name] special? (Interview 10)

DISCUSSION

This study aimed to explore how professionals perceived and navigated the fidelity–adaptations dilemma when working with an EBI out of context. The professionals delivering Cool Kids felt certain in their general inclination: They favored either delivering with fidelity or making adaptations, both to EBIs in general and to Cool Kids in particular (*I am certain of my general inclination*). However, there were times and situations when they thought it was acceptable to make adaptations (*I make adaptations*). The professionals also had feelings of uncertainty; they experienced complexity both in making adaptations and when trying to deliver with fidelity (*It is difficult to manage fidelity and adaptation*) and they were uncertain about the effect their adaptations had on the outcome of the intervention (*What have I done and what has it become?)*.

The results indicate that regardless of the professionals' attitudes toward fidelity and adaptation, the dilemma in sustained use of EBIs was unescapable: The professionals still did not, or could not, avoid adaptations. The theory of cognitive dissonance (32) offers a potential explanation for the contradiction between stated beliefs and behavior. For instance, when our cognitions are inconsistent or dissonant with a behavior, we experience a sense of discomfort or tension, which motivates us to try to reduce the dissonance we experience. According to the theory, when experiencing cognitive dissonance, we can, for example, try to justify the behavior by changing the dissonant cognition, add cognitions to make the dissonant cognition fit the behavior, trivialize the behavior or change the behavior to make it fit the dissonant cognition (33). In the current study, this may be reflected in trivialization of adaptations; when, for instance, someone with a strong belief that high fidelity was important nevertheless made adaptations due to contextual constraints. The professionals described adaptations as inescapable, indicating little room to change behavior to better fit a stated preference. To avoid the discomfort of the behavior–cognition gap, the professionals may change their perceptions of fidelity and adaptation or make justifications for the adaptations they make. This indicates that professionals' perceptions about adaptation and fidelity are an insufficient source of information for understanding how professionals navigated the dilemma and more factors are important to understand and investigate.

The findings from this study show that professionals feel certain in their general inclination toward fidelity and adaptation; they either favored delivering an EBI with fidelity or making adaptations. There may be several reasons why professionals differ in whether they favor adaptation or fidelity. For example, previous research has indicated that level of expertise may influence how adaptations and fidelity are navigated and that a higher degree of expertise makes professionals better at judging whether adaptations or delivery with fidelity is necessary (34). Another possible explanation is that the professionals may value research evidence as a knowledge source differently. In the concept of evidence-based medicine the best outcomes come from the integration of the best available treatment, clinical expertise, and patient values (35). Although these knowledge sources are emphasized as equally important the professionals

may differ in which knowledge source they value most, as indicated in the findings of this study. This may lead them to have different attitudes toward fidelity and adaptations. For example, ranking research evidence highly may lead to a preference for fidelity but ranking clinical expertise and professional autonomy higher may lead to favoring or having a more relaxed attitude toward adaptation. An inclination toward high professional autonomy may be particularly likely in the Swedish setting. For example, a study with Swedish physicians found that a large majority of physicians made independent clinical decisions according to their own individual assessments without feeling restricted (36).

The professionals, despite their varied inclinations toward fidelity or adaptation in general, also had feelings of uncertainty. They experienced complexity both when making adaptations and when trying to deliver with fidelity. Hypothetically, the professionals could be exposed to cognitive and ethical stressors in these situations and experience contradictory demands (5, 20, 21), for example, when they want to adhere to the original protocol, but this is not possible due to contextual constraints. It can also be the other way around, and the professionals think that adaptations are appropriate, but they nevertheless feel compelled to adhere, which could also be a stressor. The possible negative impact may be accentuated by the large autonomy the professionals have in their clinical practice and that they feel that they are being on their own in managing the fidelity–adaptation dilemma and the findings indicate that they want help and guidance. A lack of support can cause significant tension for professionals who may not only have a deep respect for research but also for patients' individual and cultural variation (9). To further understand whether the fidelity–adaptation dilemma affects the professionals, more studies are needed.

Another uncertainty the professionals expressed was insecurity about the effect their adaptations had on client outcomes, and the professionals expressed that they had few evaluation tools or systems available to understand the outcomes of the EBI. Previous research has highlighted the need to evaluate the impact of adaptations on a target population to avoid unsafe or ineffective programs (37). Thus, professionals may also need help in evaluating the outcomes of adapted EBIs as a way to understand whether their adaptations are positive for the outcomes they want to achieve (37, 38).

The findings clearly show the challenges that professionals faced when navigating the fidelity–adaptation dilemma, and how they perceived a need for help and guidance to deliver quality care. Giving this support is vital, especially since many of the adaptations the professionals reported doing were substantial and made for several reasons. However, solutions to these challenges should not only be sought at the professional level. Clearer terminology concerning evidence and interventions might provide professionals with a more precise language. For example, the concept of evidence in evidence-based medicine uses three knowledge sources, but in EBI only scientific knowledge is emphasized (39). Denoting interventions like Cool Kids research-supported (40) or empirically supported (41) rather than the more ambiguous term evidence-based (42) might be one such clarification. Designers and evaluators of EBIs can also support professionals by providing more useful information about, for example, core intervention components and patient and other contextual factors that may influence effectiveness (43). Such information is currently missing too often (17, 18). More research that illuminates not only if an EBI has an effect but also how, when, and why it has effects, can further help not only the professionals directly but also the guideline developers. For instance, this sort of information could have helped the organizations in the current study to develop better guidance for how Cool Kids could have been adapted to the new context. The results from this study can illuminate what type of information and recommendations are valuable for professionals when dealing with the fidelity–adaptation dilemma.

However, since adaptations are triggered in the interaction between an EBI and a specific context and contextual factors are not constant, it is unlikely that the fidelity–adaptations dilemma can be fully solved through research and more detailed guidelines and terminology. Instead, it is likely that professionals will nevertheless have to navigate the fidelity–adaptation dilemma through the sustained use of implementation, not least because of the varied preferences toward fidelity and adaptation and the multitude of reasons for making adaptations. Together, this indicates that there is a need for support for the professionals, focusing both on guiding navigation and ensuring quality care. The design and evaluation of such support, aiming to help professionals with decision-making regarding fidelity and adaptations when implementing an EBI, is currently underway (44, 45).

Methodological Limitations

This is a study representing only one professional group (psychologists), and additional studies with other professional groups, other contexts, and other EBIs are needed. However, the heterogeneity of the sample of professionals may strengthen the credibility and transferability of the study, as professionals varied in age and gender, education level, and length of work experience. The authors have expertise in qualitative methods, implementation science, psychology, and public health, which strengthens the study's credibility. Additionally, to prevent inconsistency in coding and to strengthen the study's dependability (29), one author independently coded the data (JZ). Discussions about the coding process were, however, continuously held with another author (MN), who independently coded some of the interviews to make it possible to check for consistency and to enable discussion of the relevance of the established categories and sub-categories in depth. The coding process was iteratively discussed among all the authors. Finally, a checklist was used to achieve more explicit and comprehensive reporting of the study (46).

This study focused on professionals using a specific EBI, Cool Kids, to better understand perceptions of fidelity and adaptation among professionals with experience using an EBI in a natural context. From this, 21 of the 38 potential primary care units initially approached were excluded since they did not use (or did not know if they used) Cool Kids and 6 of the 28 professionals at the included primary care units had never used Cool Kids, which were also excluded; hence, the findings do not represent

the perceptions of professionals who, for various reasons, did not use this EBI. This group *may* include professionals who chose not to work with the EBI because it was not possible to use it without adaptations.

CONCLUSION

The professionals varied in their attitudes toward fidelity and adaptation and struggled with several types of challenges when using an EBI, irrespective of their fidelity or adaptation preferences. Regardless of their attitudes or preferences, they perceived a need for adaptations, indicating that there was no escaping the fidelity–adaptation dilemma. Furthermore, the professionals experienced uncertainties when working with Cool Kids specifically and EBIs in general and had a desire for support. The result indicates a need for better information and guidance about how to use or potentially make adaptations to a specific EBI in a non-research setting. This support may be provided directly by the EBI developer during the initial implementation phases, but there is likely a remaining need for support and guidance after the initial implementation process. Finally, the results indicate that the professionals included different knowledge sources when trying to implement an EBI and were affected by other factors that probably influenced and impacted themselves, the fidelity–adaptation dilemma and the implementation. This indicates that professionals' perceptions regarding fidelity and adaptation are an insufficient source of information for understanding how professionals navigate the fidelity–adaptation dilemma; instead, other factors need to be considered.

DATA AVAILABILITY STATEMENT

The data are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The study involved human participants was reviewed and approved by the Swedish Ethical Review Authority. The participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

UT and HH organized the data collection. JZ wrote the first draft of the manuscript and performed the initial data analysis and continuously discussed the results with MN, who also analyzed some of the data. All authors contributed to the conception and design of the study, discussed the final results of the study, and to the revision, and read and approved the submitted version.

FUNDING

The data collection was supported by a grant from Forte: Swedish Research Council for Health, Working Life and Welfare (Grant No. 2014-0303). The writing of this manuscript was supported by a grant from the Swedish Research Council (Grant No. 2016-01261).

ACKNOWLEDGMENTS

We would like to extend our gratitude to all participants in this study who openly shared their thoughts and perceptions with us. We would also like to thank Ulrica Förberg for her invaluable assistance in preparing the data collection and Sara Ingvarsson and Isabella Pistone for their equally valuable help in conducting the interviews.

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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.

frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 22 July 2022
DOI 10.3389/frhs.2022.891522

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 07 March 2022
ACCEPTED 30 June 2022
PUBLISHED 22 July 2022

CITATION
Rakhra A, Mishra S, Aifah A, Colvin C, Gyamfi J, Ogedegbe G and Iwelunmor J (2022) Sustaining capacity building and evidence-based NCD intervention implementation: Perspectives from the GRIT consortium.
Front. Health Serv. 2:891522.
doi: 10.3389/frhs.2022.891522

Sustaining capacity building and evidence-based NCD intervention implementation: Perspectives from the GRIT consortium

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Background: Implementation science has been primarily focused on adoption of evidence-based interventions, and less so on sustainability, creating a gap in the field. The Global Research on Implementation and Translation Science (GRIT) Consortium is funded by the National Heart Lung and Blood Institute (NHBLI) to support the planning, implementation, and sustainability of Late-Stage Phase 4 Translational Research (T4TR) and capacity building for NCD prevention and control in eight low-and middle-income countries (LMICs). This paper highlights perspectives, including barriers, facilitators, opportunities, and motivators for sustaining capacity building and evidence-based hypertension interventions within LMICs.

Methods: Guided by the Capacity, Opportunity, Motivation, Behavior (COM-B) Model, this study surveyed GRIT consortium members on the barriers, facilitators, key motivators, and opportunities for sustaining capacity building and evidence-based hypertension interventions in LMICs. Thematic analysis was used to identify themes and patterns across responses.

Results: Twenty-five consortium members across all eight sites and from various research levels responded to the survey. Overarching themes identifying facilitators, key motivators and opportunities for sustainability included: (1) access to structured and continuous training and mentorship; (2) project integration with existing systems (i.e., political systems and health systems); (3) adaption to the local context of studies (i.e., accounting for policies, resources, and utilizing stakeholder engagement); and (4) development of interventions with decision makers and implementers. Barriers to sustainability included local policies and lack of infrastructure, unreliable access to hypertension medications, and lack of sufficient staff, time, and funding.

Conclusion: Sustainability is an important implementation outcome to address in public health interventions, particularly as it pertains to the success of these initiatives. This study provides perspectives on the sustainability of NCD interventions with a focus on mitigating their NCD burden in

LMICs. Addressing multilevel factors that influence the sustainability of capacity building and interventions will have notable implications for other global NCD efforts going forward. Current and future studies, as well as consortium networks, should account for sustainability barriers outlined as it will strengthen program implementation, and long-term outcomes.

KEYWORDS

implementation science, sustainability, non–communicable diseases, LMICs (low and middle income countries), capacity building, evidence-based interventions

Background

The burden of non–communicable diseases (NCDs) continues to rise globally with a disproportionate impact in low and middle-income countries (LMIC) (1). Deaths due to NCDs in LMICs are expected to increase from 30.8 million in 2015 to 41.8 million by 2030 (2). To address this growing disease burden, continued evidence-based interventions (EBI) addressing NCDs and capacity building for NCD investigators in LMICs is needed. Moreover, comprehensive sustainability efforts addressing barriers and facilitators to NCD EBIs and capacity building uptake are crucial to maximize the impact of these efforts to ensure long-term health outcomes are maintained (3, 4).

While program sustainability is not a new concept, the field of implementation science has focused more so on understanding factors and strategies that influence the adoption and implementation of EBIs and less so on the factors and strategies impacting sustainability (5). While studies have discussed multi-level factors influencing sustainability that relate to context (i.e., outer context, policies, legislation, funding and inner context, culture, structure), innovation or the intervention itself (i.e., fit, effectiveness), process (i.e., fidelity, monitoring, evaluation), political support, funding partnerships research on sustainability factors still needs to be more widely adopted (6, 7).

The Global Research on Implementation and Translational Science (GRIT) Consortium was convened in 2018 by the National Heart Lung and Blood Institute (NHLBI) to support the planning, implementation, and sustainability of Late-Stage Phase 4 Translational Research (T4TR) and capacity building initiatives for NCD prevention and control in LMICs. The overarching goal of the GRIT Consortium is to define and establish a strategy that connects consortium members to capacity-building initiatives that will enhance the sustainable uptake of evidence-based interventions for NCD prevention and control in LMICs (2, 8). The network comprises investigators funded by the Hypertension Outcomes for T4 Research in LMICs (HyTREC) and the Translation Research Capacity Building Initiative in LMICs (TREIN) programs. The consortium consists of research teams from eight countries, five of which (Guatemala, Ghana, Kenya, India, and Vietnam) test implementation strategies to deliver evidence-based interventions within these countries for the prevention, treatment, and control of hypertension (HyTREC sites) and three of which (Malawi, Nepal, and Rwanda) provide capacity building in NCD and D&I research needed to close the gap between research and practice (TREIN sites). Additional details of each site in the consortium are published elsewhere and can be found in Table 1 (9–16).

The GRIT Consortium's contribution to hypertension and other NCD knowledge and services is unique due to the collaborative stakeholder and implementer perspectives of multiple LMICs. The GRIT Consortium sites have identified common determinants and adoptable strategies for NCD interventions and capacity building in LMICs (2, 8). The consortium not only addresses the knowledge gap between program implementation and sustainability, but also lays a groundwork for discussing other potential gaps in dissemination and implementation (D&I) practice in LMICs.

As the TREIN and HyTREC projects are in their final phases, the consortium has been focused on sustaining both the capacity building and intervention implementation efforts. For this study, we adapted the Michie and colleagues Behavior Change Wheel framework and the COM-B Model as the model uses three factors- capabilities, opportunities, motivations for identifying changes to ensure behavior change interventions are effective (17, 18). The COM-B Model has been used in other studies addressing the implementation of hypertension interventions in LMICs, as

Abbreviations: COM-B, Capabilities, Opportunities, Motivations, and Behavior Model; Co-Is, Co-Investigators; D&I, Dissemination and Implementation; EBI, Evidence-Based Interventions; GRIT, Global Research on Implementation and Translation Science; HyTREC, Hypertension Outcomes for T4 Research within Lower Middle-Income Countries; LMICs, Low and middle-income countries; NCDs, Non–communicable diseases; NHLBI, National Heart Lung and Blood Institute; PIs, Principle Investigators; T4TR, Late-Stage Phase 4 Translational Research; TREIN, Translation Research Capacity Building Initiative in Low Income Countries.

TABLE 1 Summary of GRIT Consortium Sites.

Site & Project Title	Brief Summary of project
HyTREC Sites	
Ghana (10) *Uptake of Task-Strengthening Strategy for Hypertension Control within Community Health Planning Services in Ghana: A Mixed Method Study*	The goal of this study is to evaluate, in a hybrid clinical effectiveness- implementation cluster design, the effect of practice facilitation (PF) on the uptake of an evidence-based Task Strengthening Strategy for Hypertension control (TASSH), among 700 adults who present to 70 Community- Based Health Planning Services (CHPs) zones with uncontrolled hypertension.
Guatemala (14) *Implementing a Multicomponent Intervention to Improve Hypertension Control in Central America. A Cluster Randomized Trial in Guatemala*	A cluster randomized clinical trial to test the co-primary objectives: The effect of a multilevel and multicomponent intervention program on blood pressure (BP) control among Guatemalan hypertensive patients over an 18-month period The acceptability, adoption, feasibility, fidelity, reach, and sustainability of implementing the intervention in patients, providers, and health districts.
India (15) *Integrated Tracking, Referral, and Electronic Decision Support, and Care Coordination (I-TREC)*	The overall goal of this 5-year project is to adapt, implement, and evaluate an IT- enabled platform for integrated tracking, referral, electronic decision support, and care coordination (I-TREC) to treat hypertension and diabetes in rural communities that rely on public health care system using mixed methods approach (Quasi-experimental design).
Kenya (13) *Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS) in western Kenya: a study protocol of a cluster randomized trial*	A cluster randomized control trial evaluating the effectiveness and cost- effectiveness of a combined health information technology (HIT) and peer support intervention on referral completion, BP improvement, and CVD risk reduction in Kenya.
Vietnam (12) *Conquering Hypertension in Vietnam: Solutions at Grassroots level*	A cluster randomized controlled trial to evaluate the implementation and effectiveness of two multi-faceted community and clinic-based strategies for the control of hypertension among adults residing in the rural Red River Delta region of Vietnam with uncontrolled hypertension.
TREIN Sites	
Malawi (16) *NCD BRITE- Building Research Capacity, Implementation and Translation Expertise for non-communicable diseases*	The proposed program will build long-term, sustainable heart, lung, blood and sleeping diseases and disorders (HLBS) focused late-stage translation phase 4 research (T4TR) capacity in Malawi and will utilize this capacity together with research infrastructure and diseases burden needs assessments, to design a Malawi specific HLBS T4TR research plan. The trans-disciplinary consortium is purposefully designed to build capacity within the University of Malawi-College of Medicine (COM), the only public medical school in the country, and the Malawi Ministry of Health (MoH), to ensure sustainability.
Nepal (9) *Translational Research Capacity Building Initiative to Address Cardiovascular Diseases in Nepal*	Dhulikhel Hospital Kathmandu University Hospital, Nepal, will lead work to create a multi-sectoral, multidisciplinary collaborative team to develop Translational research capacity Building initiatives to prevent and manage CVD in Nepal. By the end of the project, we will have developed a critical mass of human Resources in Nepal, collaborating with national and International partners, to conduct Translational Research in CVD. We will have defined clearly identified prioritized needs and a well- defined Translational Research plan to address one or more major CVD Risk Factors and outcomes.
Rwanda (11) *Developing T4 translational research capacity for control of hypertension in Rwanda*	This project will create a collaborative team of academics, clinicians, community healthcare providers, and public health experts to engage in T4TR by building the competencies required to enhance uptake of proven interventions for control of hypertension in Rwanda.

well as in other contexts to develop effective interventions (19). The goal of this study was to examine the capabilities, opportunities, and motivators for sustaining hypertension and other NCD intervention implementation and capacity building in LMICs (17, 18). This study describes barriers, facilitators, motivators and opportunities identified by GRIT Consortium researchers to enhance future NCD sustainability efforts.

Methods

Study design and procedure

This was a qualitative open-ended descriptive online survey conducted across the GRIT Consortium in March and April of 2021. This study used purposive sampling to recruit researchers across study roles and from all eight GRIT Consortium sites

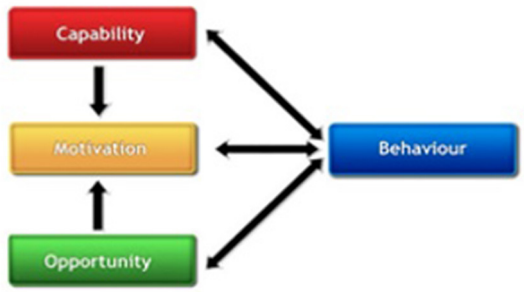

FIGURE 1
The COM-B model.

(Ghana, Guatemala, India, Kenya, Malawi, Nepal, Rwanda, and Vietnam). The survey remained open until saturation was reached.

Conceptual framework

Implementing and sustaining behavior changes (i.e., NCD control and capacity building) may occur as a result of an interaction between three components: capability, opportunity, and motivation (6). As such, the survey tool was guided by the Capabilities, Opportunities, Motivations, and Behavior (COM-B) Model (17, 18). Capability is defined as one's psychological capacity (i.e., knowledge) and physical capacity (i.e., skills) to engage in a behavior; Opportunity represents external factors that affect one's capacity to perform (i.e., physical environment, social influences and cultural norms); and Motivation represents internal factors that allow one to employ capability and opportunity to perform a behavior (i.e., wants, needs, beliefs, intentions) (see Figure 1) (17, 18).

Survey development

Guided by the COM-B model, a qualitative open-ended descriptive online survey was developed and administered to the GRIT consortium project sites. The initial survey was piloted among a sub-group of GRIT members and was subsequently revised and refined based on feedback to ensure clarity of wording and usability. In addition to demographic questions regarding the researchers' role on their study, research team members were asked about their experience as program implementers across the eight countries in the consortium. The survey assessed the three main domains of the COM-B through open-ended questions: (1) what would you say makes it easy or difficult to implement and sustain capacity building and/ or evidence-based HTN intervention implementation? (capability); (2) what would you say motivates researchers/ and or other key stakeholders to implement and sustain capacity building and/ or evidence-based hypertension intervention implementation? (motivation); and (3) what opportunities exist to continuously support researchers/ community members to implement and sustain capacity building and/ or evidence-based hypertension intervention implementation? (opportunities).

Data analysis

The survey tool was administered in English which was the common language among participants. The data relevant to each construct of the COM-B Model was documented by two authors using a data extraction sheet. The information was summarized and reported descriptively using content analysis to the COM-B Model. Discrepancies between the two authors were resolved by open discussions and consultation sessions among the research team. The consolidated criteria for reporting qualitative studies (COREQ) was followed (20).

Results

Participant characteristics

Twenty-five consortium members completed the questionnaire. Table 2 outlines the country site and study team roles of respondents within the consortium. 56 percent of respondents were principles investigators (PIs) or co-investigators (Co-Is), 24% were coordinators, and the remaining respondents included statistician(s), data manager(s), researcher(s), program manager(s), and an international liaison. All eight sites in the consortium were represented in the responses. Table 2 outlines additional respondent demographics.

Barriers and facilitators

Table 3 outlines the respondent-identified barriers and facilitators to sustaining capacity building and/ or evidence-based hypertension or NCD intervention implementation. Barriers identified by respondents included: (1) lack of hypertension medications (17%); (2) lack of time (during implementation and post-intervention) (19%); (3) lack of funding (11%); (4) lack of staff (17%); (5) low education or understanding of intervention/ disease among population/ patient and provider (17%); (6) context (local policies, lack of infrastructure, context specific social and cultural beliefs.) (11%); (7) lack of hypertension diagnosis (3%); (8) lack of epidemiology data (3%); and (9) insufficient or lack of internet access at work (3%). Facilitators included: (1) training opportunities

TABLE 2 Respondent demographics ($n = 25$).

Country	
Ghana	12% (3)
Guatemala	12% (3)
India	12% (3)
Kenya	8% (2)
Malawi	12% (3)
Nepal	8% (2)
Rwanda	24% (6)
Vietnam	12% (3)
Study Team Role	
PI/ Co-PI	20% (5)
Investigator/ Co-Investigator	36% (9)
Statistician	4% (1)
Data Manager	4% (1)
Coordinator (research, project, implementation)	24% (6)
Researcher	4% (1)
Program Manager	4% (1)
Lead International Liaison	4% (1)

TABLE 3 Barriers and facilitators to implementing and sustaining capacity building and/or evidence-based NCD interventions.

Barriers ($n = 36$)	
Lack of HTN medication	17% (6)
Lack of time	19% (7)
Lack of funding	11% (4)
Lack of staff	17% (6)
Low education (population/ patient and provider)	17% (6)
Context (policies, infrastructure, etc.)	11% (4)
Late diagnosis of HTN	3% (1)
Lack of epidemiology data	3% (1)
Insufficient or lack of internet access at work	3% (1)
Facilitators (n=36)	
Training	22% (8)
Mentorship/ Leadership Support	11% (4)
Community/ Stakeholder Engagement	17% (6)
Multi- disciplinary teams	8% (3)
Local Context (adoption to and capacity of systems)	17% (6)
Political Support	6% (2)
Motivation of staff	3% (1)
Quarterly workshops to review challenges in evidence-based hypertension interventions	3% (1)
Hypertension (less stigma, not infectious, modifiable risk factors)	8% (3)

(22%); (2) mentorship and leadership support (11%); (3) community/stakeholder engagement (17%); (4) working in multi-disciplinary teams (8%); (5) local context (adoption to and capacity of local systems) (17%); (6) political support (6%); (7) motivation of staff (3%); (8) quarterly workshops to review challenges in EBI hypertension interventions (3%); and 9) acceptance of hypertension (less stigma, not infectious, modifiable risk factor) (8%).

Key motivators

Figure 2 highlights the most-common motivators for sustaining capacity building and/ or evidence- based NCD intervention implementation. 31 percent of the respondents suggested visibility of positive impacts and receiving validation from beneficiaries; and 29% of respondents suggested professional opportunities for long term research involvement (i.e., salary support, pathways to promotion, sharing new opportunities, etc.) were key motivators driving sustainable interventions. Additional motivators included delivery of clear feedback and expectations (11%), strong collaborations from authorities (i.e., local government officials, local researchers, stakeholders) (14%), and availability of basic resources to carry out the intervention (i.e., minimal funding, administrative and research software, logistics) (11%).

Opportunities

Opportunities to support researchers and community members implementing and sustaining capacity building and evidence-based NCD intervention implementation are outlined in Figure 3. 42% of responses included training, mentorship, and funding for junior researchers, followed by 21% of involvement of key stakeholders (i.e., community-based partnerships, Ministry of Health), followed by 17% identifying political commitment and support. Funding (i.e., public and private funding, financial analysis & incentives) (12%), effective monitoring (4%), and adherences and perceived benefits of the intervention were also identified as areas of opportunity (4%).

Discussion

This study examined the capabilities, opportunities and motivations for sustaining capacity building and evidence-based NCD intervention implementation across eight LMICs. Our study is in accordance with other research findings that discuss multi-level factors that impact sustainability such as political support, funding stability, partnerships, and program evaluation and adaptation (3, 6, 7). Overall, these findings highlight the need for commitment from the various stakeholders including research funding agencies, national and local governments, national and global philanthropy and multilateral organizations to make progress in LMIC research capacity for NCDs (3, 21).

While there was high diversity in respondents, with over 50% being PIs or Co-Is, the need for training, mentorship and funding for junior or early researchers was a prominent theme

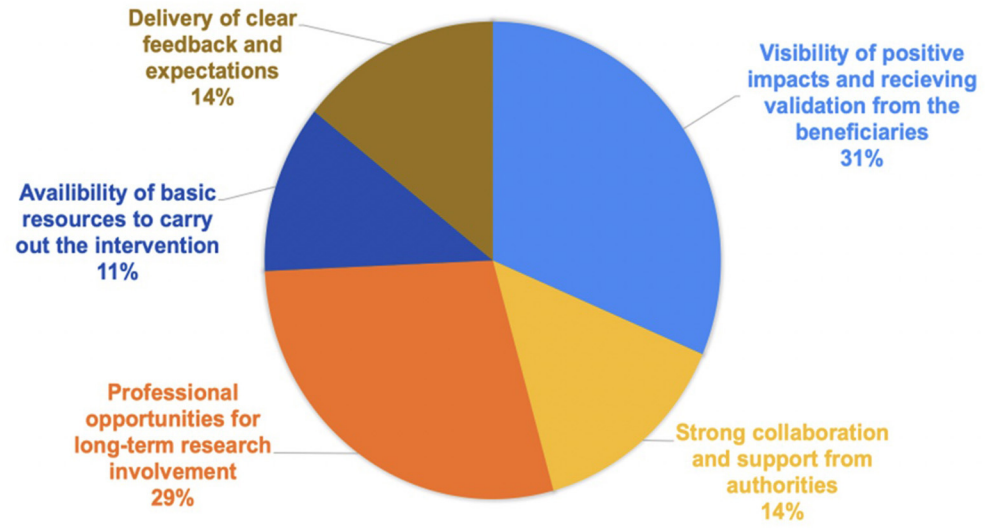

FIGURE 2
Motivators to Sustaining Capacity-Building and/or Evidence-Based NCD Intervention Implementation.

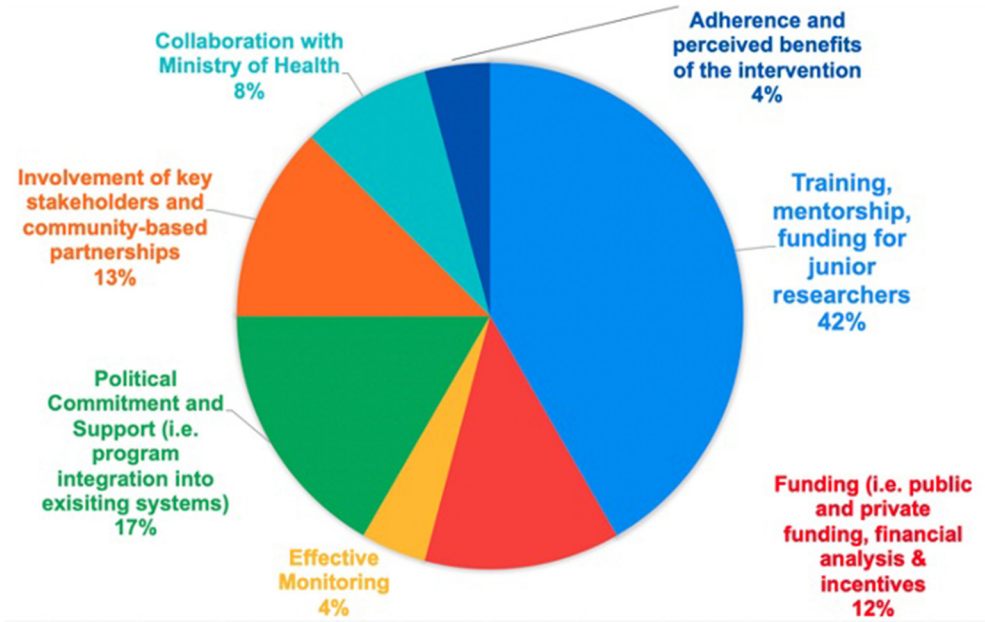

FIGURE 3
Opportunities to Continuously Support Researchers/Community Members to Implement and Sustain Capacity-Building and/or Evidence-Based NCD Interventions.

among all respondents. Training and mentorship are proven strategies that lead to scientific success for junior researchers (22). The lack of support for early-stage investigators in LMICs interested in the global NCD field has resulted in numerous barriers (22), many of which were reported in the findings of this study, including lack of sufficient staff, lack of knowledge among providers and researchers on the research process as well as addressing the interplay between local contextual setting factors. Studies have consistently shown that LMIC investigators are best positioned to address health challenges given their understanding of context, such as the cultural and political climate and health system readiness, in their home countries

(5). While there is growing effort for access to training and mentorship to be a long-term goal of projects and institutions (16, 22, 23), including the uptake from TREIN sites within the GRIT Consortium (22, 24, 25), increased access to mentorship still need to be adopted more widely to continue building local research capacity.

An additional finding of this study highlighted in the Integrated Sustainability Framework is the visibility of positive impacts and receiving validation from beneficiaries (5). This included seeing improved health and well–being, building capacity of healthcare workers, and appreciation as motivators for sustaining the work they are doing (22). Visibility of the program impact can be addressed through comprehensive evaluation with a focus on process measures (26). An additional way in which implementers can see positive impacts and receive validation of their efforts is to openly connect with the communities they work with (22). Nearly a quarter of responses identified the involvement of key stakeholders such as community-based partnerships, and Ministry of Health (MOH) as an opportunity to continuously support researchers and community members. Stakeholder involvement in intervention implementation not only encourages community support and creates a program that is more likely to be sustained due to changed community social norms and increased usage (2, 27), but would allow researchers to engage with stakeholders on the program impact.

In addition to stakeholder engagement, partnering with policy makers and financing institutions in the planning and implementation of NCD research and capacity building is crucial for securing funding or other resources needed for the continuation of sustainability efforts post intervention (6). Involving policy makers and funding agencies when developing implementation programs and research to consider sustainability allows for more appropriate planning and allocation of funds potentially resulting in a much better understanding of why and how some interventions and programs last and others do not (4). Lastly, engaging with policy makers and funding agencies could address limited national funding and financial barriers that reduce access to hypertension medications in this study as well as in others (28, 29).

Implications and recommendations

Sustaining EBIs remains challenging, especially in LMICs where resources may be scarce. Based in eight countries across three continents, the current study adds renewed perspectives on how sustainability can be planned for, and considered in implementation research, which has received limited scientific attention– particularly in LMIC contexts. Findings from this study may serve as a springboard to identify specifically where implementation gaps exist and where targeted strategies are necessary. Findings also points to the need for equitable participation and stakeholder engagement with implementation practitioners and research funders to exchange knowledge on what influences sustainability throughout the life cycle of an EBI and to understand the values of the organization/health system that supports the sustainability of EBIs. Future research consortia may consider supplements or non-competitive funding opportunities to advance both knowledge and action related to the sustainability of evidence-based NCD interventions in LMICs.

Strengthens and limitations

This study has a number of strengths including the use of data and implementer/ researcher perspectives from eight LMICs, making the findings more generalizable. Second, the study was guided by the COM-B Model. Limitation of this study include the small sample size of survey responses. Additionally, the results were self-reported by respondents thus needing to be validated in a study of long-term project sustainability. Lastly, the structure of the survey grouped both capacity building and intervention implementation in the same questions. While these could have been surveyed as separate concepts, the structure and sustainability of the GRIT Consortium addresses both capacity building and intervention implementation as integrated approaches.

Conclusion

This study describes the perspectives from key implementers of capacity building and NCD intervention implementation efforts across eight low-and-middle income countries. This study addresses a gap in literature by examining the sustainability of evidence-based NCD implementation. Addressing multilevel factors that influence the sustainability of capacity building and interventions will have notable implications for other global NCD efforts going forward. Current and future studies, as well as consortium networks, should account for sustainability barriers and facilitators outlined as it will strengthen program implementation and long-term outcomes.

Data availability statement

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

Author contributions

JI developed the survey using the COM-B Model. AR coordinated survey distribution and data collection. AR and

SM conducted the content analysis and drafted the manuscript. SM, AA, and CC all provided feedback on manuscript sections. All authors reviewed and approved the final manuscript. All authors contributed to the article and approved the submitted version.

Funding

This study was supported by a grant from the National Heart, Lung and Blood Institute (NHLBI), (1-U01 HL 138638).

Acknowledgments

We would like to thank GRIT Consortium members for their participation in this survey and sharing their perspectives regarding sustainability of capacity building and implementing evidence based NCD interventions in their respective sites. Additionally, the authors would like to acknowledge the tremendous and impactful contributions that Dr. Jacob Plange-Rhule made to capacity building efforts and the Hypertension program in Ghana within the GRIT Consortium.

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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frontiers | Frontiers in Health Services

TYPE Systematic Review
PUBLISHED 11 August 2022
DOI 10.3389/frhs.2022.889390

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 04 March 2022
ACCEPTED 19 July 2022
PUBLISHED 11 August 2022

CITATION
Engelhart A, Mason S, Nwaozuru U, Obiezu-Umeh C, Carter V, Shato T, Gbaja-Biamila T, Oladele D and Iwelunmor J (2022) Sustainability of breastfeeding interventions to reduce child mortality rates in low, middle-income countries: A systematic review of randomized controlled trials.
Front. Health Serv. 2:889390.
doi: 10.3389/frhs.2022.889390

Sustainability of breastfeeding interventions to reduce child mortality rates in low, middle-income countries: A systematic review of randomized controlled trials

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Child mortality is the lowest it has ever been, but the burden of death in low- and middle-income countries (LMICs) is still prevalent, and the numbers average above the global mean. Breastfeeding contributes to the reduction of child mortality by improving chance of survival beyond childhood. Therefore, it is essential to examine how evidence-based breastfeeding interventions are being maintained in resource-constrained settings. Guided by Scheirer and Dearing's sustainability framework, the aim of this systematic review was to explore how evidence-based breastfeeding interventions implemented to address child mortality in LMICs are sustained. The literature search included randomized controlled trials (RCTs) of breastfeeding interventions from the following electronic databases: Cochrane Library, Global Health, PubMed, Scopus, and Web of Science. Literature selection and data extraction were completed according to the PRISMA guidelines. A narrative synthesis was used to investigate factors that contributed to sustainability failure or success. A total of 497 articles were identified through the database search. Only three papers were included in the review after the removal of duplicates and assessment for eligibility. The three RCTs included breastfeeding interventions predominately focusing on breastfeeding initiation and exclusivity in rural, semi-rural, and peri-urban areas in South Africa, Kenya, and India. The number of women included in the studies ranged from 901 to 3,890, and the duration of studies stretched from 6 weeks to 2.5 years. In two studies, sustainability was reported as the continuation of the intervention, and the other study outlined program dissemination and scale-up. Facilitators and

barriers that influenced the sustainability of breastfeeding interventions were largely related to specific characteristics of the interventions (i.e., strong intervention implementers—facilitator; small number of CHWs involved—barrier). Optimizing the sustainability of breastfeeding interventions in LMICs is imperative to reduce child mortality. The focal point of implementation must be planning for sustainability to lead to continued benefits and changes in population outcomes. A defined action plan for sustainability needs to be included in both funding and research.

KEYWORDS

sustainability, breastfeeding interventions, child mortality, low- and middle-income countries, randomized controlled trial

Introduction

In 2020, there were 5.0 million children who died before the age of 5 years (1); that is about 13,698 children who die per day globally. However, the global child mortality rate is the lowest it has ever been at 37 deaths per 1,000 live births down from 93 deaths per 1,000 live births in 1990 (1). Health-sector investments and economic growth contribute to the reduction of child mortality in low- and middle-income countries (LMICs) (2). Even with improved efforts, low- and middle-income countries (LMICs) still average at 41 deaths per 1,000 live births (4.1%) (3), which is a higher than the global average. The range of child deaths is predominately large and burdensome within LMICs, ranging from 2 deaths per 1,000 births (0.2%) in Montenegro to 117 deaths per 1,000 births (11.7%) in both Nigeria and Somalia (3), highlighting the need for implementation and sustainment of interventions to reduce child mortality. Currently, the world is not projected to reach the Sustainable Development Goal (SDG) for child mortality in 2030—to reduce the death of children to a rate of at least 2.5% globally (4), about 25 deaths per 1,000 live births (5). Children under the age of 5 are dying every day from pneumonia and other lower respiratory diseases, preterm births and neonatal disorders, diarrheal diseases, congenital defects, and infectious diseases (4). However, populations and individuals can prevent many under-5 child deaths, yet interventions that save children's lives are not evenly dispersed among children aged from birth to 5 years old. Preventing the death of older children has a predominantly higher percentage of success (65%) compared to that for babies (39%) (4). While older children often die from diseases that can be prevented through vaccinations, babies typically die from pre-and post-term birth difficulties (4). In terms of all-cause child mortality, breastfeeding infants early plays a vital factor in saving their lives (6) because the benefits of breastfeeding are advantageous and extend into adulthood for all children no matter their location.

The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) recommend beginning breastfeeding within 1 h of a child's birth, exclusive breastfeeding (EBF) for at least the first 6 months of the child's life, and introduction of nutritious, complementary foods after 6 months (7). Along with these recommendations, the WHO and UNICEF suggest mothers continue with breastfeeding until the child is at least 2 years old (7). The nutritional content of breast milk changes as a child ages in order to fulfill the child's nutritional needs (8) and allows protection with maternal antibodies to fight infection for both the mother and baby (8). Not participating in or continuing with breastfeeding can increase infant and child mortality (9). Breastfeeding has high coverage rates (10), and LMICs have high percentages of children who are breastfed, but only 37% of children under 6 months are exclusively breastfed (11). In high-income countries, about 1 in 5 children are breastfed for the first 12 months (11).

Many barriers inhibit mothers' ability and desire to breastfeed, such as the marketing of breast milk substitutes industry, access to and education through health care facilities/professionals, lack of resources and/or health insurance, and not an adequate amount of paid maternity leave (9, 12, 13). Though the International Code of Breastmilk Substitutes ("the Code") was adopted in 1981 to restrict the marketing of breastmilk substitutes, not all countries aligned with the code, and legislation in many countries still has gaps (14). Even in South Africa, an LMIC that is "substantially" aligned with the Code (14), violations of the Code through aggressive marketing tactics have impacted EBF (15). Yet,

Abbreviations: AE, Alexis Engelhart; CHW, Community Health Worker; CO, Chisom Obiezu-Umeh; DO, David Oladele; EBF, Exclusive breastfeeding; FP, Family planning; IUD, Intrauterine device; JI, Juliet Iwelunmor; LMICs, Low- and middle-income countries; PHC, Primary Health Care; PNC, Postnatal care messages; PPC, Postpartum checklist; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCTs, Randomized controlled trials; SA, South Africa; SDG, Sustainable Development Goal; SM, Stacey Mason; SMS, Short message service; SSA, Sub-Saharan Africa; TG, Titilola Gbaja-Biamila; TS, Thembekile Shato; UN, Ucheoma Nwaozuru; UNICEF, United Nations Children's Fund; VC, Victoria Carter; WHO, World Health Organization.

despite these barriers, if breastfeeding was increased to universal measures, 823,000 children's lives would be saved each year in high mortality rate LMICS (11) because breastfeeding can reduce death due to diarrhea (16), respiratory infections (16), and infectious diseases (17), to name a few (11). In the first 2 years of a child's life, higher risks of child mortality are observed with poor breastfeeding practices, or suboptimal feeding per WHO and UNICEF breastfeeding recommendations (18). The 1-year breastfeeding prevalence is highest worldwide in sub-Saharan Africa (SSA), South Asia, and areas in Latin America (11), yet 1 out of 13 children born in SSA never live to the age of 5 (1, 4). Breastfeeding in these regions is not often sustained until the recommended 2-year mark (11). Scientific literature has been published showing the continued low rates of breastfeeding regardless of the innovative implementation programs, strategies, and evidence (19). Because breastfeeding is a cost-effective intervention to reduce child mortality (19, 20), there is an increasing need to sustain breastfeeding in high mortality areas, LMICs, to uphold the recommended WHO breastfeeding recommendations and contribute to changing the narrative of a child's life.

Sustainability is described in various literature, and according to Proctor et al., an adopted combination of definitions from various scholarly sources, sustainability is "the extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations" (21, 22). Shediac-Rizkallah and Bone used three definitions to describe sustainability: (1) preserving advantages brought about through a primary initiative, (2) keeping an existing implemented program and (3) strengthening a community's ability to maintain a lasting intervention after depletion of funds (23). The WHO and UNICEF created the breastfeeding recommendations to encourage mothers to provide their infants and children with optimal feeding for the suggested timeframes. It is well-known that breastfeeding provides children with nutritious benefits that support their overall health and wellbeing (9). Moreover, breastfeeding for longer periods helps reduce rates of infectious diseases (17); children's risk of chronic diseases such as allergies, asthma, diabetes, obesity, irritable bowel syndrome, and Crohn's disease throughout childhood and adulthood (24–32); and the number of under-5 child deaths (7). To aid this, there are a number of global interventions that are designed with a focus on promoting breastfeeding and strengthening breastfeeding behavior to improve child outcomes (20, 33). And while it's evident that not all interventions are successful, the sustainment of breastfeeding interventions is rarely or never considered.

Despite the importance of sustainability, there are several gaps in research. Lack of sustainability definitions or inexplicit explanations of an intervention's continuation is more common than not. Scheirer and Dearing also mentioned the data collection and evaluation process needs to extend beyond program implementation to reach continuance of activities and outcomes (34). Alongside their definition of sustainability as "the continued use of intervention or program components and activities for the maintained achievement of advantageous intervention or program and population outcomes," the authors presented dependent variables, or sustainability outcomes: (1) continuation of service advantages and outcomes, (2) preservation of original program or intervention activities, (3) maintenance of program created collaborations and partnerships, (4) prolongation of applications and strategies brought about during implementation, (5) preservation of the main issue being addressed throughout the study, and (6) dissemination of intervention and activities to other diverse settings (34). Additionally, they provided what influences sustainability through three independent factors: (1) the intervention's characteristics, (2) components of the organizational or program setting, and (3) components in the environment of the intervention location (34). Though sustainability is not always the end goal, especially if the intervention does not need to be sustained due to undesirable intervention or population outcomes, it should be the key objective if an intervention is needed in a specific area, contingent on research-based evidence (35).

Initiation and duration of breastfeeding are crucial and well-researched, but many systematic reviews fail to explore how to sustain breastfeeding interventions in LMICs or center around implementation or cost-effectiveness of interventions to reduce under-5 mortality. There is considerable research on the implementation of and scaling up breastfeeding practices, but there is limited evidence-based research on if breastfeeding interventions are sustained beyond a certain period; thus, the aim of this systematic review was to determine (i) how breastfeeding interventions are continued or sustained in low- and middle-income countries to reduce child mortality rates, and (ii) identify the barriers and facilitators to the sustainability of breastfeeding interventions in LMICs.

Methods

Search strategy

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used to develop and outline the search strategy (36). We searched Cochrane Library, Global Health, PubMed, Scopus, and Web of Science using the following search terms: (child OR children OR infant OR infants OR neonate OR neonates OR newborn OR newborns OR "under-five child" OR "under-five children") AND ("child mortality" OR "child death" OR "infant mortality" OR "infant death" OR "neonatal mortality" OR "neonatal death" OR "under-five mortality" OR "under-five death") AND (breastfeeding OR "breast feeding" OR breast-feeding OR breastfeed OR "breast feed" OR breastfed OR "breast fed"

TABLE 1 Evidence-based breastfeeding and child mortality definitions.

Term	Definition
Breastfeeding	Children receive breast milk (including breast milk which has been expressed or from a wet nurse) and are allowed to also receive any food or liquids which includes non-human milks and formulas (37, 38)
Exclusive breastfeeding (EBF)	Infants (<6 months) are fed only breast milk (including breast milk which has been expressed or from a wet nurse) and nothing else, except for oral rehydration salts (ORS), prescribed medicines, vitamins, and minerals (37–39)
Predominant breastfeeding	Infants are predominantly fed breast milk (including breast milk which has been expressed or from a wet nurse) and nothing else, except for certain liquids such as water, water-based beverages, fruit juice, ritual solutions and ORS, prescribed medicines, vitamins, and minerals (37, 38)
Mixed feeding	Infants (<6 months) receive both breast milk and other foods and liquids which includes non-human milks and formulas (39)
Complementary feeding	Children (recommended > 6 months) receive solid, semi-solid, soft foods, or liquids which includes non-human milks and formulas while also breastfeeding (37–39)
Early initiation of breastfeeding	Children who were introduced to the mother's breast within 1 h of birth in the last 24 months (37, 38)
Continued breastfeeding	Children who receive breast milk measured at both ages 12–15 months of age (continued breastfeeding at 1 year) and 20–23 months (continued breastfeeding at 2 years) (37, 38)
Infant	A child who is <1 year old (40)
Child/under-five mortality	The death of a child before the age of 5 years (rate expressed per 1,000 live births) (41)
Infant mortality	The death of a child before the age of 1 year (rate expressed per 1,000 live births) (41)

OR "infant feeding" OR "newborn feeding" OR "human milk" OR "breast milk" OR "exclusive breastfeeding" OR "exclusive breast feeding") AND ("randomized controlled trial") AND (sustainability OR sustain OR sustainable). We used other systematic reviews relating to breastfeeding implementations and child mortality to help guide our search strategy (18). Language limitations and the setting of LMICs were not applied in the search; countries were assessed manually. The search was from 10/14/20 to 04/07/21.

Study selection

After identifying articles through the database search, duplicate records were removed, and an initial screening of all titles and abstracts was conducted separately by two authors (AE, CO). The full-text articles with possible significance were also independently assessed by the same authors (AE, CO) using eligibility criteria. We identified relevant articles and performed data extraction for those articles included in this review.

Definitions

The following table provides a list of evidence-based definitions we used to add credibility and consistency when determining breastfeeding practices and child mortality (Table 1).

Sustainability framework

Sustainability was defined based on the sustainability framework adapted from Scheirer and Dearing (Figure 1) (34). This conceptual framework for sustainability includes factors affecting sustainability (independent variables) and sustainability outcomes (dependent variables) and their placement within the broader context of social, policy, and financial environments (34). This framework displays factors influencing sustainability and outcomes of sustainability are linked with financial resources, and the environments encompassing the organizational environment are impactful to the sustainability of an intervention (34).

Inclusion and exclusion criteria

Inclusion and exclusion criteria were created, and titles, abstracts, and keywords were examined by two reviewers to determine eligibility for inclusion in the systematic review.

Our inclusion criteria were randomized controlled trials that included (i) infants and children (≤2-years-old) that participated in the initiation of breastfeeding practices, exclusive breastfeeding for the first 6 months of life, or breastfeeding between 6 and 23 months of age, (ii) sustainability of breastfeeding interventions implemented in low- and middle-income countries (inclusion of articles that specifically mentioned breastfeeding and also based

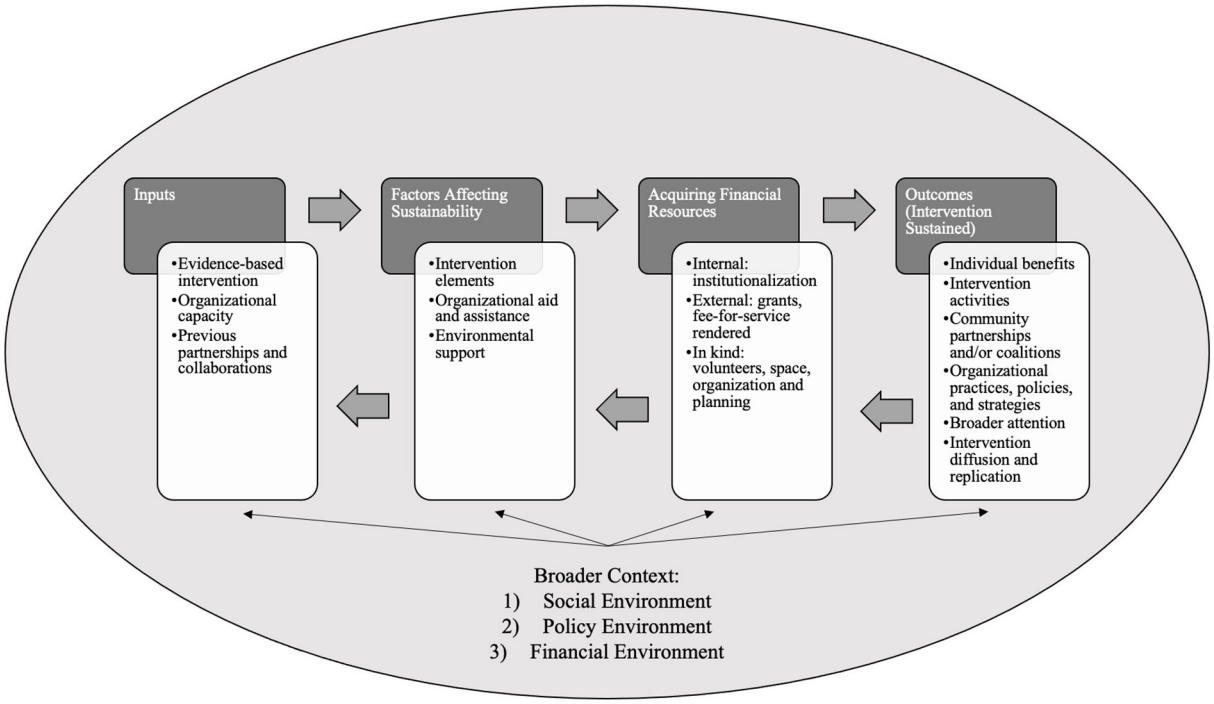

FIGURE 1
Conceptual sustainability framework.

on the definition of sustainability provided), (iii) past or current status of breastfeeding practices, and (iv) criteria i-iii related to confirmed or potential contribution to or reduction of child mortality in LMICs. No timeframe was specified for inclusion. The current WHO and UNICEF definitions were used to determine breastfeeding practices (37–39) (Table 1) and child mortality criteria (41), and sustainability criteria were adapted from Iwelunmor et al. (42). Reasons for exclusion throughout the selection of studies, derived from the inclusion criteria, were noted and are summarized in the PRISMA diagram (Figure 2). If insufficient information was included in the paper to determine study eligibility/inclusion in the review, the author of the paper was contacted. If the author did not respond, the study was excluded from the review.

Data extraction

After assessing full-text articles using predetermined inclusion and exclusion criteria, data extraction was performed separately by two authors (AE, CO). Key concepts and findings from each relevant article were recorded in an excel spreadsheet for comparison. Data extracted included: author and year, intervention country, study population, theory or framework used, outcomes, type of breastfeeding, breastfeeding intervention, the definition of sustainability, and results. A summary table was created to examine the key study details and the sustainability of the breastfeeding intervention included in each study.

Data analysis

Narrative synthesis, "an approach to the systematic review and synthesis of findings from multiple studies that relies primarily on the use of words and text to summarize and explain the findings of the synthesis" (43), or an analysis of relationships between studies, was used to examine data from the articles in this review. Two authors (AE, CO) independently conducted the narrative synthesis. Narrative synthesis is distinctive for the reason in which it is a literary method to describe study findings (43). There are four main elements of narrative synthesis: (1) development of an intervention theory or framework answering the questions how it works, why, and for whom it is for; (2) development of an initial synthesis; (3) investigation of parallels in data; and (4) assessment of vigor of the synthesis (43). Any discrepancies during screening, data extraction, and data analyzation were discussed until agreed upon by the two authors (AE, CO). If there wasn't

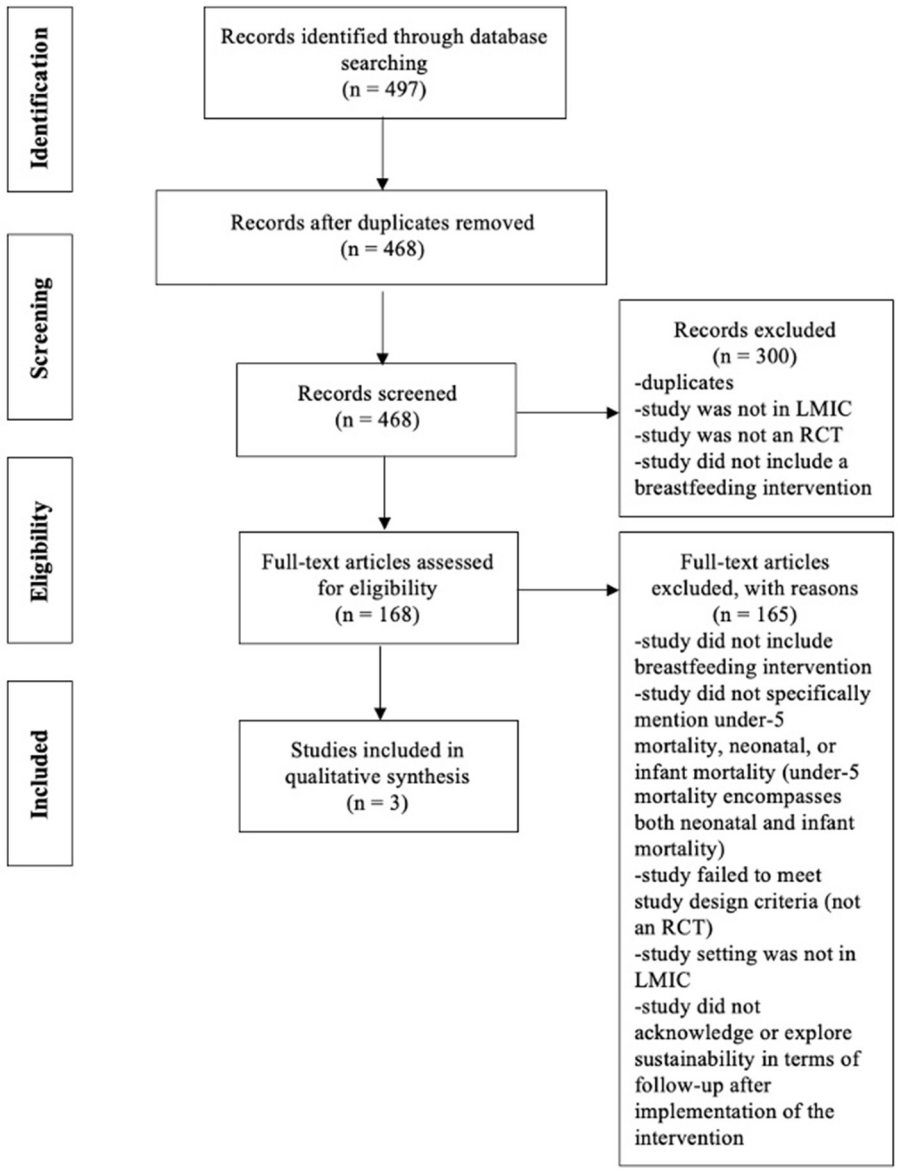

FIGURE 2
The preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow diagram.

agreement, a third author (UN) was brought in to break the tie.

Risk of bias

The quality and risk of bias of each RCT was assessed using the Cochrane risk of bias tool and reported in Table 2. The Cochrane tool for RCTs assesses five domains: (1) bias emerging from randomization (selection bias,) (2) bias due to veering from planned interventions (performance bias), (3) bias due to absent outcome data (attrition bias), (4) bias in assessing the outcome (detection or measurement bias), and finally, (5) bias in preference of reported result (selective reporting bias) (47). Per the training handbook and tool for randomized trials (47, 48), signaling questions were answered independently to determine the risk of bias for each domain: low risk of bias, some concerns, or high risk of bias. Two authors (AE, CO) assessed the risk of bias for each domain in each article. Discrepancies were noted, and a final decision was determined using a third author (UN), if needed. While each RCT was assessed for quality and risk of bias, no RCT was excluded based on results of the bias assessment.

TABLE 2 Characteristics of included articles in the review.

References	Location/setting	Study population	Theory/ framework	Outcomes	Mortality	Type of breastfeeding
Daviaud et al. (44)	Umlazi district in KwaZulu-Natal province of South Africa	Pregnant women, ages 17+, and their newborns who were living in the 15 intervention clusters during the recruitment period and provided consent. The study included 30 randomized clusters (15 intervention and 15 control).	None	Primary—assess the effects of CHW antenatal and postnatal home visits through measurements of HIV-free survival, EBF at 12 weeks after birth, care coverage, behavioral indicators (antenatal HIV testing, postnatal visit to clinic within 7 days post birth, uptake of cotrimoxazole for infants subject to HIV exposure, and making use of available family planning practices), and levels of post-partum depression	Neonatal	EBF
Jones et al. (45)	Kiambu County, Kenya	Women from postnatal wards aged between 18 and 40 years old who had a vaginal delivery at 1 of the 3 public health facilities with access to a mobile phone	None	Assess knowledge of danger signs and seeking care related to that knowledge, general postnatal care, and family planning	Maternal and neonatal	EBF
Kumar et al. (46)	Shivgarh, rural block in Uttar Pradesh, India	Pregnant women in 39 village administrative units of 104,123 people total	None	Changes in newborn care applications and neonatal mortality rates	Neonatal	Early initiation of breastfeeding

References	Breastfeeding intervention definition	Design description	Data collection	Definition of sustainability	Project timeline	Results
Daviaud et al. (44)	Intervention assessed exclusive and suitable infant feeding at 12 weeks through Community Health Worker antenatal and postnatal home visits	30 randomized clusters of which 15 were intervention and 15 control; CHWs were trained through role plays, demonstrations, real-life experiences, and discussions. CHWs carried out two antenatal visits, a visit within 48 h of birth, four postnatal visits (between days 3–4, days 10–14, 3–4 weeks, and 6–7 weeks), and a final visit between 7 and 8 weeks.	Medical record reviews (routine health data and delivery data) and in-person interview assessments (at 12 weeks postpartum, documentation of CHWs (training, supervising, retention, coverage of visits), 12 week endpoint data and intervention delivery through mobile phones, tool developed by authors to estimate costs, dried blood spots from infants with HIV infected mothers through heel prick (at 12 weeks interview) and tested using DNA PCR testing	Continuation of intervention and scale-up: a multi-purpose CHW now carries out the intervention through Primary Health Care Re-engineering.	Intervention from Jun. 2008–Dec. 2010	EBF prevalence at 12 weeks increased from 15% in the control cluster to 29% in the intervention clusters [Relative Risk 1.92 (95% CI: 1.59–2.33)]. The intervention had a greater effect on mothers who were HIV negative [RR 2.16 (95% CI 1.71–2.73)]. There was not a difference in effect in relation to mothers' education or socioeconomic status. Each additional CHW home visit correlated with a 6% increase in EBF. There was no influence on HIV-free continuation (5.4 vs. 4.5%).

(Continued)

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TABLE 2 Continued

References	Breastfeeding intervention definition	Design description	Data collection	Definition of sustainability	Project timeline	Results
Jones et al. (45)	Breastfeeding included in postpartum checklist messages ("yes/no" questions to assess for insufficient breastfeeding) and general postnatal care messages (general breastfeeding information)	Randomized controlled trial with 4 study arms in which participants were randomized (through a random number generator) into 1 of the 4 groups and uploaded into SMS system: Arm 1-control group in which participants received only standard care (no SMS), Arm 2-intervention group that received postpartum checklist (PPC), Arm 3-intervention group that received PPC plus postnatal care messages (PNC) and reminders 4 weeks post discharge, Arm 4-intervention group that received PPC as well as family planning (FP) messages and reminders 4 and 6 weeks post discharge	Baseline surveys, postpartum checklists "Yes/No" questions throughout intervention, messages tested through focus groups, endline data surveys (8 weeks postpartum)	Continuation and replication of intervention through expansion of access to messaging platform to 5 counties in Kenya, including Kiambu County (setting of study); messaging service now named "PROMPTS"	Enrollment Nov. 2017–Mar. 2018; endline data collection May 2018	Women who received PPC messages were 1.6 times more likely to list 1+ postpartum danger signs (OR = 1.60, 95% CI: 1.07–2.38), 2.57 times more likely to list fever/chills (95% CI: 1.10–5.96), and 3.51 times more likely to seek treatment (95% CI: 1.22–10.07) compared to control group. No difference in general maternal care-seeking or newborn-care seeking behaviors between intervention groups and control. Women who received FP messages were 1.85 times more likely to use FP services (OR 1.85, 95% CI 1.16–2.94), those who were told about FP by healthcare professionals were 2.27 times more likely to use FP services (OR 2.27, 95% CI 1.53–3.35), and women who received FP messages were 2.1 times more likely to use an implant or IUD contraceptive method (OR = 2.10 95% CI 1.06–4.15) compared to controls.

(Continued)

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TABLE 2 Continued

References	Breastfeeding intervention definition	Design description	Data collection	Definition of sustainability	Project timeline	Results
Kumar et al. (46)	Intervention focused on behavior change management aimed toward thermal control and modifying newborn care (birth preparedness, delivery and cod care, thermal care, promoting breastfeeding and recognizing danger signs).	3-arm cluster-randomized controlled trial; control group only received the governmental and non-governmental services, 1 intervention group received the same services as the control group combined with a preventative necessary newborn care package, and the other intervention group was given the newborn care package along with a liquid crystal sticker to identify hypothermia (ThermoSpot). There was 1 community worker per cluster unit. Stratified cluster randomization-39 cluster units were divided among the 3 groups equaling 13 clusters in each group. Volunteers helped with advocacy, building trust, and promoting behavioral changes, and mothers who were great examples of the intervention were used as role models for other pregnant women in the community. Daily and monthly meetings occurred for regional supervisors and their teams. CHWs completed meetings and 2 antenatal and postnatal home visits with intervention groups.	Demographic and socioeconomic indicators collected per household; neonatal deaths and stillbirths assessed through retrospective recall (1 year prior to intervention); knowledge, attitudes, practices, and limitations (maternal and newborn care) collected through a random sample of women who delivered (1 year prior to intervention); pregnancy and birth outcomes identified in study population; baseline surveys identified pregnant women in study areas through 3 monthly door-to-door visits followed with outcome on expected delivery date; 2 door-to-door inspections on pregnancy outcomes; stillbirths and neonatal deaths recorded through questionnaires; knowledge, attitudes, practices, and limitations (maternal and newborn care) collected for those who delivered in study clusters through semi-structured format	Program diffusion, scale-up, and replication: approach is included in the child survival program In Uttar Pradesh and scaled-up through the public health structure.	2003–2006; intervention from Jan. 2004–May 2005	Findings of improvements within the intervention groups were in birth preparedness, hygienic deliveries, newborn thermal care, umbilical cord cutting and care, skin care, and initiation of breastfeeding within 1 h of birth. Adjusted neonatal mortality rate was 54% lower in the newborn care group than control (Rate Ratio 0.46, 95% CI 0.35–0.60, $p = 0.0001$) and 52% lower in the newborn care plus ThermoSpot group than control (RR 0.48, 95% CI 0.35–0.66, $p = 0.0001$).

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Results

Search results

As documented in the PRISMA diagram, the final database search identified a total of 497 articles. Of these articles and after duplicates were removed, 468 titles and abstracts were screened, and 168 full-text articles were independently assessed using inclusion and exclusion eligibility criteria. Only three randomized controlled trials (44–46) were included in our review after excluding ineligible manuscripts (Figure 2). The characteristics of included articles are shown in Table 2 and described below.

Characteristics of included studies

Characteristics of the three RCTs that met the eligibility criteria are outlined in Table 2. The studies were published in 2008, 2017, and 2020. The interventions incorporated populations from rural, semi-rural, and peri-urban areas in South Africa (SA), Kenya, and India. Two studies (44, 45) included interventions that evaluated EBF, and one study (46) concentrated on the initiation of breastfeeding. The study populations ranged from 901 (45) to 3,890 (46) participants. Two of the three studies engaged with pregnant women (44, 46), and the other recruited new mothers from postnatal wards (45). The duration of the interventions ranged from 6 weeks (45) to 2.5 years (44). All three studies (44–46) mentioned characteristics of sustainability. However, none used clear definitions of sustainability to describe the continuation of the intervention. Rather, sustainability outcomes of the three RCTs were briefly reported as two of the six dependent variables introduced by Scheirer and Dearing (34).

The included three studies assessed different outcomes using distinct intervention components and data collection methods and measurements. The first study by Daviaud et al. was an economic evaluation of community-based maternal and newborn care from the 2008–2010 South Africa (Goodstart III) cluster-randomized controlled trial (44). This article sought to assess the cost implications of Community Health Worker (CHW) antenatal and postnatal home visits with findings related to the coverage of the intervention, costs of the intervention, and time utilization to determine the sustainability of the program and viability of program replication (44). This paper included background of the RCT, but two other papers, the RCT protocol (49) and a manuscript published on the results (50), were obtained to extract additional data from the study. The intervention was implemented from June 2008 to December 2010 in peri-urban settlement in Umlazi with the costing covering April 2009 to March 2010 (44). The study included 30 randomized clusters of which 15 were in the intervention and 15 were in the control group (44, 49, 50). Participants in the study sample were pregnant women aged 17 and older, who were able to give informed consent to engage in the study, and their newborns in the intervention clusters throughout the recruitment span (44, 49). The intervention's primary outcomes were to gauge the effect of CHW antenatal and postnatal home visits through a set of specific measurements: (1) HIV-free survival, (2) EBF at 12 weeks after the birth of the child, (3) care assurance, (4) behavioral measures (HIV testing before the birth of the child, visit to clinic within 7 days post birth of the child, uptake of cotrimoxazole for babies subject to HIV exposure, and making use of family planning applications), and (5) extent of post-partum depression (44, 49). In terms of breastfeeding, this study's intervention utilized CHWs to assess exclusive and suitable infant feeding at 12 weeks after the child's birth. CHWs were trained thoroughly through a variety of methods such as role-playing, presentations, and conversations (44, 49) to prepare for their antenatal and postnatal home visits to the mothers. CHWs completed eight total visits during the intervention: two antenatal visits; a visit within 48 hours of the child's birth; four postnatal visits between 3–4 days, days 10–14, 3–4 weeks, and 6–7 weeks; and the last visit between 7 and 8 weeks. EBF was recorded for each mother at each visit, and at 12 weeks, mothers participated in in-person interviews with a final assessment of EBF. The intervention proved to be significant in regard to EBF (95%, CI: 1.59–2.33), and a dose-response effect was determined between CHW visits and EBF (6% increase with each visit) (44).

Jones et el. highlighted an RCT study focused on increasing knowledge and pursuit of care behaviors of mothers in peri-urban public facilities in Kiambu County, Kenya, through 6-week short message service (SMS) content intervention (45). Study participants were women aged 18–40 years old from postnatal wards in three public health facilities which assisted individuals from both semi-rural and peri-urban sites (45). Eligible women were those who performed a vaginal delivery at one of the three facilities and obtained a mobile phone (45). Women included in the study were randomized into 1 of 4 study arms and added into a SMS system. The arms were as follows: Arm (1) control group in which participants received only standard care (no SMS), Arm (2) intervention group that received postpartum checklist (PPC), Arm (3) intervention group that received PPC plus postnatal care messages (PNC) and reminders 4 weeks post discharge, and Arm (4) intervention group that received PPC as well as family planning (FP) messages and reminders 4- and 6-weeks post-discharge (45). The primary outcomes of the study were to assess mothers' knowledge of danger signs and seeking care related to that knowledge, postnatal care, and family planning. Outcomes allied to danger signs and seeking care, allied to postnatal care, and allied to family planning were compared to women in the respected arms and then to

all women clustered together (45). The intervention gauged EBF using an SMS messaging platform: PPC close-ended, "yes/no," messages were implemented to evaluate for insufficient breastfeeding and general postnatal care messages including information on breastfeeding, infant care, and family planning were communicated every 3 days after the child's birth from day 6 to 36 (45); FP messages were also included in one arm of the intervention that specifically focused on guidance appertained to 2-year birth spacing, contraception methods, and prompt to remind mothers they can become pregnant after the birth of their child before beginning menstrual periods (45). Significance was identified between participant groups that received PPC messages and those that received FP messages. Participants who received PPC messages were 1.6 times more likely to list postpartum danger signs, 2.57 times more likely to list fever/chills, and 3.51 more times likely to seek further treatment compared to the control group (45). Participating women who received FP messages were 1.85 times more likely to utilize FP services and 2.1 times more likely to employ an implant or intrauterine device (IUD) contraceptive method (45).

Finally, the Kumar et al. study was a cluster-RCT located in a rural area in Uttar Pradesh, India. The trial was a community-based behavior change management intervention that sought to evaluate changes in newborn care applications and neonatal mortality rates (46). Thirty-nine clusters were either randomly assigned to the control group or one of the two intervention groups, equaling 13 clusters per group (46). The control group only received the typical organizational services within the area whereas one intervention group received those same services as the control group with an addition of the preventative necessary newborn care package and the other intervention group was given the newborn care package along with Thermospot (a color changing sticker used to determine hypothermia) (46). The newborn care package included birth readiness, sanitary delivery of the baby, and prompt newborn management: cleansed umbilical cord and skin care, skin-to-skin care, breastfeeding, and seeking care from providers (46). There were 1,141 pregnant women in the control group, 1,600 pregnant women in the first intervention group, and 1,149 pregnant women in the second intervention group (46). To design the intervention, participatory social mapping and qualitative research actions were utilized to learn more about the community and identify and develop an intervention strategy (46). CHWs delivered the newborn care packages to the intervention groups through meetings and four home visits, two before the birth of the baby (60 and 30 days) and two after the birth of the baby (within 24 h of delivery and on day 3 post-delivery) (46). The intervention time span was over 1 year lasting from January 2004 to May 2005 (46). Behavior change management—thermal control and modifying newborn care—was evaluated through door-to-door CHW visits and questionnaires. The findings included improvements in initiation of breastfeeding within 1 h of birth within the intervention groups and in adjusted neonatal mortality rates, with rates 54% lower the newborn care group and 52% lower in the newborn care plus ThermoSpot group than the control (46).

Narrative synthesis

Facilitators and barriers toward sustaining breastfeeding interventions were identified in the three articles (Table 3). According to Scheirer and Dearing (34), facilitators and barriers of sustainability, or independent variables that affect the sustainability of the intervention, can be categorized into three themes: (1) characteristics of the intervention, (2) factors in the organizational setting, and (3) factors in the community where the intervention is placed, as seen in their conceptual sustainability framework (Figure 1) (34). Facilitators and barriers of the included articles were identified and categorized into the three main categories of sustainment from Scheirer and Dearing (Table 4). Majority of facilitators and barriers were characteristics of the interventions.

Characteristics of the intervention, specifically

Facilitators Characteristics of the intervention were recognized by all articles as facilitators of sustainability. In South Africa, well-resourced supervision of the CHWs positively affected sustainability of the maternal and newborn care intervention (44). The intervention was noted for its effectiveness and used multipurpose CHWs during re-engineering of the PHC platform (44). A second study by Jones et al. was efficacious particularly with postpartum and postnatal knowledge and care-seeking behaviors (45). Intervention characteristics like family planning messages and postpartum checklists influenced odds of uptake and supported knowledge and care-seeking, respectively (45). In an intervention in India, the implementers of the program, the *Saksham Sahayaks*, played a valuable role in the effect of the study (46).

Barriers Several barriers were identified in the articles. Many barriers in Daviaud et al. were related to CHWs such as the limited number of CHWs, the concept of ideal utilization of CHW time and the time CHWs actually spent on program activities, low remuneration of CHWs, and the lack of an accountability for CHWs and supervisors (44). Additionally, the researchers noted that the cost of the intervention was very high (44). Jones et al. recognized that ownership and access to mobile phones, the broad messaging around postpartum check-ups, and the generalizability of the intervention in terms of phone ownership, literacy, and facility delivery rates were barriers to sustain the intervention (45).

TABLE 3 Summary of intervention sustainability.

References	Sustainability outcomes as defined by Scheirer and Dearing: dependent variables of the intervention	Facilitators and barriers as defined by Scheirer and Dearing: factors affecting sustainability	
		Facilitators	Barriers
Daviaud et al. (44)	Continuation of intervention and scale up: a multi-purpose CHW now carries out the intervention through Primary Health Care Re-engineering	1. Supervision was well-resourced 2. Complex mHealth system was set up 3. Evidence-based intervention effectiveness 4. Multipurpose CHWs during e-engineering of PHC platform	1. High intervention cost 2. Low remuneration of CHWs 3. CHWs spent minimal hours on programme activities (CHW performance) due to several challenges/reasons 4. Concept of "optimal use of CHW time" 5. Small number of CHWs involved 6. Reliability of time monitoring 7. Lack of accountability system for CHWs and supervisors
Jones et al. (45)	Continuation and replication of intervention through expansion of access to messaging platform to 5 other counties in Kenya, including Kiambu County (setting of study); messaging service now named "PROMPTS"	1. Evidence based intervention effectiveness (postpartum and postnatal knowledge and care-seeking behaviors) 2. Family planning messages influenced odds of uptake at 8 weeks postpartum 3. Postpartum checklist supported knowledge and care-seeking	1. Participant resources—reliance on women who own or have access to mobile phones 2. Messaging around postpartum check-ups was broad 3. Generalizability of intervention—phone ownership, literacy, and facility delivery rates—innovation characteristics
Kumar et al. (46)	Program diffusion, scale-up, and replication: the intervention is included in the child survival program in Uttar Pradesh and scaled-up through the public health structure.	1. Evidence based intervention effectiveness 2. Active participation of community members 3. Strong intervention implementers 4. Support from community volunteers and newborn-care stakeholders	1. Behavior change and differing cultural barriers

TABLE 4 Facilitators and barriers as defined by Scheirer and Dearing: factors affecting sustainability.

Factors affecting sustainability	Facilitators	Barriers
Characteristics of the intervention	1. Strong intervention implementers (46) 2. Supervision was well-resourced (44) 3. Multipurpose CHWs during e-engineering of PHC platform (44) 4. Family planning messages influenced odds of uptake at 8 weeks postpartum (45) 5. Postpartum checklist supported knowledge and care-seeking (45) 6. Evidence based intervention effectiveness (44, 46) 7. Evidence based intervention effectiveness (postpartum and postnatal knowledge and care-seeking behaviors) (45)	1. CHWs spent minimal hours on programme activities (CHW performance) due to several challenges/reasons (44) 2. Concept of "optimal use of CHW time" (44) 3. Small number of CHWs involved (44) 4. High intervention cost (44) 5. Low remuneration of CHWs (44) 6. Lack of accountability system for CHWs and supervisors (44) 7. Participant resources—reliance on women who own or have access to mobile phones (resources) (45) 8. Messaging around postpartum check-ups was broad—context (intervention structure) (45) 9. Generalizability of intervention—phone ownership, literacy, and facility delivery rates—innovation characteristics (45)
Factors in the organizational setting	1. Complex mHealth system was set up (44)	None
Factors in the community environment	1. Support from community volunteers and newborn-care stakeholders (46) 2. Active participation of community members (46)	1. Behavior change and differing cultural barriers—context (climate, culture) (46)

Factors in the organizational setting, specifically

Facilitators Factors in the organizational setting were other facilitators identified. In one article, Daviaud et al., it was found that the complex mHealth system, which was established for research and supervision, aided with data collection, supervision, monitoring, and scheduling (44).

Factors in the community environment of each intervention site, specifically

Facilitators Factors in the community environment of each intervention site were also categorized as facilitators. Only one article, Kumar et al., communicated facilitators favoring sustainability such as the support from community volunteers and newborn-care stakeholders and active participation of community members for the duration of the research (46).

Barriers Only one barrier was identified in the articles. Kumar et al. highlighted behavior change and differing cultural barriers (46).

Sustainability outcomes

Sustainability of breastfeeding interventions were grouped based on sustainability outcomes (dependent variables), as categorized by Scheirer and Dearing (34) (Table 3).

Continuation of intervention

The RCT by Daviaud et al. presented sustainability of the intervention as a continuum of the program through Primary Health Care (PHC) Re-engineering carried out by a multi-purpose CHW, constituting 19% of CHW time for 95% coverage of mothers (44). Leading motives of PHC re-engineering are to improve the geographical context and quality of health, prevention strategies, and health outcomes; enhance efforts of community PHC forces, initiate awareness of social determinants of health, and design a well-structured and effective health system (51). The PHC Re-engineering program goal is to complete seven visits per mother (44).

Program dissemination and replication

Kumar et al. mentioned program diffusion and scale-up of the intervention in the study (46). The intervention was accepted as a scale-up framework and approach for expansion and growth and merged into the state's (Uttar Pradesh) public child survival program in India (46). This development and scale-up fosters the newborn care package and extends engagement to over 30 million individuals within the state (46).

The study by Jones et al. yielded both sustainability outcomes mentioned above. This study continued, replicated, and expanded its breastfeeding intervention to five counties in Kenya, including the original setting of the study (45). The findings led to an expansion of opportunity, or increased access, of the messaging platform to women in different counties across Kenya. The study's original enrollment began in November 2017, with endline data collection finalized in May 2018 (45). By May 2020, in just 2 years, and with a new name, PROMPTS, over 150,000 expecting and new mothers enrolled to receive communication from the SMS platform (45).

Quality of evidence

The articles of RCTs included in the results were assessed for risk of bias (47, 48) and included in Table 5. The risk of bias was similar in all articles, though one of the articles (44) was found to have a high risk of bias arising from the randomization process resulting in a 16.7 % risk of bias overall. The other two interventions had no risk of bias.

Discussion

Several studies have examined breastfeeding through an implementation science lens (52–54), but to the best of our knowledge, there is no article discussing sustainability outcomes in the context of breastfeeding interventions to reduce child mortality. This systematic review aimed to analyze how breastfeeding interventions, with intentions of decreasing child mortality rates, are being sustained in resourced-limited LMICs and identify if any barriers or facilitators that contributed to the sustainability of breastfeeding interventions in LMICs. To our knowledge, this review is the first that looks at the sustainability of breastfeeding interventions in LMICs. It extends the literature on breastfeeding to address child mortality and the area of sustainability in general. Only three breastfeeding interventions in India, Kenya, and South Africa were identified and reported on, and their sustainability was assessed.

Findings communicate that sustainability outcomes of breastfeeding interventions in LMICs were either (1) a continuation of the intervention's activities or components or (2) a diffusion and replication of the intervention as categorized by Scheirer and Dearing (34). Facilitators and barriers toward sustaining breastfeeding interventions in LMICs were largely those of characteristics of the interventions. Facilitators included strong intervention implementers (46), well-resourced supervision (44), use of multipurpose CHWs (44), positive influence of family planning messages (45), supportive postpartum checklist (45), and evidence based intervention effectiveness (44–46). Barriers consisted of a variety of different reasons such as minimal hours being spent on program activities (44), concept of "optimal use of CHW time" (44), not enough CHWs involved (44), high intervention cost

TABLE 5 Risk of bias assessed in randomized controlled trails included in review.

References	Bias arising from the randomization process (selection bias)	Bias due to deviations from intended interventions (performance bias)		Bias due to missing outcome data (attrition bias)	Bias in measurement of the outcome (detection/ measurement bias)	Bias in selection of the reported results (reporting bias)	% risk of bias
		Effect of assignment to intervention	Effect of adhering to intervention				
Daviaud et al. (44)	High risk	Low risk	Low risk	Low risk	Low risk	Low risk	16.7%
Jones et al. (45)	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	0.0%
Kumar et al. (46)	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	0.0%

(44), low remuneration of CHWs (44), lack of accountability system (44), lack of participant resources (45), broad messaging (45), and generalizability (45). In the organizational setting, specifically, one facilitator was a complex mHealth system (44). In the community environment, there was support from community volunteers and newborn-care stakeholders as well as participation from the community members (46), but a barrier included behavior change and differing cultural context (46). Of the three studies, none included a clear definition of sustainability backed by literature, and there were limited sustainability plans.

With regard to sustainability, the literature reiterates the importance of the timing of research concerning sustainability and the importance of considering sustainability as a set of outcomes or variables rather than a process (34). Not only, it highlights planning for sustainability during the planning and design of the evidence-based intervention rather than after the implementation and evaluation, or latter stages, where researchers generally place the development (55–58). The articles call attention to sustainability as an outcome, but consistent with findings from Iwelunmor et al. (42), planned sustainability efforts were not addressed across all of the studies, even if planned, coinciding with the literature whereby there is, unfortunately, a great deficiency in the planning of sustainability (59). But costing and human resources of the Daviaud et al. Goodstart III intervention were analyzed, and health systems issues of connections to sustainability planning and assurance were identified (44). The study accentuates its goal of developing, assessing, and costing the intervention delivered by CHWs to scale-up and continue the intervention (44, 49, 50). Daviaud et al. highlights the critical call for "planners" to ensure the sustainability of interventions as the lack of financial sustainability of program funding contributes to the collapse of program sustainability (44). Although this is appreciable, the "planners" (44) need to be the researchers. The responsibility of planning to sustain programs is the researchers', the funders', physicians', and program recipients' rather than assuming that sustainability planning is allocated to a "planner" (59).

Not only should sustainability planning be implemented and fulfilled during the intervention development phase, but sustainability definitions and proper use and modeling of evaluated sustainability frameworks should be incorporated within the research (60). This can aide researchers to understand the issues pertaining to precision, adaptation, and essence of the intervention scheme (61). The lack of sustainability frameworks used in research is unfortunately common (60, 61) but framework selection and application should remain a priority.

While it is well-known that there is no universal, confirmed definition of sustainability (62), sustainability was approached in the three studies based on Scheirer and Dearing's sustainability outcomes (34) of continuation of intervention and scale up (44); program diffusion, scale-up, and replication (46); or both (45). Consistent with other literature (63–65), sustainability in these studies reached continuance of activities and outcomes (34). Evidence shows that there is a narrowed focus of sustainability in research, or it is not clearly applied in research (57). In these three studies (44–46), there was minimal reporting on sustainability which made it difficult to determine the extent to which the intervention was sustained. However, these studies identified drivers or barriers that affected the sustainability of breastfeeding interventions.

Earlier reviews have discovered and categorized various facilitators and barriers that affect the sustainability of interventions (55, 61, 63, 66, 67) utilizing different frameworks such as Stirman's influences on sustainability (innovation, organizational context, capacity, and processes) (61), Mays's General Theory of Implementation (capability, capacity, contribution, and potential) (68), Lennox's Consolidated Framework for Sustainability Constructs in Healthcare (initiative design and delivery, negotiating initiative processes, the people involved, resources, organizational setting, and

external environment) (69), and Schell's nine domain framework (political support, funding stability, partnerships, organizational capacity, program evaluation, program adaption, communications, public health impacts, and strategic planning) (70). Moreover, few reviews identified facilitators and barriers of breastfeeding interventions (71, 72), but we are unaware of any that particularly assessed those combined, relating to the sustainability of breastfeeding interventions. We categorized facilitators and barriers of interventions in this review by Scheirer and Dearing's factors affecting sustainability (intervention characteristics, organizational setting factors, and community environmental factors) (34), of which other reviews have utilized as well but in different aspects such as youth peer health education network in primary schools (73) and in a school-based bullying prevention program (74). While these factors are similar to those of other frameworks and models, we still see gaps and variations in evidence across the sustainability domain (75).

We are not informed of any other RCTs that specifically define sustainability, plan for sustainability, include a framework of sustainability, and/or discuss the sustainability of a breastfeeding intervention in-depth or even those that explain the reasoning behind an intervention that is not sustained. These gaps present a challenge to evaluate the sustainability of breastfeeding interventions in LMICs. Sustaining a successful intervention should be the objective, but many fall short of this goal in under-resourced locations that need these basic interventions the most. Studies found that were not RCTs primarily accessed breastfeeding knowledge, were not specific interventions for maintaining breastfeeding among mothers, and/or exhibited the relationship between factors and characteristics to lead to breastfeeding practices. Though limited in the number found, the included RCTs provided the information we needed in terms of breastfeeding interventions but occasionally lacked inclusion criteria. Future implications to mind the gap include approaches to address research in practice, specifically, that of sustainability (55). Along with adoption and implementation, sustainability needs to stay at the forefront.

Limitations

Our review has several limitations. First, a possible limitation would be the specifics of our inclusion criteria that resulted in a limited number of articles in our search. Second, our study is not exhaustive of all studies, but it focuses on evidence-based interventions. Third, the studies did not include definitions of sustainability, nor did they assess sustainability in due course which hosted a challenge when performing a narrative synthesis. Fourth, there is a limited number of peer-reviewed articles pertaining to the sustainability of breastfeeding interventions. This may mean breastfeeding interventions are not sustained so researchers are not documenting the lack of sustainability, researchers are not considering sustainability while planning for and implementing their intervention, or researchers may be avoiding including sustainability in their manuscripts due to lack of knowledge or other specific reasons.

Despite the limitations, there are strengths to this work. According to protocol, this systematic review was completed in a robust manner. A narrative synthesis was used to analyze results, in which a risk of bias assessment (Table 5) was completed for all included studies to establish clarity of our synthesis findings.

Conclusion

Our findings call attention to sustaining breastfeeding in LMICs to decrease the burden of child mortality. We recommend researchers use implementation science sustainability definitions, frameworks, and literature to guide conceptualization and planning of sustainability of breastfeeding interventions. We also suggest these researchers report on the sustainability of their interventions, whether sustainability was achieved or not (and why), how sustainability was reached, what factors contributed to sustainability, and any challenges faced when managing sustainability. Thorough accountability and communication on sustaining breastfeeding interventions may encourage researchers to follow suit. Future research and interventions should tackle barriers of breastfeeding in LMICs and scale up family- and community-level interventions to foster sustainment of breastfeeding.

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

AE was the first reviewer and main contributor in drafting and writing the manuscript. SM was the second reviewer and contributed to reviewing and editing the manuscript. UN was the third reviewer and contributed to reviewing and editing the manuscript. CO, VC, TS, TG, and DO reviewed and edited the manuscript. The manuscript preparation was supervised by JI. All authors read and approved the final manuscript.

Acknowledgments

For assistance with the literature search, the authors would like to thank Donghua Tao, Assistant Director for Information

Services at Saint Louis University's College for Public Health and Social Justice.

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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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 30 August 2022
DOI 10.3389/frhs.2022.940936

OPEN ACCESS

EDITED BY
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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 10 May 2022
ACCEPTED 08 August 2022
PUBLISHED 30 August 2022

CITATION
Nadalin Penno L, Graham ID, Backman C, Fuentes-Plough J, Davies B and Squires J (2022) Sustaining a nursing best practice guideline in an acute care setting over 10 years: A mixed methods case study. *Front. Health Serv.* 2:940936. doi: 10.3389/frhs.2022.940936

Sustaining a nursing best practice guideline in an acute care setting over 10 years: A mixed methods case study

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Background: To improve patient outcomes many healthcare organizations have undertaken a number of steps to enhance the quality of care, including the use of evidence-based practices (EBPs) such as clinical practice guidelines. However, there is little empirical understanding of the longer-term use of guideline-based practices and how to ensure their ongoing use. The aim of this study was to identify the determinants and knowledge translation interventions (KTIs) influencing ongoing use of selected recommendations of an institutional pain policy and protocol over time from an organizational perspective and 10 years post implementation on two units within an acute care setting.

Methods: We conducted a mixed methods case study guided by the Dynamic Sustainability Framework of an EBP 10 years post implementation. We examined protocol sustainability at the nursing department and unit levels of a multi-site tertiary center in Canada. Data sources included document review ($n = 29$), chart audits ($n = 200$), and semi-structured interviews with nurses at the department ($n = 3$) and unit ($n = 16$) level.

Results: We identified 32 sustainability determinants and 29 KTIs influencing ongoing use of an EBP in acute care. Three determinants and eight KTIs had a continuous influence in all three time periods: implementation phase (0–2 yrs), sustained phase (>2–10 yrs.), and at the 10-year mark. Implementation of KTIs evolved with the level of application (e.g., department vs. unit) to fit the EBP within the context highlighting the need to focus on determinants influencing ongoing use. Sustainability was associated with continual efforts of monitoring and providing timely feedback regarding adherence to recommendations. KTIs used to embed recommendations into routine practices/processes positively influenced high adherence rates. Use of a participatory approach for implementation and sustainment and linking KTIs designed to incrementally address low adherence rates facilitated sustainment.

Conclusion: This research provides insight into the relationship between implementation and sustainability determinants and related KTIs during implementation and sustained use phases. Unique determinants identified by department and unit nurses reflect their different perspectives toward the innovation based on their respective roles and responsibilities. KTIs fostered changed behaviors and facilitated EBP sustainment in acute care. Findings confirm the concept of sustainability is a dynamic "ongoing process."

KEYWORDS

sustainability, Best Practice Guidelines, evidence-based practices, quality improvements, nursing, interventions, innovations, pain

Introduction

The sustainability of evidence-based practices (EBPs) in clinical practice remains the least understood aspect of the research translation process (1, 2). Sustaining hospital based innovations remains suboptimal (3) posing a significant challenge to hospital practitioners and researchers (3, 4). Specifically, Wiltsey-Stirman et al. (5) highlight partial sustained use of EBPs within most studies (64% or 80 out 125 studies) varies between 6 months to over 2 years following initial implementation. One of the key aspects underlying partial sustainability in healthcare is the nature of the complex ever-changing environments into which the EBPs are being integrated (6). Managing and supporting the adaption of an EBP, within a changing context (6, 7) implies it is never isolated from the context within which it is implemented, nor from the individuals it impacts. Studies have identified, in specific contexts key innovation (3, 5, 8–15), individual user (3, 14, 16, 17), contextual determinants (3, 18–20), and in some studies, specific leadership determinants influencing the sustained use of EBPs among nurses (3, 17, 21–28). To date, reviews also indicate sustainment of EBPs remains a persistent challenge across a range of healthcare settings (1, 2, 29–31) highlighting the need to examine the determinants influencing sustainability in specific healthcare contexts, such as acute care (1, 3). This is particularly important given governments and health agencies growing interest in expenditures within acute care settings. For example, Ontario Ministry of Health and Long Term Care (MOH and LTC) reports indicate expenditures remain the largest in tertiary settings (32) and sustained EBPs not only could improve the quality of patient care but potentially reduce costs. Due to the gap that exists in our understanding of the determinants and KTIs influencing sustainment of EBPs, there is a need to conduct studies aimed at uncovering the "complex and evolving nature of healthcare innovation sustainability" (33), especially in acute care settings over time.

In acute care, nurses are often faced with the challenge of assessing and intervening to manage people's pain as part of their nursing practice. Evidence demonstrates unrelieved or poorly managed pain is a burden on the person and health-related system throughout the world (34). It is estimated that ∼19% of the population in industrial countries live with some form of pain (35). In Canada, pain is the most common reason health consumers seek assistance and accounts for up to 78% of presenting complaints in emergency departments (36). Reports further reveal the prevalence of persistent pain in 65% of older adults (>65 years of age) (34, 37), and inadequate management of pain remains across all age groups (38).

In 2007, to address an identified need for "consistent pain care," the study site's Nursing department, partnered with Register Nurses Association of Ontario (RNAO) to implement nine Best Practice Guidelines (BPGs), referred internally as the BPG Implementation Program (BPG-IP). The RNAO's Pain Assessment and Management BPG (Pain BPG) (39) was used to develop an internal pain policy and protocol (Pain P/P). Unlike the other eight (out of nine) BPGs, the Pain P/P was uniquely implemented across all inpatient units. By 2016, in a research planning meeting, nursing leaders reported that despite early implementation success, internal monitoring had demonstrated inconsistent use of Pain P/P recommendations among the Medicine care units compared to other inpatient units. Inconsistencies highlighted the need to examine what the organization had done to sustain the use of the Pain P/P

Abbreviations: APN, Advance Practice Nurse; BPG, Best Practice Guideline; APS, Acute Pain Service; BPG-IP, Best Practice Guideline-Implementation Program; BPSO, Best Practice Spotlight Organization; C1:P#, Subcase-1, participant /informant code; C2:P#, Subcase-2, participant /informant code; CAN, Canadian Association of Nurses; CNO, College of Nurses of Ontario; DSF, Dynamic Sustainability Framework; EBP, Evidence based practices; ED#, External document code, numbered 1 to 2; ID#, Internal document code, numbered 1 to 20; KTIs, Knowledge translation interventions; NPP, Nursing Professional Practice; P#, participant informant /code; Pain P/P, Pain policy/protocol; Rt#, Report code, numbered 1 to 7; RNAO, Registered Nurses' Association of Ontario.

over time (2007–2017), and to uncover the factors and point of care processes/practices influencing Medicine care nurses' use of the Pain P/P 10 years post initial implementation (2017). Thus, to advance knowledge on the long-term sustainability of a nursing BPG we examined the ongoing use of the Pain P/P with the expectation it would have broad application to a variety of nursing environments.

The aim of this study was to understand from a nursing department and unit level, the determinants and knowledge translation interventions (KTIs) that influenced nurses' use of selected Pain P/P recommendations, over a 10-year period (e.g., 2007–2017), within a large, multi-site, academic, acute care center. The objectives included (i) identifying nurses' perceptions of the determinants influencing department and unit level nurses' use of the Pain P/P recommendations over time and 10 years post implementation, (ii) verifying unit nurses' Pain P/P use 10 years post-implementation, and (iii) identifying the related KTIs influencing Pain P/P use over time, and 10 years post-implementation. This system wide approach to identify determinants influencing adherence and the changes needed to address the sustained use of an EBP in practice aligned with the primary investigator's leadership experience in clinical administration (e.g., Chief Executive Officer, Academic Dean) and management (e.g., Chief Nursing Officer, Director Critical Care). It also aligned with coauthors' expertise in theory development and application, long term research programs, and practice changing implementation research.

Methods

Design

We conducted an explanatory mixed method case study (40, 41) in a multi-site, academic, acute care center to understand the complexity of sustainability in a natural, organizational setting (41) and to further explain quantitative results from a chart audit (40). Specifically, to address study objectives 1 and 3; we first reviewed all documents related to the initial implementation (0–2 yrs) and ongoing use of the Pain P/P over time (>2–10 yrs) followed by qualitative interviews of departmental level nurses to examine how the Pain P/P was sustained at the nursing department level over time (2007–2017). To address objective 2, we then conducted a chart audit 10 years post implementation (2017) to verify nurses documented adherence to selected Pain P/P recommendations on two Medicine care units (embedded subcases). This was followed by qualitative interviews of same to further explain audit findings and to address objectives 1 and 3 at the unit level. The reporting of this case study adheres to Mixed Methods Article Reporting Standards (MMARS) (42) (see Supplementary material 1).

Setting and pain BPG recommendations

Setting

The setting was a large Canadian, urban, multi-site, academic, acute care center composed of three sites with ~50,860 patient admissions annually, more than 60 inpatient and outpatient units combined, 1,122 staffed beds and more than 4,500 nurses. The decision point to use the Pain P/P rested with nurses at the clinical practice level.

Pain BPG recommendations

In 2007, the Pain P/P was comprised of 8 recommendations (R) which was updated to include a ninth recommendation (R9) based on the 2013 RNAO Pain BPG (38) (see Table 1). Recommendations included: (R1)—assess pain on admission to the unit; (R2)—assess pain once per shift and during hourly rounding; (R3)—establish pain management goals; (R4)—collaborate with patients to establish interventions to manage pain; (R5)—evaluate patient outcomes and effectiveness of interventions; (R6)—consult with pain management experts as required; (R7)—educate patients about their pain management plan; (R8)—document pain goal and management plan; and (R9)—educate nursing staff and physicians on pain assessment and management. Recommendations 1 and 2 are outlined in the policy as required assessments. All remaining recommendations are dependent on patient need. For this study, we examined 5 of 9 Pain P/P recommendations (R1–R4, R7) based on the following reasons:(i) they can all be evaluated clinically using an objective measure (e.g., numeric rating, prescribed intervention, pain goal rating), (ii) they are all explicitly documented in specified locations within inpatient health records, and (iii) they are all supported by one of the highest levels of evidence (1b), namely at least one randomized control trial (38). Initially the hospital took advantage of several RNAO external KTIs designed to support implementation and build capacity at the individual, and organizational levels, such as Best Practice Spotlight Organization (BPSO) symposia, summer institutes, champion network events, and toolkit training. Post the implementation use phase, the site's Nursing Professional Practice (NPP) department lead the initiative with the assistance of nursing managers, educators and champions, To date, the NPP department goals within the hospital remain: to improve patient outcomes and the quality of nursing care. Similarly, nursing strategic objectives remain: to support the utilization of EBPs and the evaluation of nurse sensitive indicators hospital–wide.

Data collection

We used the Dynamic Sustainability Framework's (DSF) (6) (see Supplementary material 2) to guide data collection,

TABLE 1 Pain P/P target behaviors, RNAO Pain Assessment and Management BPG (38, 43) recommendation and level of evidence (44).

Site Pain P/P number.	Pain P/P target behavior	RNAO pain assessment and management BPG Recommendation Number Level of Evidence
	Selected recommendations under review	
1	Screen inpatients for presence of pain on 1) Each initial contact/admission (2007 and 2013)	**Assessment** Recommendation - 1.1 Level of Evidence -Ib
2	Ongoing assessments of Pain using standardized tools 1) Once per shift (2007). 2) During hourly rounding (2013)	**Assessment** Recommendation - 1.2 Level of Evidence - Ib
3	Establish an individualized goal for pain management with the patient (2007 and 2013).	**Planning** Recommendation - 2.1 Level of Evidence – Ib
4	Collaborate with the patient in establishing an individualized strategy and interventions to manage the patient's pain based on the best evidence and available resources (2007 and 2013).	**Planning** Recommendation - 2.1 Level of Evidence – Ib
7	Educate patient and families about their individualized pain management plan (2007 and 2013).	**Implement** Recommendation - 3.3 Level of Evidence – Ib
Recommendations not under review in this study		
5	Assess effects of pharmacological interventions at peak effect following administration and on an ongoing basis (2007 and 2013).	**Implement** Recommendation - 3.1 Level of Evidence – IIb
6	Consult with pain management experts (interdisciplinary team members) as required (e.g., in complex situations, escalating or unrelieved pain after a reasonable trial of management) (2007 and 2013).	**Planning** Recommendation - 2.2 Level of Evidence- Ib
8	Ensure ongoing documentation reflects patient goals, pain mgmt. plan, assessment, response to treatment, outcomes, and communicate to inter professional team (2007, 2013)	**Evaluation** Recommendation - 4.4 Level of Evidence - IIb
9	Completion of self-learning training modules for nurses and physicians (2013)	**Education** Recommendation - 5.4 Level of Evidence - IV

Key: Level of Evidence
R, Recommendation; CA, C.hart Audit; Q, Question; mgmt., management; hxy, history; txmt, treatment.
Ia Evidence obtained from meta-analysis or systematic reviews of randomized controlled trials.
Ib Evidence obtained from at least one randomized controlled trial.
IIa Evidence obtained from at least one well-designed controlled study without randomization.
IIb Evidence obtained from at least one other type of well-designed quasi- experimental study, without randomization.
III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.
IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

analysis, and to present results for the following three time periods: implementation phase (0–2 yrs.), sustained use phases at 2–10 year, and at 10 years. Documents and departmental nurses' responses' provided data for study objectives 1 (determinants), and 3 (KTIs) over time. Audits provided data for objective 2 (adherence rate to selected BPG recommendations) at the 10-year timeframe. Audits, documents and unit nurses' responses provided data for study objectives 1, 2, and 3 at the 10-year timeframe.

Document collection for the implementation (0–2 yrs) and sustained use phases (>2–10 yrs)

The period of study was 10 years (2007–2017). We collected data from 29 documents (i.e., seven reports, 20 internal and

2 external), spanning 2005–2017, related to the Pain P/P, to gain a historical perspective of the determinants and KTIs used to sustain the Pain P/P over time. All documents were provided by nursing administration and included in this study. Notably, a significant amount of work was done to prepare for the implementation phase, hence the inclusion of documents between 2005 and 2007.

Audit data collection for the 10 year timeframe

Organizational leaders purposefully selected two Medicine care units as "critical sub-cases" (41) among the existing five Medicine units. Subcase selection was based on maximum variation, managers' willingness to participate, biannual prevalence results, site uniqueness, and representation from different campuses. In early 2019, we conducted the chart audits for the selected subcases. We audited 100 randomly selected "unique" inpatient charts, for each subcase (total $n = 200$) to verify subcase nurses' adherence to five Pain P/P recommendations at the 10-year timeframe. We used the following audit dates, which were outside holiday periods, and proceeded established audit survey processes: August to October 2016, January to March 2017, and July to October 2017. The following audit tools were used: (i) process algorithm (see Figure 1), (ii) a coding dictionary, and (iii) an excel data extraction spreadsheet based on recommendation measures. Audit tools were subject to "face validity" testing (45) by two site representatives and one knowledge user (i.e., previous employee at study site) on the research team, then piloted. Two reviewers independently assessed the "reliability" of the extraction tool for 15 records (45) with minimal modifications to expand two data categories: patient admission diagnoses, alternative therapies used. For each recommendation, we specified inclusion criteria and sources. To maintain measurement consistency, we used the "first shift on the unit" as a measure of "*on admission*," and the "next five consecutive shifts" as a measure for "*ongoing assessments*" (during patient stay). Post audit, an independent reviewer randomly tested extracted data calculations to confirm accuracy.

Interviews: Departmental and unit level

Semi-structured interview guides for department and unit nurses were developed based on DSF tenets (6) and the Pain P/P target behaviors. Pilot testing of interview guides (46) was undertaken with NPP representatives not selected for interviews. Only minor changes to the wording of the guide questions were made to ensure they were more open ended (available upon request).

In late 2018, we obtained REB approval. Based on similar studies (33, 47), we purposefully selected three department level participants who continued to be part of the implementation team over 10 years, and still available for interview. With the help of an internal gatekeeper, participants were emailed a study information letter and followed-up *via* phone and or email. All agreed to participate. Interviews were conducted in early 2019 *via* phone separately, each lasting 40–45 min. With consent, all interviews were digitally recorded and transcribe verbatim. Interviews were conducted sequentially by the researcher (LNP) and redundancy of responses was evident (46).

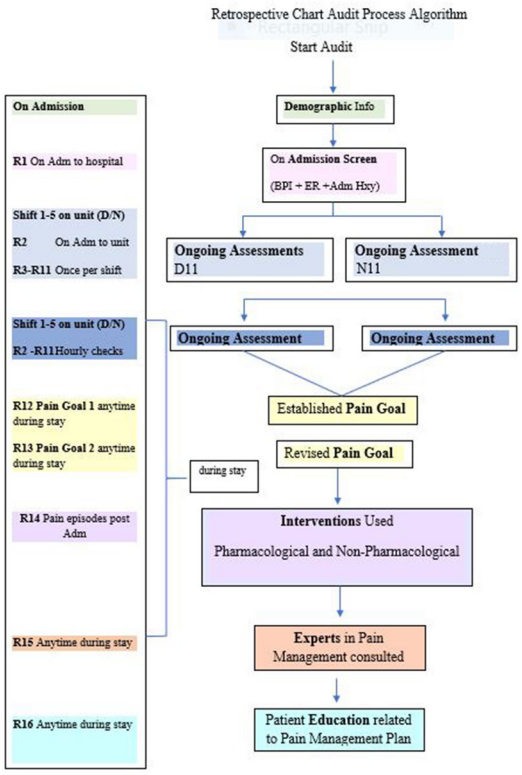

FIGURE 1
Retrospective chart audit process algorithm.

By late summer 2019 we obtained special permission from nursing administration to conduct unit interviews despite restrictions due to ongoing internal electronic health record changes. Managers on the selected units facilitated recruitment of nurses. Unit nurses were provided information regarding the study and were given allotted time to attend an interview while on duty with the researcher (LNP). Each unit consisted of ~30 full-time and several part time RNs. Participation was voluntary. Inclusion criteria for unit nurses included: full or part-time status, employed at least 2 years or more on the unit, and registered with the College of Nurses. Unit interviews were conducted between August and September 2019, completing one unit before moving onto the second. All interviews were held separately on each unit, lastly ~35–45 min. Interviews were recorded and transcribed verbatim. Based on similar studies (15), a convenient sample of eight to ten staff nurses per unit

was planned. Interviews were conducted sequentially one unit at a time, until no new themes emerged, redundancy of responses was evident (46, 47).

Analysis

Document analysis for the implementation (0–2 yrs) and sustained use phases (>2–10 yrs)

Initially, based on available data (i.e., 29 documents) we conducted a review of the changes that occurred over time. First we mapped the measures used in the biannual prevalence audit tools with the Pain P/P recommendations and education training records. Subsequently, a document review was conducted and a listing of KTIs (i.e., strategies) used over time (2005–2017), across all units to promote use of the recommendations was developed (see Supplementary material 3). We triangulated data sources with interview findings from departmental participants who worked across all units to clarify and enhance data completeness related to the determinants and KTIs influencing Pain P/P use. We aggregated all data findings to the nursing department level.

Audit data analysis for the 10 year timeframe

We analyzed audit data using descriptive statistical techniques using SPSS 25. Adherence rate calculations (i.e., the degree to which practitioners continued to adhere to guideline recommendations) (48, 49) involved determining indicators for targeted behaviors and computing frequency measurements. Adherence rates were calculated separately for each subcase. Findings were compared to adherence rate categories (high to low) consistent with previous studies (48, 49). Aggregated unit level adherence rates to guideline recommendations are described as high (80–100%), moderate (between 50 and 80%) or low (<50%) for each targeted behavior (48, 49). We compared differences in proportions between the subcases using Pearson's chi-square test for each of the recommendations (45). We used chart audit standards for quality set out by Gregory et al. (50). We triangulated findings with collated documents to validate the interpretation and inferences attained from the adherence rates (46).

Interview analysis for the three timeframes

Two independent reviewers conducted coding and interpretation of qualitative data, using content analysis (51). Interviews were digitally recorded, transcribed verbatim, and text were analyzed continuously until saturation. Specifically, we used NVivo 10 software to organized and facilitate coding of the data. Content analysis involved deductively separating and coding the interview responses and document data into groupings as per the DSF tenets (e.g., themes) (41), then inductively into smaller groupings (e.g., factors and related KTIs) (51) by timeline, by two independent reviewers (LNP and JF) for the department nurses. Similarly, the same analysis was conducted for the unit nurse responses. The few discrepancies were resolved through discussion and agreement. *Determinants* were considered factors that affected use of the Pain P/P, such as *barriers and facilitators*. *KTIs* were considered *strategies/actions* deliberately employed with the intention of promoting Pain P/P use. Within-in subcase descriptions, themes and summaries were analyzed separately, integrating all data sources. We analyzed themes "across subcases" for similarities and differences (41). In the final integration, we combined results for all three timeframes, and drew conclusions. Consistent with previous research (33), we used Lincoln and Guba's criteria (52) (credibility, dependability, confirmability, and transferability) for the qualitative portions to ensure rigor (see Table 2).

TABLE 2 Qualitative strategies for study rigor.

Criterion	Strategies
Credibility	• Used data from multiple sources, • Included multiple subcases, • Debriefing the research team, • Substantiated findings with participants during interviews
Dependability	• Adhering to study protocol, • Documenting decision points, • Maintaining organized databases, • Composing field notes, • Maintaining master lists of definitions and codes.
Confirmability	• Confirming eligibility, • Using the stopping criteria of three or more interviews where no new themes emerged as a measure of data redundancy (47), • Remaining close to verbatim transcripts, • Reviewed findings with knowledge users.
Transferability	• Providing detailed characteristics of the setting and participants, • Reported in-depth descriptions of findings • Used conceptual framework • Included critical subcases

Ethics approval

Before commencement of data collection, ethical approval was obtained from the Research Ethics Boards for the site and the University of Ottawa. Organizational consent to examine

ongoing use of the pain BPG was provided by all levels of nursing administration. Participation was voluntary. Participants signed a consent and completed a demographic form confirming eligibility prior to participation. We used unique identifiers to ensure anonymity of datasets and findings. Only aggregated data are reported. All quantitative extracted data were encrypted and password protected. The primary researcher and a site representative, maintained a table linking inpatient charts and coded reference numbers for each. Data remains stored in a secure location.

Results

We first present a summary of the overall findings identified to sustain the ongoing use of the Pain P/P as they relate to the three study objectives. Details of department and unit level findings were mapped to the DSF constructs (e.g., innovation, context or practice setting, broader system) and organized chronologically using the three time periods; implementation use phase (0–2 yrs), sustained use phase (>2–10 yrs), and 10 years post implementation (2017) (see Table 3). For each timeframe, we outline the study objective(s) the findings address, briefly describe the characteristics of the data sources, followed by the determinants and related KTIs reported by department and or unit level participants.

Summary of overall findings

We identified a total of 32 unique determinants ($N = 32$) and 29 unique KTIs ($N = 29$) that influenced Pain P/P use over time (2007–2017), providing answers to study objective 1 (e.g., determinants influencing Pain P/P use) and 3 (e.g., KTIs influencing Pain P/P use), respectively. Notably, department and unit level nurses identified 3 determinants that continuously influenced Pain P/P use over all three time periods. This is a novel finding related to study objective 1. Department nurses separately identified 10 determinants that influenced Pain P/P use across all inpatient units during the sustained use phase (>2–10 yrs.). Two of these 10 determinants, along with an additional 19, were identified by unit nurses at the 10-year mark. Details related to determinants for all time periods, including supportive participant responses, and document evidence are available in Supplementary material 4.

Additionally, department and unit nurses described eight out of 29 KTIs that continuously promoted Pain P/P use over all three time periods. This is a novel finding related to study objective 3. An additional 4 KTIs were identified unique to the implementation use period (0–2 yrs.), 14 KTIs more unique to the sustained use period (>2–10 yrs.), and 3 KTIs unique only to the 10-year timeframe. Details related to KTIs, including supportive participant responses, and document evidence are available in Supplementary material 5.

At 10-years, audit results provided evidence that partially addressed study objective 2 (e.g., verifying unit nurses Pain P/P use 10 years post implementation), which were further explained by subcase nurses during interviews. Overall audit results revealed subcase nurses maintained high adherence rates for three out of five selected recommendations: namely R1-*assessing pain on admission to the unit*; R2- *once per shift and ongoing hourly assessments*, and R4-*establishing interventions to manage pain 10* years post initial implementation of the Pain P/P. Subcase nurses confirmed adherence to these recommendations was facilitated by innovation and context related KTIs. Furthermore, subcase nurses identified context related KTIs attributed to the low to moderate adherence rates evident by audit results for the remaining 2 selected recommendations: namely R3 – *establishing pain goals*; R7-*providing patient education related to pain management*.

Implementation use phase (0–2 yrs)

Data sources

We interviewed three female department level Registered Nurses, who were part of the initial implementation team. Participants were involved in promoting the use of the Pain P/P over time (i.e., 2005–2017) while holding department-wide leadership positions, working across more than one nursing unit. Overall, there was consistency in their responses related to the determinants (i.e., objective 1) and the related KTIs (i.e., objective 3) influencing use of the Pain P/P recommendations during the implementation phase (0–2 yrs).

Documents collected provided a historical and organizational-wide perspective of the efforts used to sustain the Pain P/P's use across ∼60 inpatient and outpatient units over time (2007–2017; see Supplementary material 3). Specifically, documents provided evidence that efforts were focused on policy and procedure development, training champions, assembling department infrastructure supports (e.g., Pain Council, interprofessional committees), followed by the use a multi-modal implementation approach led by NPP representatives and unit level champions.

Determinants

Department nurses identified the following 3 implementation determinants (1 innovation, 1 context, and 1 broader system) that influenced the hospital's decision to establish the Pain P/P as a "corporate-wide priority" in 2007:

(1) The *need for guideline* (innovation) to improve/standardize pain care based on patient satisfaction reports.

TABLE 3 Integrated case study findings for sustainability of pain BPG in acute care context.

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
Innovation (defined as: new process/change/ product/practice or program, innovation, intervention)	*Relevance/consistent with competitive strategy (to addresses need/problem)	✷✓		✷✓			
	Adaptability of innovation				⁂Embedding of Pain P/P into existing unit processes	⁂Embed ongoing refinements into existing routine practices/processes and Pain P/P	⁂Routinize recommendations into nursing forms and practices/processes: embed prompts
							Digitalized Pain P/P and forms into new eHealth record
					Pain P/P established Interdisciplinary for all disciplines		
	Benefits to patient, staff, organization (cost effective, efficiency and quality of care)			✓1			
	Barrier identification				Use frameworks to guide implementation and Id barriers		

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
Practice setting (defined as inner context)	Human resources—recruitment, processes, succession and leave planning (staffing/compliment)		✓		Secure internal financial commitment—time and Human resources to participate on cttees and to implement KTIs		
	Student turnover (medical)		✓				
	Individual commitment to innovation			✓2			
	Individual competency (skill knowledge, absorptive capacity) to perform innovation and time management to use innovation			✓3			
	Expert consultants /resources			✓5			

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
	Internal cohesion between individual and commitment within the organization /stakeholder engagement leads to increased performance [senior nurse mentors /influencers vs. Clinical Care Leaders]			✓6			Mentorship used by senior nurses to support Pain P/P use:
	Stakeholder Commitment to innovation			✓4	⁂Joint collaboration of human resources from all levels of nursing plus other disciplines to develop departmental implementation plan		⁂Engages IP stakeholder involvement: all professions to follow policy participate on cttees
	Stakeholder beliefs, attitude, perceptions, emotions, expectations toward innovation and user motivation/resistance		✓	✓			
	Population characteristic/needs/acuity level			✓13			
	Users awareness / familiarity with innovation			✓14			

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
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		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
Practice setting (defined as inner context)	Leadership commitment (department level)	✸✓	✸✓		⁂Formalize BPG Coordinator role	⁂Comparing survey results among units created a sense of competition among leaders and users to improve	⁂**Leadership strategies** - Clinical Coordinator-department level: (support for big issues during shifts) - Clinical Care Leaders—unit level (get involved in unit level issues to support ongoing improvements) - Unit Managers—unit level (get involved in unit wide issues, help with remedial action plans to reinforce target behaviors, review incidents, encourages education training)
	Management approach and engagement (commitment unit level)		✓	✓			
	Senior Leadership involvement and actions		✓				

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
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		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
Practice setting (defined as inner context)	Infrastructure support- Policies and Procedures based on Innovation (i.e., cttees, key people in nsg department–i.e., educators, champions, NPP reps)			✓7			
	Infrastructure support for innovation in job description with mechanism for recognizing achievement					Performance evaluation indicators for monitoring rt innovation= leaders, managers, and staff	
	Infrastructure support-equipment and supplies for innovation (and resources = pamphlets)			✓15			
	Physical layout/structure of wards			✓16			
	Competing corporate priorities		✓				
	Cultural—Beliefs, values and perceptions to innov			✓10			

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
	Cultural—Climate (doing research)			✓11			
	Cultural—innovation integrated into Norms (documents, protocols, manuals)			✓12		Unit leaders lead department and unit level patient centered initiatives for pain care based on unit routine practices -with adoption of EBP care	
	Team culture embraces innovation			✓9	⁂Obtaining buy-in and Formalize nurse leaders' involvement on Steering Cttee	⁂Corporate level Internal cttees' support ongoing review of clinical tactics support sustained use i.e., Patient Experience Steering cttee and Accreditation workgroup	⁂Fostering an IP and EBP culture among IP team to support Pain P/P use:
	Political internal stakeholder coalition, power, influence					Department determine EBP priorities	

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
	Financial performance budgeting and measurement				⁂ **Secure external funds** (a) RNAO PBSO—secure operating funds for initial training and resource s to build capacity (b) secure capital external financial support—for point of care surveying system	⁂Development of an electronic monitoring system to measure nursing sensitive indicators provide monitoring of BPG adherence	
Practice setting (defined as inner context)	Workload /staffing patterns			✓17			
Practice setting (defined as inner context)	Education and training processes				⁂Pain Council established—Interdisciplinary taskforce leads initial policy development, education strategies and future policy revision ⁂Educating Champions—to be clinical experts on units, with APNs	⁂NPP reps develop formal and informal education initiatives at department and unit level in 2014 initially performed by the Pain Council. ⁂Trains 170 Unit level expertise to support use of Pain P/P s = Champions, educators, APNs, work across units as clinical resource	⁂Ongoing education to support Pain P/P use by NPP and educators: - education days, - mandatory online modules - updates, refreshers, seminars ⁂Ongoing Training to support Pain P/P use by NPP and educators: - general hospital orientation, - 1 on 1 training, in-services, solve recurrent problems

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
						Ongoing pain care education support at department and unit levels becomes tailored over time ie 1 on 1, case studies	
						Mandatory eLearn training system	
						Unit specific training of staff provided based on audit remedial action plans to improve on related BPG survey indicators	
						Develop unit specific additional resources/tools over time	
	Processual—planning, method, and timing of embedding innovation			✓18	Use multi-modal approach to disseminate		
	Processual—project structure and system to monitor/manage innovation					Spread EBP to additional areas	

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
					⁂Established Pain BPG taskforce/workgroup in NPP department—enduring central reporting and monitoring structure for ongoing implementation and evaluation	⁂NPP and Unit Leaders facilitate/lead remedial action plan for underperforming units	⁂Monitoring and evaluation: Department level—ongoing training to do survey Unit level—audit and feedback provided (timely sharing of audit data, focuses biannual audit questions on target behaviors) Unit level—Patient satisfaction survey results shared reviews incidents and develop strategies to prevent them in staff mtgs
	Organization—communication capacity for monitoring (exchange and feedback)			✓8		Ongoing biannual training of staff to conduct prevalence survey NPP Establishes regular performance monitoring: includes results from biannual prevalence audit and internal incident reporting	

(Continued)

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
						Timely exchange of prevalence survey results led to course correcting changes	
	**Formal communicating/reporting systems for client info btwn practitioners (documented)			19			Establishing effective communications between providers, reporting practices—bedside exchange, whiteboards, clipboards
Broader system (defined as: external condition, context, system, or environment)	External conditions, compatibility for innovation (consumer demand)		✓				
	External pressure/demand (e.g., professional/regulatory bodies, Ministry, funding bodies)	✷✓	✷	✷✓		New evidence released—Integrating into BPG and ongoing education	
	Connection to broader external context (regional, national, international links)		✓			Staff participation on a regional network—provide access to new research and related outcomes for pain management	

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TABLE 3 (Continued)

DSF themes/ constructs	Integrated determinants (factors) $N = 32$	$N = 32$ unique determinants			$N = 29$ unique KTIs		
		Department RNs Implementation factors (0–2 yrs) $n = 3$	Department RNs Sustained factors (>2–10 yrs) $n = 12$	Unit RNs Sustained factors (at 10 yrs) $n = 31$	Department RNs Implementation phase (0–2 yrs) KTIs ($n = 12$)	Department RNs Sustained phase (>2–10 yrs) KTIs ($n = 21$)	Unit RNs Sustained phase (at 10 yrs) KTIs ($n = 9$)
		3 ongoing determinants			8 ongoing KTIs		
			+10 unique factors	+19 unique factors	+ 4 unique implementation KTIs	+ 14 unique sustained KTIs	+ 3 unique sustained KTIs
	External support for innovation from stakeholders (recognition)		✓			Benchmarking to external sources best practices	
	**Goal alignment with external agencies (e.g., education institutes)		✓				

✷✓Determinants (factors) common across subcases over three timeframes.
⁂KTI common across subcases over three timeframes. *represent common determinants across all 3 timeframes; 3 stars in a triangle shape represent common KTIs across all 3 timeframes; Green highlights represent common findings across timeframes; Blue highlights are used to separate 3 constructs (i.e. innovation, practice setting, broader system).

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(2) Nursing *leaders' commitment* (context) to EBP use influenced Pain P/P use across all units.
(3) An *external demand* (broader system) by RNAO's call for proposals to establish a BPSO provided guideline recommendations, plus start-up funding to support efforts.

KTIs

Departmental nurses identified a total of 12 KTIs used across all inpatient units during the first 2 years. The following four KTIs (i–iv) were unique to the implementation phase (0–2 yrs.):

(i) *establishing an interdisciplinary policy* that applied to all disciplines including nursing;
(ii) *using knowledge translation models* they were familiar with, such as the Ottawa Model for Research Use (OMRU) (53) to guide guideline implementation, and the Knowledge to Action (KTA) framework (54) to assess potential barriers;
(iii) *allocating staff resources and time* to participate on BPG-IP committees and implement KTI initiatives across all units; and
(iv) using a *multi-modal dissemination approach* to initially train unit nurses which focused on providing education, development of assessment and documentation tools, and monitoring adherence.

The following eight KTIs (v to xii) promoted continuous use over all three time periods revealing how efforts evolved over time to address determinants influenced by changing underlying conditions:

(v) *obtaining buy-in from senior administration and formalizing their involvement* on a steering committee over the 10 years;
(vi) *getting joint collaboration from all levels of nursing* (Executive to point of care) and the engagement of other interprofessional stakeholders (i.e., Pharmacists, Therapists, and Medical Residents) in the development of ongoing implementation plans for all to follow influenced sustainment;
(vii) *establishing an interdisciplinary education and training structure* -a Pain Council/Taskforce that facilitated initial policy development, educational strategies and future direction for policy revisions. By 2014, these formal and informal departmental level education initiatives were assumed by NPP representatives and Champions. Over time, efforts by unit level Educators became more targeted to address unit level BPG adherence and related training needs;
(viii) *formalizing BPG-IP Coordinator role and related taskforces/workgroups* for each BPG within the NPP department;
(ix) *establishing a central reporting and monitoring structure* within the NPP department facilitated timely feedback of prevalence survey results to units and promoted formal reporting of unit level remedial plans designed to address low adherence rates. This monitoring structure reportedly "promoted ongoing use and evaluation" (P1);
(x) *embedding Pain P/P recommendations* using prompts and ongoing refinements *into already established documentation and quality care infrastructures* for hospital-wide implementation such as "general orientation" (P2), "mandatory eLearn modules" (P3), and "policy revisions" (P1) promoted high adherence rates during the first 2 years and over time;
(xi) *securing external financial support* from the RNAO facilitated training and access to a combination of external strategies to build capacity at the individual and department level (55). Securing external capital support of $30,000.00 from Canadian Nurse Foundation funded the development of an electronic point of care prevalence survey monitoring and evaluation system currently in use (56);
(xii) initially *educating* 60 practice *champions* to provide clinical expertise on pain care at both the department and unit levels. By 2017, 170 champions were trained.

Sustained use phase (>2–10 yrs)

Data source

There was consistency in the responses of department nurses related to the determinants (i.e., objective 1) and the related KTIs (i.e., objective 3) influencing use of the Pain P/P recommendations during the sustained use phase (>2–10 yrs.) as well. Additionally, we interviewed 16 unit nurse participants (P), eight per subcase (e.g., Case 1: P1 to 8, Case 2: P1 to 8), seven female and one male per unit. Each unit had their own Manager, separate Educator and a mix of novice and senior unit nurses. Previous internal restructuring of the Medicine Care department resulted in both units being comprised of three inpatient wards, not all on the same floor, having approximately the same number of beds (e.g., 80 beds). Unit participants were Registered Nurses, the majority degree prepared ($n = 13$), between age 26 and 30 years of age ($n = 9$). Two participants in Subcase 1 and one participant in Subcase 2 were over 41 years of age. Subcase 1 nurses reported the average time working in the profession in their current job on their unit for 8 years, and Subcase 2 nurses reported the same for 9 years. No significant difference was noted between subcase nurses with respect to age ($p = 0.599$) or time in their current position ($p = 0.823$; see Table 4).

Documents provided evidence that in 2010 and beyond, sustained use phase efforts focused on securing funds to purchase software, develop a point of care prevalence survey tool to evaluate use of BPG recommendations, and increasing

TABLE 4 Characteristics of unit level subcase participants.

Key "subcase" participants	Case 1	Case 2
Total participates (nurses)	$N = 8$	$N = 8$
Current job title		
Registered nurse	8	8
Female	7	7
Male	1	1
Age distribution		
26–30 yrs.	4	5
31–40 yrs.	2	2
41–50 yrs.	1	0
>50 yrs.	1	1
Highest level of education		
Diploma	2	1
Degree (bachelor degree in nursing)	6	7
Time in the profession distribution		
2.5–5 yrs.	3	4
6–10 yrs.	3	2
11–15 yrs.	1	1
>20 yrs.	1	1
Average time in the current job	8 yrs.	9 yrs.
	Documents (see Supplementary material 3)	***N* = 29**
	Reports	$N = 7$
	Internal documents	$N = 20$
	External documents	$N = 2$

To determine if differences existed between Subcase 1 and Subcase 2 groups, a Mann-Whitney U-test was conducted. Results indicated that there was no significant difference with respect to age across groups p-value = 0.599 or time in position across groups p-value = 0.823) (given $p > 0.05$).

unit nurses' adherence rates to selected BPG recommendations. Notably, between 2010 and 2015 the prevalence measures used to audit Pain P/P recommendations varied, targeting recommendations for short periods of time (e.g., 0–7 consecutive data points; see Supplementary material 3).

Determinants

We identified 10 determinants (6 context, 4 broader system) that influenced Pain P/P use across all inpatient units over time. Together, department and subcase nurses jointly identified the following six context determinants:

(1) "*Nurses' positive attitude* toward pain management and their commitment to quality… filtered throughout the hospital" (P1, P3) facilitating ongoing Pain P/P use.

(2) *Senior leadership's commitment* (i.e., Board of Directors) to leading a multi-disciplinary Quality Framework and working together on EBPs, influenced ongoing use.

(3) Together *department* (i.e., Chief Nursing Officer (CNO) and NPP representatives) and *unit level leaderships' commitment* (i.e., Educators, champions) supported ongoing use.

(4) Other *corporate priorities*, such as infection control rates, were identified as a barrier, temporarily refocusing attention from guideline adherence initiatives, competing with unit BPG priorities.

(5) A "*bimodal staffing complement* of novice and senior nurses on most inpatient units presented different ongoing education needs related to Pain P/P use" (P1).

(6) The constant *turnover of students* (e.g., medical, nursing) common in teaching hospitals, posed difficulties maintaining consistent practices between rotations.

The following 4 broader system determinants (7–10) were identified solely by department nurses:

(7) The local *university's goal* to use EBPs during medical and nursing student practicums *aligned with the hospital's goal*.

(8) *Increasing health consumer (patient) demand* for information on pain care management influenced nurses' active participation on internal committees.

(9) The RNAO's *formal recognition* of the electronic prevalence survey system encouraged ongoing accountability for BPGs.

(10) During the past decade the *increased focus internationally/nationally on Pain Care* broadened the knowledge base for nurses to draw upon.

KTIs

Department nurses uniquely identified 14 KTIs (11 context, 3 broader system,) used to sustain Pain P/P use across all units over time.

The 11 context KTIs included:

(i) By 2012, *units determined priorities for EBPs* based on inpatient needs and prevalence audit results;

(ii) Managers and Clinical Leaders lead the *integration of department and unit level patient centered EBPs into unit routine practices*, the latter varying between units;

(iii) In 2013, providing support for the development of *additional pain assessment tools* (e.g., Patient Information Booklets, verbal bedside shift reports, in room care boards with pain scales to communicate patient pain scores and goals, post-surgery pain management pamphlet) facilitated ongoing use of the Pain P/P on all units;

(iv) *sharing (e.g., spreading)* of pain practices/procedures and *tools* with outpatient departments;

(v) expanding efforts to provide *ongoing pain education* related to pain care and policy updates over time at the department and unit level (e.g., facilitating unit-wide case debriefings to resolve complex situations to offering 1 on 1 pain management training);

(vi) By 2013, the development and implementation of *mandatory pain care eLearn training modules* promoted ongoing Pain P/P use among new hires;

(vii) In 2014, Clinical Directors included "a *BPG-related performance criteria in evaluations* of their Clinical Nurse Leaders, who included the same in staff performance reviews" (P1). This specific KTI reportedly spurred the following four exchange and feedback KTIs (i.e., viii–xi);

(viii) providing *biannual prevalence training of staff to conduct the survey* "encouraged ongoing accountability internally for EBP process activities and results while building capacity" (P2);

(ix) NPP representatives began to provide regular performance results to units. The comparing of survey results among units *created a sense of competition* among unit leaders and staff to improve;

(x) timely exchange of results led to three incremental "*course-correcting changes*" (33):

- Measurements (e.g., survey questions) became more focused and sophisticated to target selected BPG behaviors. For example, leaders set increasingly specific benchmarks that were incrementally obtainable and modified survey questions to reflect benchmarks.
- Unit champions and Educators reportingly "designed KTIs to address targeted BPG behaviors evaluated" (P3).
- Survey methods expanded over time. For example, increasing numbers of nurses and interprofessional staff were trained to collect data on units not their own. This "increased awareness of BPGs and expanded accountability for patient safety performance among point of care practitioners" (P3); and

(xi) *under performing "unit teams"* and Clinical Nurse Leaders began to report back to NPP representatives on how they planned to respond to survey results" (P3) by *providing formal remedial action plans*. These monitoring and evaluative efforts "served to build nurses' problem-solving capacity and support continued Pain P/P use" (P1).

The 3 broader system KTIs (xii–xiv) included:

(xii) facilitating *staff participation on a regional network* to access new pain research;

(xiii) supporting the *integration of new evidence* (i.e., medication/treatment releases) into the Pain P/P; and

(xiv) *learning from and benchmarking to external sources* on best practices for pain care.

Ten-years post implementation (2017)

To address study objective 2: verifying unit nurses Pain P/P use post implementation, a chart audit was conducted. To address study objectives 1 (i.e., identifying determinants) and 3 (i.e., identifying KTIs) we interviewed subcase nurses. Similarities and differences identified among the two subcases are presented.

Data sources

Chart audit results revealed similar patient profiles were admitted to each subcase unit (see Table 5). Female patients represented 55 and 58% of admissions for Subcase 1 and 2, respectively. The average patient age was 72. Patients were admitted from the emergency department, except two for subcase 1, and six for subcase 2. The primary admission diagnosis was decline/failure to cope/generalized weakness, referred to as non-specific, followed by a respiratory diagnosis. All other admission diagnoses included system related illness (e.g., cardiac). Length of stay was 9 days for Subcase 1, and 11 days for Subcase 2 patients.

Chart audit results (see Table 6) provided evidence for study objective 2 indicating subcase nurses maintained high adherence levels (>80% of the time) (48) to three of the five recommendations (R) 10 years post implementation: R1-*assessing pain on admission to the unit* (R1), R2- *once per shift and ongoing hourly assessments*, and R4-*establishing interventions to manage pain*. Low adherence rates (<50%) (48) existed across subcases for R7-*providing patient education related to pain management*. There was a significant difference in the adherence rate for R3-*to establishing Pain Goal*(s) for patients who had pain during their hospital stay (over five shifts); Subcases 1 (C1) had low adherence, and Subcase 2 (C2) had moderate adherence (between 50 and 80%) (48).

Determinants

We identified 19 additional determinants (1 innovation, 18 context) subcase (C1, C2) participants (P) stated influenced their Pain P/P use at the 10-year timeframe, addressing study objective 1 (e.g., determinants).

Subcases nurses identified 1 innovation determinant:

(1) Nurses described how Pain P/P use *benefited patients* stating, "we can make the most difference... noticing (assessing) if my patients are in pain and advocating for . . . prns . . . using the Pain P/P" (C2:P4).

Subcase nurses identified the following 18 context (2–19) determinants:

TABLE 5 Patient profiles included in chart audit by subcase.

Subcases		**'Case 1' vs Subcase 1**	**'Case 2' vs subcase 2**	
Dates		Aug -Oct 2016, Jan-Mar 2017, Jul-Oct 2017	Aug -Oct 2016, Jan-Mar 2017, Jul-Oct 2017	
Male admissions to unit		45	42	
Female admissions to unit		55	58	
Patient average age		72 yrs. old	72 yrs. old	
1st	Other	44	38	*Non-specific
2nd	Respiratory	23	21	Respiratory
3rd	NYD	13		
3rd			12	Gastrointestinal
3rd			12	Neurological
4th	Cardiac	10	6	Cardiac
5th	Musculoskeletal	5	4	Musculoskeletal
5th	Gastrointestinal	5		
5th			4	NYD
6th			3	Cancer
ALOS		**8.6 days**	**11.4 days**	
Emergency to medicine		98	94	
Directly to medicine		0	3	
ICU/urgent care to medicine		2	2	
Endoscopy to medicine		0	1	

*Non-specific—decline/failure to cope/Altered LOC/ confusion/general weakness.

(2) Nurses reported their *commitment to the innovation* influenced their use of the Pain P/P, declaring "we are very supportive of the use of evidence-based practices, like the Pain P/P" (C1:P3).

(3) Nurses also indicated they felt *competent providing pain care* stating "we have the knowledge and skill to use the Pain P/P, as it [pain care] has been ingrained in us for a very long time, … since our training" (C1:P1).

(4) Nurses claimed "the *commitment of multiple stakeholders* such as managers" (C1:P5) …and "healthcare aides" (C2:P4) influenced their use of the Pain P/P.

(5) Having access to *collaborative expert consultants* (e.g., Acute Pain services, Palliative Care Services) to "deal with difficult pain care situations…when MDs can't control patients' pain" (C1:P1) supported Pain P/P use.

(6) The *internal cohesion between individuals* on the units (subcases) and their commitment to the Pain P/P differed among subcases, yet both promoted Pain P/P use. For example, Subcase 1 nurses claimed their clinical leaders (manager and educator) mainly influenced their use of the Pain P/P. Whereas, Subcase 2 nurses emphasized *senior nurse mentors* influenced their competency/skill performing pain care avowing "everything I have learned about pain control has come from senior nurses" (C2:P6).

(7) Nurses confirmed the *presence of infrastructure support* within the nursing department (i.e., committees/workgroups, educators, champions, NPP representatives) influenced use over time.

(8) The use of the following processual methods such as "hourly rounding, bedside shift reports" (C1: P6) and "in room care boards" (C2:P4) reportedly influenced *enhanced communications (exchange and feedback)* related to patients' pain status and management among nurses.

(9) The existence of a *team culture* on committees throughout the hospital that embraced new initiatives/approaches to pain management encouraged nurses' "openness to use alternative therapies" (C1:P5) and evidence-informed "new treatment modalities" (C2:P2).

(10) Subcase nurses indicated the clinical Managers were key to fostering *an EBP culture (beliefs, values, perceptions) toward pain care* on their units "supporting and encouraging them to attend pain education days, conferences related to new meds, techniques, and ways to control pain" (C2:P6).

TABLE 6 Audit results for subcases' adherence rates to Pain P/P recommendations.

Recommendation		Case 1 (C1)	Case 2 (C2)	Adherence rate
R1	Pain assessment on admission to unit (shift 1) Range of pain scores = 0–10	98% (98/100) charts had initial assessment on unit admission history. 2/100 charts had missing data	99% (99/100) charts had initial assessment on unit admission history. 1/100 charts had missing data	High adherence to R1
R2	Ongoing pain assessment (shifts 2–5)	98.5% (98.5/100) charts/four shifts had ongoing pain assessment for next four shifts 1.5 /100 charts/shift had missing data 98.75% (98.75/100) charts/five shifts had hourly round checks completed	98% (98/100) charts/four shifts had ongoing pain assessment for next four shifts 2/100 charts/shift had missing data 99.5% (99.5/100) charts/five shifts had hourly round checks completed	High adherence to R2 Once per shift and hourly rounds Hourly rounds—no documented pain scores
R3	Establishes Pain Goal for patients who had pain during stay (over five shifts)	R3-19/53 (36%) charts of patients who had pain score >0 had Pain Goal set during stay evidence in IPN and or progress notes. • 9/19 collaborated with pt on PG • 10/19 had pain scores ≥4	R3-32/55 (58%) charts of patients who had pain score >0 had Pain Goal set during stay evidence in IPN and or progress notes. • 17/32 collaborated with pt on PG • 22/32 had pain scores ≥4	R3 C1- Low adherence to setting of Pain Goal 1 on admission history R3 C2- Moderate adherence to setting Pain Goal 2 during stay
R4	Establishment of interventions to manage pain for patients with pain	52/53(98%) charts of patients who had pain score >0 had evidence of prescribed interventions to manage pain • 35/53 charts only prescribed Pharm • 12/53 charts with combo of prescribed Pharm and Non-Pharm interventions • 3/53 charts prescribed Pharm+Methadone • 2/53 charts with prescribed Pharm prn • 1/53 no intervention	55/55 (100%) charts of patients who had pain score >0 had evidence of prescribed interventions to manage pain • 45/55 charts only prescribed Pharm • 9/55 charts with combo of prescribed Pharm and Non-Pharm interventions • 0/55 charts prescribed Pharm+Methadone • 1/55 charts with prescribed Pharm prn • 0/55 no intervention	High adherence to establishing pain mgmt interventions
R7	Patient or family education related to pain management for patients with pain	0/53 (0%) charts with Pt. Education Form 0 /53 (0%) charts with evidence of pt education on pain mgmt provided in IPN	• 1/55 (2%) charts with Pt. Education Form (re: Atrovent and neb use)[] • 0 /55 (0%) charts with evidence of pt education on pain mgmt provided in IPN	• Low adherence No use of Pt Education Form. No documented evidence of "Pt education" provided on pain management plan in IPN.

High adherence rate (>80%), moderate adherence rate (50−80%), and low adherence rate (<50%) of the time (48).

(11) Five subcase 1 nurses claimed their Manager's focus on improving pain care was supported by *a climate for doing research* on the unit, encouraging "one nurse to do her Masters on non-verbal pain indicators . . . on the unit" (C1:P5).

(12) Subcase 2 nurses stated, they "work within a very close dynamic interprofessional team" (C2:P8) that *integrated pain care into unit norms*; such as "patient daily rounds" (C2:P2), which influenced their use of the Pain P/P.

Subcase nurses identified seven barriers to Pain P/P use at the 10-year mark:

(13) *Patient/family characteristics* influenced their use of the Pain P/P admitting "assessing pain is challenging when patients are afraid of taking pain medication" (C2:P1), and or "if families are scared to ask for medications" (C1:P8).
(14) A lack of user *familiarity/awareness of the Pain P/P* indicating, they "don't think many people refer to it [Pain P/P] beyond orientation" (C1:P5), nor were aware "it was an actual legit document" (C2:P6).
(15) Subcase 2 nurses indicated the *lack of available pain management resources* on the unit, such as "a formal clinical pathway for pain control" (C2:P4) or "pain standing orders" (C2:P3) as a barrier. Nurses further indicated there was a need for unit in-services on *specialized equipment,* like CADD pain pumps" (C2:P8) on the units.
(16) The recent internal unit restructuring was identified as a barrier. Specifically, the *physical structure/layout* was "more than one floor" (C2:P8), and "too large, containing more than 80 beds" (C1:P1).
(17) Nurses indicated increased *workload* or decreased *staffing ratios* was a barrier, explaining "assigning one nurse to six patients is too much to maintain and control pain levels" (C2:P6).
(18) The *utility of the new electronic patient information charting (EPIC) system* was identified as barrier. Nurses stated "it's [EPIC] so frustrating going back and forth from the bedside to the EPIC system to scan your patient, then go back to the med cart to get your meds" (C1:P7).
(19) Nurses stated use of the established Education Form: a *formal information reporting system between practitioners* "was an unrealistic charting expectation" (C1:P7) revealing "we do education all the time, but don't document it, even on that form" (C2:P2). Additionally, nurses claimed a lack of MD and nurse communication related to the pain care they provide existed, indicating "very rarely do physicians prompt nurses about patient pain" (C2:P2).

KTIs

Three unique KTIs (1 innovation, 2 context) were identified by subcases that facilitated Pain P/P use at the 10-year mark, addressing study objective 3.

The 1 innovation KTI included:

(i) *digitalizing of Pain P/P recommendation prompts* into the new EPIC system promoted use.

The 2 context KTIs (ii-iii) included:

(ii) *senior nurse mentorship* of novice nurses' Pain P/P use "especially in pain crisis situations" (C2:P2), and providing "tips on non-verbal pain assessment and management techniques at bedside" (C1:P4, C2:P2); and
(iii) *establishing communication practices between providers* to report on patients' pain status (e.g., verbal bedside shift reports, documentation on patient care boards, vital sign clipboards) facilitated Pain P/P use at the 10-year mark.

Discussion

Our findings provide insight into the sustainability of a Pain BPG, from a nursing department and unit level, within an acute care context. We identified a total of 32 sustainability determinants that address study objective 1, and 29 sustainability-orientated KTIs that fostered innovation sustainment in an acute care context over 10 years addressing study objective 3, These findings not only provide a listing of sustainability determinants and related KTIs for those planning or implementing BPGs in clinical practice, but more importantly the pairing of the KTIs to the determinants; whether a facilitator or barrier, to promote sustained use over time adds to the current knowledge (see Table 3).

In addition to identifying sustainability determinants and related KTIs, several key observations related to study findings are presented. For example novel findings revealed three determinants had a continuous influence during the implementation and sustained use phases. Unique determinants identified by department and unit nurses not only reflected changing context influences over time but a perspective based on their respective roles and responsibilities to the innovation. Unit nurses demonstrated a range of high to low adherence to the five selected guideline recommendations at the 10-year mark, addressing study objective 2. Combined department-wide level KTI efforts designed to standardize nursing documentation and unit level processes/practices contributed to these rates. Another novel finding revealed eight KTIs that continuously influenced Pain P/P use in implementation and sustained use phases. Lastly, five key observations related to the KTIs that were paramount to resolving the fit between the innovation (Pain P/P) and the changing context, during both phases are presented.

Three determinants having continuous influence over time

Our research provides insight into the relationship among three determinants across both phases important for sustainment: (i) a *need;* (ii) *external demand*, and (iii) *leadership commitment*. Although these determinants have been identified for sustainment of EBPs (5, 8, 14, 57–59), our study provides novel evidence of the potential impact of implementation determinants on sustainability of innovations in acute care

context recently proposed in the literature (58, 60). The following discussion examines the influences underlying these three determinants over time and their impact on sustainment.

During the implementation phase (0–2 yrs.) a *need* was identified among department nurses to ensure a consistent approach to pain care across all inpatient units facilitating the development of an interdisciplinary Pain P/P (i.e., innovation) designed for all disciplines to follow. Whereas, during the sustained phase (>2–10 yrs.) *ongoing need* for the innovation by internal stakeholders (i.e., inpatients) at the clinical level (unit) contributed to sustained use. Department and unit nurses' ongoing perception of the innovation's need, its' safety and quality, and over time its' relevance to addressing a need (perceived benefit to patients) reportingly influenced ongoing use. This finding is congruent with the evidence in the literature (14, 16, 61). Similarly, expectations (*external demand*) from healthcare regulatory bodies on hospital leaders to embrace evidence-based care in the implementation phase, over time shifted to a requirement by the Ministry and accrediting bodies to report related quality and standards of care data. Brewster et al. (61) purports efforts such as these "transform innovations from a practice imposed on an organizational system, to habits that are reinforced by the system" (61). Thus, external pressure/demand eventually took on the role of holding the EBP in place, promoting sustainment of the Pain P/P over time and at the 10-year timeframe. Lastly, the combination of *leadership commitment* expanded over time to include both department and unit level leaders as the focus on Pain P/P use moved from a department level (implementation phase) to the clinical practice level (sustained phase). Leadership engagement at all levels is identified in previous studies as a key factor influencing sustainment (1, 3, 21, 24, 62).

Clearly, attention to these three determinants and how they influenced use of the Pain P/P during both phases, at multiple levels, was necessary for sustainment. This finding provides evidence that changing conditions (e.g., level of application) do impact not only the fit between the innovation and the context, but ongoing use over time corroborated by other researchers (6, 63, 64). The fact that the underlying condition influencing these determinants did evolve over time further supports the conceptualization of sustainability as an "*ongoing dynamic process*" (58). Thus, we recommend these determinants be considered early in the knowledge to action cycle when planning and in the development of sustainability action plans indicated by other researchers (1, 57, 60, 65, 66).

Unique department and unit nurses' determinants

Together, department and unit level nurses identified 32 sustainability determinants that not only addressed study objective 1, but revealed insights not anticipated. Specifically, unique determinants identified by the department and unit nurses reflected a viewpoint based on their respective roles and responsibilities related to the innovation. For example, department nurses reported broader system (e.g., connections with external networks) and organizational-wide practice setting (e.g., internal competing priorities) determinants impacting sustainability over time. These determinants reflect an "outward focus" and insight into their roles and responsibilities across all units which positioned them "to act as conduits, linking outer and inner contextual influences" to ensure sustainment of the innovation over time in a changing context. This finding adds to the nurse leadership roles identified in a previous study wherein the mid-level management role is described as being critical to enacting a tie between the unit level leaders and point of care (24).

Conversely, determinants identified by unit nurses, focused mainly on the "innovation" and how it meets patient needs, and nurses' use of it within their daily practice, related structures and processes on the unit: the local context. Unit nurses identified that "patient/family perceived benefits of an innovation" influenced their use of BPGs. This finding aligns with a recent study wherein hospital-based nurses reported continued benefits as an essential innovation characteristic for sustainability of BPGs (15). Researchers further suggest provider collaboration as a key determinant influencing the implementation of BPGs in hospitals (67, 68). A novel finding in our study stems from the linkages/interactions between and attributes of unit level leaders, senior nurse mentors and interprofessional team members on the subcase units. The literature suggests dynamic elements of context, such as increasing complexity and acuity of inpatients, often requires interdependence among nursing colleagues and other interprofessional team practitioners to maintain BPGs (67). Unit nurses reinforced how nursing work is dependent on linkages within the network of care it is located in (e.g., between the persons and clinical processes on the unit) noted in a previous study (15) which impacted their sustained use of BPGs. Thus, despite differences in supervision (e.g., unit leaders) and organization culture/climate (mentors and IP team members) determinants, the linkages/interactions between and attributes of these key individuals are important for sustainability, which has not been previously reported, adding to current knowledge.

Adherence to selected guideline recommendations

Findings related to study objective 2 revealed a range of high to low adherence rates to the selected five recommendations among subcase nurses 10 years post implementation. Specifically, unit nurses demonstrated high adherence to three recommendations: R1 (assessment on admission), R2 (assessment once per shift and hourly rounds), and R4

(establishment of interventions to manage pain). These findings further support evidence in the literature that standardized documentation practices (69), the integrations of recommendations into daily processes and practice routines (70), and ongoing audit and feedback related to guideline recommendations (70) promotes formal documentation of recommendations necessary to accurately measure sustainment. It is unclear if one or the combination of all efforts made a difference. Likely, over time all played a role.

Given our findings, we cannot say with certainty there is an evidence-practice gap for recommendations R3 (setting pain goals) and R7 (educating patients/families regarding their pain management plan) 10 years post implementation. Although we found a significant difference in adherence to R3 (i.e., moderate adherence) establishing pain goals on subcase 2 compared to subcase 1 (i.e., low adherence), findings revealed unit level practices (e.g., use of whiteboards and bedside shift reports) influenced nurses' lack of documentation in the clinical records. Similarly, for R7, although no formal documentation (i.e., on Patient Education Form) was evident indicating patients received pain education, nurses indicated they provided pain care education all the time. The accuracy of nursing documentation among acute care nurses has previously been studied (71, 72). These studies have reported low scores on (i) the accuracy of nursing intervention documentation (71, 72) and (ii) that nurses' documented EBP "assessments of patient status" more frequently than the "nursing interventions they were preforming" (72). Uncovering informal processes at point of care for recommendations exhibiting moderate to low adherence rates is necessary in order to develop effective KTIs to promote accurate documentation of nursing interventions to effectively measure sustainment.

Eight sustainability KTIs used over 10 years

We identified a total of 29 sustainability-orientated KTIs that influenced the ongoing fit between the innovation (Pain P/P) and the changing context which addressed study objective 3. Another novel finding in this study is both department and unit nurses described eight KTIs that continuously promoted the use of the Pain P/P over 10 years. These eight KTIs provided insight into how the focus of the KTIs evolved over time with the change in level of application (e.g., across units/department vs. unit specific application). This novel finding is important to consider when designing KTIs to be used in ever-changing healthcare settings. Our findings demonstrate sustainability requires continual efforts but if undertaken as an integrated part of improving overall institutional performance, can create a supportive climate for EBP sustainment. Given the continued impact of the eight KTIs over time we recommend they be considered early in the planning stage for those aiming to sustain BPGs in similar acute care settings.

Key observations related to sustainability-orientated KTIs

Five key observations about KTIs that we perceive fostered changed behaviors and facilitated sustainment overtime in our study are: (i) two implementation KTIs had an enduring impact in both phases; (ii) the linking of KTIs to one recommendation at time (e.g., an incremental approach) promoted sustainment; (iii) use of a participatory approach that engaged leaders and unit nurses in the development of KTIs; (iv) development of an infrastructure to monitor adherence that engaged nurses promoted accountability for EB care and built capacity, and (v) creating an institutional system that held leadership accountable for EBP outcomes.

First, two implementation phase KTIs that had an enduring impact in both phases were: the *use of frameworks* and *securing external financial resources* for the BPG-IP. Using "framework-inspired method" (e.g., KTA and OMRU) (53) to "facilitate early identification of barriers" (65) and to tailor KTIs is a creative way to provide guidance on how to proceed, while promoting stakeholder engagement and interest in facilitating ongoing decision-making, to ensure sustainability of EBPs (65). This recommendation corroborates that of other researchers (14, 18, 58, 73–75). *Securing external financial resources* to develop an "electronic point of care prevalence monitoring system" that measured nursing sensitive indicators beyond implementation, was recognized externally as a key sustainability-orientated KTI. Securing funds to support innovation initiatives is congruent with existing sustainability frameworks (14, 16).

Second, findings revealed the adapting and refinement of EBPs to local context over time also requires continual efforts focused on designing KTIs that address changing contextual influences to promote ongoing use. Specifically, during the implementation phase, KTIs were focused on integrating recommendations into existing organization-wide documentation and orientation processes/practices. During the sustained phase, the focus and design of KTIs changed to address unit specific low adherence rates. This change likely stemmed from the realization they could not obtain high adherence to all BPG recommendations on all units at the same time. The added value or effectiveness of tailoring KTIs overtime to support the integration of the innovation into routine practices/processes (in context), previously identified as an implementation strategy to overcome barriers to change (76, 77), now adds to sustainability knowledge. These findings further reinforce that a balance is needed between maintaining ongoing organization KTIs and allowing units the latitude to link KTIs, designed specifically to address unit specific low adherence rates, to facilitate successful

sustainment. This novel finding substantiates that innovation sustainability is broader than just maintaining the fidelity of the original EBP (Pain P/P) but instead one that exhibits ongoing continuous adjustments and refinements to optimize its utility within a changing context (6). Our findings also add credence to the conceptualization that sustainability of healthcare innovations in clinical practice is as an "*ongoing dynamic process*" (58).

The third, involves the use of a participatory approach that engaged point of care users in the development of KTIs to enhance adherence: a bottom-up participatory approach. This strategy effectively built on their successes related to guideline adherence rates while continuing to improve patient outcomes. These findings confirm the notion that to produce real world change over time there is a "need to consider staff and system domains as active components in the change process rather than imposing change" (4). This active participatory and incremental approach to develop strategies by unit level users (4, 78–80), led by clinical leaders (33, 79) contributed to sustainment in the changing acute care context.

A fourth observation involves the combining of two KTIs (e.g., monitoring and training) designed to promote accountability while building capacity for evidence-based care. In a recent review of sustainability approaches used to sustain innovations in healthcare "monitoring progress overtime" emerged as "a consistent construct across approaches regardless of the proposed innovation, settings or application types" (79). Efforts by the study site to establish a point of care *monitoring and feedback system*, that provided *regular reports* on nurses' *adherence rates* to BPG recommendations produced the necessary data critical to determine *unit level remedial action plans* (e.g., feedback mechanisms). These efforts reportedly contributed to sustainment and have been reported by others (79, 81). Additionally, the training of users to conduct the surveys and engage in feedback processes reportedly *enhanced capacity to monitor progress* overtime contributing to sustained use. These KTIs should be considered by those planning or in the process of creating a sustainability monitoring infrastructure system.

Fifth, the integrations of a *BPG-related performance criterion* into the performance evaluation system had a trickledown effect into the nurse manager and subsequent unit nurses' performance expectations and was critical to the process of change (e.g., adherence to guideline recommendations) and likelihood of sustained use over time. This KTI focused on obtaining shared accountability (e.g., getting buy-in) to deliver the innovation [Pain P/P] in support of the departments' vision for EB care. This finding is congruent with a study wherein point of care nursing leaders promoted shared accountability by reinforcing the expectation of BPG as the practice standard on their units (15, 24). Consistent reinforcement and evaluation of guideline standards by leaders with teams of nurses was a key KTI consideration for sustained use of BPGs in our study.

Strengths and limitations

To our knowledge this is the first study to provide theory-informed, in-depth, contextualized evidence about the determinants and related KTIs used over a 10-year timeframe to sustain the use of a nursing guideline in acute care. Novel insights related to the relationship between determinants and KTIs and their level of application (department and unit levels) over time were revealed. Detail and in-depth descriptions needed to determine the extent or transferability of our findings to similar settings is provided. We used multiple forms of data, conducted debriefings with the research team, and substantiated findings with knowledge users to enhance credibility. Adhering to the study protocol, documenting decision points, maintaining organized paper and electronic databases, and maintaining a master list of definitions, questions, and codes enhanced dependability. Referencing multiple data sources, remaining close to participant verbatim transcripts, and demonstrating data congruency between two or more participants ensured confirmability.

Limitations include the possibility of non-response and recall bias among department level nurses given the retrospective nature of interview process. Although the interviews occurred at the 10-year mark, participants remembered details from start to present day, given they remain currently engaged in ongoing efforts to support sustainment. Other potential biases include sampling, participant social response bias, and potential researcher bias. Sample selection was limited given the capacity of the primary researcher who collected all data. Subcase selection was based on maximum variation criteria providing potentially contrasting patterns of findings established by internal representatives and voluntary participation. Furthermore, including additional subcases (units) in future sampling may provide further insights and or confirm findings. Social response bias may have occurred if participants' responses to the interview questions indicated what they thought would be acceptable rather than their perspective. Steps taken to decrease social response biases included triangulating data sources and validating themes within the qualitative analysis. To reduce researchers' bias, we used multiple data sources and substantiated findings with knowledge users. Finally, the examination of one BPG, within one multi-site healthcare organization, from solely a nursing perspective, is a limitation. Given the Pain P/P is an interdisciplinary policy, perceptions from medical and allied health professionals, other than department and unit level nurses were not included and may have.

Conclusion

Sustainability of EBPs in acute care has been recognized as a challenge. Together, determinants and KTIs influence

the way in which healthcare innovations are sustained over time. It is important to understand the influences underlying the determinants in real world settings and how the focus of the KTIs must evolve over time with the integration of an innovation at different levels of application (e.g., department vs. unit level). KTIs that fostered behavior changes to sustain a BPG were paramount to resolving the fit between the innovation and the changing context over time. Given healthcare innovation sustainability is a "process" or "ongoing stage," it is noticeable from these findings what really matters is how and what the organization does to sustain the innovation at all levels over time within ever-changing acute care contexts. Future inquiry needs to focus on examining KTIs that promote documentation of nursing interventions related to recommendations (e.g., R4-setting pain goals, R7-providing patient/family pain management education) which revealed low to moderate adherence rates. To further our understanding of sustainability, qualitative methodologies should be used to uncover unit level determinants and KTIs underlying nurses' adherence to guideline recommendations across a range of healthcare settings with the intention of adding to the existing sustainability knowledge base.

Data availability statement

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

Ethics statement

The studies involving human participants were reviewed and approved by Research Ethics Boards for the Ottawa Health Science Network (OHSN-REB) and the University of Ottawa. The patients/participants provided their written informed consent to participate in this study.

Author contributions

LNP, IG, BD, CB, and JS conceived the study design. LNP was responsible for the data collection, synthesis, conducted the quantitative data analysis, and produced all tables, figures, and Supplementary materials. LNP and JF-P conducted analysis of qualitative data. JS, IG, and CB provided input into the analysis and interpretation. The initial draft of the manuscript was prepared by LNP as part of dissertation research and then circulated among all coauthors for comments and revision. All authors read and approved the final manuscript.

Funding

IG is a recipient of a CIHR Foundation Grant, FDN#143237.

Acknowledgments

Acknowledgment to Daniella Cho-Young for assistance testing the reliability of the quantitative extraction tool. Thank you to Nicole Graham and David Hemsworth for assistance in verifying quantitative data sets and calculations, respectively. Further acknowledgment to Caitlin Britton for her assistance in the extraction of transcripts into working files for analysis.

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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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.940936/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 31 October 2022
DOI 10.3389/frhs.2022.1004805

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 27 July 2022
ACCEPTED 10 October 2022
PUBLISHED 31 October 2022

CITATION
Agulnik A, Schmidt-Grimminger G, Ferrara G, Puerto-Torres M, Gillipelli SR, Elish P, Muniz-Talavera H, Gonzalez-Ruiz A, Armenta M, Barra C, Diaz-Coronado R, Hernandez C, Juarez S, Loeza JdJ, Mendez A, Montalvo E, Penafiel E, Pineda E, Graetz DE and McKay V (2022) Challenges to sustainability of pediatric early warning systems (PEWS) in low-resource hospitals in Latin America.
Front. Health Serv. 2:1004805.
doi: 10.3389/frhs.2022.1004805

Challenges to sustainability of pediatric early warning systems (PEWS) in low-resource hospitals in Latin America

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Background: Sustainability, or continued use of evidence-based interventions for long-term patient benefit, is the least studied aspect of implementation science. In this study, we evaluate sustainability of a Pediatric Early Warning System (PEWS), an evidence-based intervention to improve early identification of clinical deterioration in hospitalized children, in low-resource settings using the Clinical Capacity for Sustainability Framework (CCS).

Methods: We conducted a secondary analysis of a qualitative study to identify barriers and enablers to PEWS implementation. Semi-structured interviews with PEWS implementation leaders and hospital directors at 5 Latin American pediatric oncology centers sustaining PEWS were conducted virtually in Spanish from June to August 2020. Interviews were recorded, professionally transcribed, and translated into English. Exploratory thematic content analysis yielded staff perceptions on PEWS sustainability. Coded segments were analyzed to identify participant perception about the current state and importance of sustaining PEWS, as well as sustainability successes and challenges. Identified sustainability determinants were mapped to the CCS to evaluate its applicability.

Results: We interviewed 71 staff including physicians (45%), nurses (45%), and administrators (10%). Participants emphasized the importance of sustaining PEWS for continued patient benefits. Identified sustainability determinants

included supportive leadership encouraging ongoing interest in PEWS, beneficial patient outcomes enhancing perceived value of PEWS, integrating PEWS into the routine of patient care, ongoing staff turnover creating training challenges, adequate material resources to promote PEWS use, and the COVID-19 pandemic. While most identified factors mapped to the CCS, COVID-19 emerged as an additional external sustainability challenge. Together, these challenges resulted in multiple impacts on PEWS sustainment, ranging from a small reduction in PEWS quality to complete disruption of PEWS use and subsequent loss of benefits to patients. Participants described several innovative strategies to address identified challenges and promote PEWS sustainability.

Conclusion: This study describes clinician perspectives on sustainable implementation of evidence-based interventions in low-resource settings, including sustainability determinants and potential sustainability strategies. Identified factors mapped well to the CCS, however, external factors, such as the COVID pandemic, may additionally impact sustainability. This work highlights an urgent need for theoretically-driven, empirically-informed strategies to support sustainable implementation of evidence-based interventions in settings of all resource-levels.

KEYWORDS

sustainability, pediatric early warning systems (PEWS), resource-limited settings (RLS), pediatric oncology, global health, implementation science (MeSH)

Introduction

Much of implementation science focuses on adopting and implementing evidence-based interventions, and sustainability, or the ongoing use of an evidence-based practice resulting in maintained patient benefits, is the least studied phase of the implementation continuum (1, 2). Ideally, interventions should be sustained unless they are no longer effective or more effective interventions become available (3–5). Many interventions are abandoned when they should be continued, often when external support, such as grant funding or collaborative assistance, is removed (6–9). Implementing interventions is costly, and if interventions are not sustained, then initial investments are lost (10, 11). Most importantly, evidence-based interventions that are not sustained cannot provide continued health benefits to patients.

Framing sustainability

The current body of scientific literature focuses primarily on conceptualizing and theorizing sustainability in health (11, 12). Sustainability follows successful implementation, typically after external support for an intervention has been withdrawn (13). Similar to contextual factors that impact implementation, a general consensus within the literature establishes the relationship between the immediate context where interventions are implemented and the likelihood of intervention sustainability (12). However, factors impacting the initial implementation of evidence-based interventions are likely not the same as those impacting long-term sustainability. For instance, staff turnover may not impact initial implementation, but is often discussed as a barrier to sustainability.

While there are several conceptual frameworks identifying sustainability determinants, few have guided empiric examinations. The Clinical Capacity for Sustainability Framework (CCS) characterizes the resources needed to successfully sustain an intervention that represent the most proximal contextual determinants influencing intervention sustainment and continued patient benefit (10, 14, 15). Briefly, clinical capacity for sustainability includes engaged staff, leadership and stakeholders, organizational readiness, workflow integration, implementation and training, and monitoring and evaluation (14, 15). This framework was empirically developed, and has subsequently been leveraged to inform measures and tools to assess and plan for intervention sustainability (16).

Sustainability in low-resource settings

Sustainable implementation is particularly important in low-resource settings, where resources available for implementation are limited. Low-resource settings experience disproportionate burden of poor health outcomes, making sustainable implementation of evidence-based interventions particularly crucial. However, there are

limited examinations of sustainability in these settings; a recent review of determinants of hospital interventions sustainability did not include a single study from a low-income country (17).

Pediatric early warning systems improve childhood cancer outcomes in low-resource hospitals

The global burden of pediatric cancer is disproportionately shifted to low- and middle-income countries, which bear over 90% of childhood cancer cases (18), with a dismal survival rate of ∼20% (19). Hospitals in low-resource settings frequently lack adequate infrastructure and staffing to deliver needed supportive care during cancer treatment (20–23), resulting in late identification of clinical deterioration due to treatment toxicity and high rates of preventable deaths (24–26). To more rapidly identify clinical deterioration, many hospitals use pediatric early warning systems (PEWS), which are nursing-administered bedside clinical acuity scoring tools associated with escalation algorithms (27). PEWS accurately predict the need for pediatric intensive care unit (PICU) transfer in pediatric oncology patients in high-resource hospitals (28–31). Escala de Valoración de Alerta Temprana (EVAT) is a valid Spanish-language PEWS adapted for low-resource settings (32–35), with implementation resulting in a 27% reduction in clinical deterioration events, optimized PICU utilization (33), improved interdisciplinary and family communication, provider empowerment and perceived quality of care (36–39), and an annual cost-savings of over US$350,000 (40).

Proyecto EVAT is a quality improvement collaborative of pediatric oncology centers in Latin America which has supported PEWS implementation in over 40 low-resource hospitals (41), with preliminary results showing improvements in patient outcomes (42–47). Recent work by our team identified multiple barriers to PEWS implementation among centers participating in Proyecto EVAT, with many of these barriers converted to enablers by local implementation teams during the implementation process (48). This work, however, focused primarily on PEWS adoption and implementation, and didn't evaluate factors contributing to PEWS sustainability in participating centers. In this paper, we conduct a secondary analysis of this study using the CSS to evaluate staff perspectives on successes and challenges sustaining PEWS in these low-resource hospitals. We then discuss the utility of the CCS and make recommendations on its use to understand sustainability in real-world clinical settings. Finally, we explore innovative strategies used by hospitals to improve their capacity to sustain PEWS.

Methods

This is a secondary analysis of a study designed to evaluate barriers and enablers to PEWS implementation in low-resource hospitals. This study was approved by the St. Jude Children's Research Hospital (St. Jude) institutional review board as minimal risk; additional approvals were obtained locally at participating centers as needed. As an exempt minimal risk study, written consent was waived, and verbal consent was obtained prior to the start of each interview. The Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines were used for rigor of qualitative reporting (49). A detailed description of study methods have been previously described, and are briefly summarized below (48).

Site and participant recruitment

Centers participating in Proyecto EVAT who had completed PEWS implementation prior to March 2020 (the start of the COVID-19 pandemic in Latin America) were recruited to this study. All Proyecto EVAT centers self-identify as resource-limited due to a range of limitations in staff and material resources needed for childhood cancer care. Of 23 centers meeting these criteria, hospitals were purposefully selected based on time required for PEWS implementation, including 3 'fast' implementing centers (3–4 months between pilot start and implementation completion) and 2 'slow' implementors (10–12 months). At the time of this study, these centers had been sustaining PEWS for 8 to 23 months (see Supplementary Table 1 for center characteristics). At each participating center, a study lead identified 10–15 participants who were involved in PEWS implementation (PEWS implementation leaders, hospital directors and administrators, and others indirectly involved in implementation).

Interview methods

To study barriers and enablers of PEWS implementation, an interview guide was developed using the Consolidated Framework for Implementation Research (CFIR) (50, 51) with adaptations for low-resource settings (52) (Supplementary Figure 1). This interview guide was translated to Spanish and iteratively edited by bilingual members of the study team, then piloted among 3 individuals at non-participating centers but representative of the target participants. Interviews were conducted in Spanish via videoconference by bilingual members of the study team (SRG and PE) from June to August 2020. Interviewers were not previously known to the participants and were not involved in PEWS implementation. Interviews were audio recorded, transcribed, translated, and de-identified prior to analysis.

Analysis

For the primary study on barriers and enablers to PEWS implementation, a codebook was originally developed using *a priori codes* from the CFIR and novel codes derived through iterative review of 9 transcripts by two investigators (AA and GF). The transcripts were independently coded using MAXQDA (VERBI Software GmbH) by two investigators (AA and GF), with a third investigator resolving discrepancies (DEG), achieving a kappa of 0.8 to 0.9. "*Sustainability*" was identified as an inductive theme during this this primary analysis, defined as "the perceived likelihood of continued use of PEWS and activities for the continued achievement of the desired outcomes on patient care, any mention of sustainability or sustainment of use in the long-term, including it becoming part of 'routine' or 'practice' at the hospital."

Secondary analysis for this study focused on exploring participant perspectives on PEWS sustainability at their centers, including challenges and successes. Three investigators (AA, GSG, VM) conducted thematic content analysis of segments coded as *sustainability*, with iterative review of transcripts and constant comparative analysis of themes by center. Segments originally coded for *sustainability* were analyzed to identify participant perception about the importance of PEWS sustainability, factors contributing to sustainability successes and challenges (determinants), and overall evaluation PEWS sustainability at each center at the time of the study.

Identified themes regarding sustainability determinants were then mapped to the CCS, (14, 15) which describes clinical capacity for sustainability within 7 domains: (1) engaged staff and leadership—frontline and administrative staff who are supportive of the intervention; (2) engaged stakeholders—other individuals, such as patients or parents, who are supportive of the intervention; (3) organizational readiness—organizational internal support and the resources needed to effectively manage the intervention; (4) workflow integration—how well the intervention fits into work that is done or will be done; (5) implementation and training—the process of implementing and training to deliver and maintain an intervention; (6) monitoring and evaluation—a process to evaluate the intervention to determine its effectiveness; and (7) outcomes and effectiveness—using monitoring and evaluation to determine outcomes for clinicians or patients.

Examples of how centers overcame challenges to successfully sustain PEWS were then further explored as potential sustainability strategies.

Results

Among 5 pediatric oncology centers, 71 staff including physicians (45%), nurses (45%), and administrators (10%) were interviewed. Of these, 39 (54.9%) were implementation leaders and 21 (29.6%) hospital directors. Characteristics of study participants can be found in Table 1. Sixty-four interviews (90%) mentioned PEWS sustainability; analysis explored participant perceptions of sustainability, determinants that influenced sustainability, and innovative strategies used by participating centers to enhance capacity and PEWS sustainability.

TABLE 1 Participant characteristics ($n = 71$).

Characteristic	*n* (%*)
Sex	
Male	21 (29.6%)
Female	50 (70.4%)
Professional role	
Physician	32 (45%)
Nurse	32 (45%)
Administrator	7 (10%)
Role in PEWS	
Implementation leader	39 (54.9%)
Hospital director	21 (29.6%)

*Percentages may not add to 100% due to rounding.
PEWS, Pediatric Early Warning System.

Perceptions of PEWS sustainability and its value

Participant perceptions on PEWS sustainability are described in Table 2. While all participants valued sustaining PEWS, staff from different centers described a range of PEWS sustainability, ranging from use only in pediatric oncology patients and limited infrastructure to maintain PEWS, to extensive use in multiple units and a robust infrastructure for PEWS maintenance.

Staff from all centers recognized the importance of sustaining PEWS after implementation to continue patient benefit: *"It's something that should be permanent because the benefits are many. And the benefits are for the patients, that's why we are here"* (Nurse, Xalapa). Similarly, positive outcomes from PEWS reinforced staff participation in its continued use: "*this is a tool that has allowed us to give a favorable help to the patients, it's something sustainable that, something that makes us participate, and go beyond the normal evaluation of the patient*" (Physician, San Salvador). Participants also recognized that sustainability isn't automatic and requires ongoing work from the leadership team: "*Still, I think we need to keep working because it's not like we already implemented it and now it works alone.*" (ICU Physician, Lima)

Despite the strong desire for PEWS sustainability, participants at different centers described variable degrees of ongoing PEWS use at their hospitals at the time of the study.

TABLE 2 Perceptions of PEWS sustainability and its value.

Themes		Examples
Continued patient benefit		"… at this stage we've seen the impact, it's a project that will continue because it's been beneficial for the patients." (Nurse, San Salvador)
Benefits of PEWS encouraging ongoing use		"It was the motivation of seeing the children who could have had a fatal ending, return to the [ward] in a better condition" (Nurse, Cuenca)
Variable perception of current PEWS sustainability	High sustainability	"We think the work keeps going, the scale keeps working and we haven't had difficulties." (Nurse, San Salvador) "We are satisfied that [PEWS] will continue in [our hospital] for the rest of time for children's care." (Physician, Cuenca)
	Medium sustainability	"It works, maybe not 100% but an 80-90% works fine. (Physician, Lima)
	Low sustainability	"At this moment, we're just surviving with PEWS, we're not 100%, we're trying not to let it fall down, maintain it, if we cannot have it at the level we did at the end of last year, at least maintain it, prevent its fall, knowing that when all people return, we must start again." (Nurse, Xalapa) "At the beginning, I think they applied the scale to most of the children, but as times passed things got a bit more relaxed and the nurses… would apply this scale only to patients with oncology or hematology diagnosis" (Physician, San Luis Potosi)

PEWS: Pediatric Early Warning System.

While some centers felt confident about sustaining PEWS: "*Despite everything, EVAT has been working exactly the same, we haven't let that affect our project.*" (Nurse, Cuenca), others felt they were "just surviving: "*I think [PEWS] is not 100% like we used to be before…but we are surviving.*" (Nurse, Lima). Some participants voiced concerns that PEWS was not being sustained, reducing patient benefits: "*This year unfortunately we've returned with the sudden deaths, so we didn't learn from the mistakes*." (Nurse, Xalapa). These descriptions of the degree of PEWS sustainability were consistent among participants from a given center, including both implementation leaders and hospital directors, allowing for classification of high-sustainability (Cuenca, San Salvador), medium-sustainability (Lima), and low-sustainability (Xalapa, San Luis Potosi). Table 2 provides more examples of staff perception of the degree of PEWS sustainability at their hospitals.

Determinants of PEWS sustainability

Six themes regarding determinants influencing PEWS sustainability emerged in our analysis: (1) supportive leadership encouraging ongoing interest in PEWS, (2) beneficial patient outcomes enhancing perceived value of PEWS among staff, (3) integrating PEWS into the workflow for routine patient care, (4) ongoing staff turnover creating training challenges, (5) adequate material resource to promote PEWS use, and (6) COVID-19 as an external stressor. Themes and example quotes can be found on Table 3.

Supportive leadership encouraging ongoing interest in PEWS

The importance of leadership support was one of the most prominent themes that participants felt influenced the sustainability of PEWS: "If *we don't have the support of the authorities, it's more difficult to apply a project like this.*" (Physician, Lima) Common types of support included providing financing, equipment needed to use PEWS, and staff acknowledgment for their work. Leadership helped ensure staff were able to maintain expertise needed for PEWS sustainment: *"[The leadership] support us in everything, permissions to travel, the courses, … and also to continue with the project."* (Physician, Xalapa). Some hospital directors also approved new institutional policies that helped further codify PEWS as the standard of care: *"I was informed that the nursing PEWS guide is ready to be signed, because our managing documents need the signature of our institutional chief.*" (Nurse, Lima)

Beneficial patient outcomes enhancing perceived value of PEWS among staff

Participants at all centers emphasized that the clear benefit of PEWS encouraged staff to continue using it in patient care: *"we didn't expect to have this much motivation… but the project turned out to be so useful that we never imagined to evaluate the patients in the correct way and to identify their deterioration in an early way."* (Nurse, Cuenca). Many participants were initially skeptical about

TABLE 3 Determinants of PEWS sustainability.

Determinant theme	Examples
Supportive leadership encouraging ongoing interest in PEWS	"To us, it's a process that came to stay and our work as supervisor, bosses, is to monitor and make new people learn and practice this tool as a form of attention for the patient." (Physician, San Luis Potosi) "And also count with the support of the authorities, not to see it as an isolated project for the departments, because that's the only way projects can be long-term, and that's important." (Physician, San Salvador)
Beneficial patient outcomes enhancing perceived value of PEWS among staff	"There are the statistics that show we have reduced the mortalities, the complications, the impact has been for the benefit of our patients. … we received the reward of excellence … The moment we got the rewards, we took them to the institutional director and told him what was the fruit of the nurse's work, the doctor's work, all the team." (Nurse, Lima) "At first we didn't know what the impact was going to be; we had some data but we didn't know what the impact was going to be in the patient, but I think at this stage we've seen the impact, it's a project that will continue because it's been beneficial for the patients." (Nurse, San Salvador)
Integrating PEWS into the workflow for routine patient care	"PEWS is in green, yellow, it doesn't matter, it's part of our everyday work." (Nurse, Lima) "The same way we've taken vital signs, we've done it our entire lives, now PEWS is an evaluation which is part of the routine of our service." (Physician, San Luis Potosi)
Ongoing staff turnover creating training challenges	"Very bad, every time there's a change in management, the new group of nurses that take new positions, like the supervisors, because most of the problems we've had are with them, they should be trained in this project too." (Nurse, Lima) "Three months ago, new colleagues started working here and they were trying to learn how this works, unfortunately we had a little bit of delay in the development of the project because of them, waiting for them to adapt to the projects we have, at the end it did influence, even though we explained everything, but the fact to start working at an oncology hospital, which is not their field, it has influenced in losing the path we're walking on." (Physician, Xalapa)
Adequate material resources to promote PEWS use	"I think they also faced those needs along the road saying we have the project but there are certain things that we cannot get but we needed." (Administrator, Xalapa) "My recommendation is to continue with that process, you'll always have problems related to material and human resources." (ICU Physician, Lima)
COVID-19 as an external stressor	"And everything got worse with the pandemic, so we're still working on it." (Physician, Xalapa) "COVID is something that is damaging the system, it's a topic we have to evaluate." (Physician, Lima) "We're still using EVAT, recording EVAT, the algorithm is being used the same as before, despite all the effort we have been making, because honestly this has been very hard, with less staff and more work" (Nurse, Cuenca)

PEWS, Pediatric Early Warning System; ICU, Intensive Care Unit; COVID, Coronavirus Disease.

their centers' ability to implement PEWS, and the sense of accomplishment from successful implementation resulting in measurable outcomes further encouraged staff to continue PEWS: *"we had good statistics, … we felt victorious."* (Nurse, San Salvador). Similarly, support from authorities was often obtained through demonstrating the positive benefits of PEWS: "*I think the sustainability of the project will depend on our results, so the authorities continue with this and support us.*" (Physician, Lima)

Integrating PEWS into the workflow for routine patient care

At several centers, PEWS became the standard of care for both nursing and physician staff: *"Now it [PEWS] is already part of our routine and part of us."* (Physician, Cuenca). Initially, both nurses and physicians were wary of change and resisted using PEWS: "*At the beginning, the barriers we had were nursing staff because it's difficult to change the working style of people who have been here for 15 or 20 years.*" (Physician, Lima). After a few months, however, staff were finding PEWS protocols easy to follow: *"we learned a lot from that [pilot] and we got to see our mistakes. … then it started to flow. So, right now it is very easy, it's part of what you do and they even memorized it."* (Physician, San Louis Potosi). Interventions that promoted integration of PEWS into routine patient care included institutional policies and continuous training. The ability to permanently integrate PEWS into the hospital routine was seen as unique compared to other initiatives: "*The goal is to be able to reset the staff's thinking and say this is not temporary like all the other things we've had, this is permanent, this is something that should stay in our everyday work.*" (Nurse, Xalapa)

Ongoing staff turnover creating training challenges

Staff turnover in centers trying to sustain PEWS created training challenges as new staff, unfamiliar with PEWS, joined the team. This theme emerged as one of the greatest barriers to sustaining PEWS. Rotation of experienced staff after PEWS implementation required additional training, which was challenging: *"[the staff] were not the same we trained in the pilot… they would change people without the right skills so we had to invest time with them and explain how to take the vital signs. That implied more effort… that was the biggest barrier related to the staff."* (Nurse, San Salvador). In academic hospitals, frequent rotation of clinical trainees was an additional barrier: *"It gives us uncertainty to be monitoring these people because the rotation in the service is just for 3 months… these people leave and new people come in and we must start all over again. And that has brought severe consequences to the PEWS project."* (Quality Improvement Staff, Xalapa). Changes in hospital leadership were also problematic, requiring extra effort by the PEWS team to convince them of the importance of sustaining this initiative: "*We haven't been able to meet with the general director, to it's the most important part because they can help us maintain it*." (Nurse, Xalapa)

Adequate material resource to promote PEWS use

Participants at all centers mentioned the need for ongoing availability of economic support to provide material resources, such as vital sign equipment and other supplies, to facilitate ongoing PEWS use: "*So, you need to see both the operative and the economic part to make them sustainable in time*." (Nurse, San Salvador). Lack of needed material resources, or organizational capacity, was seen as a barrier to sustainability: "*Finance… to get materials… is a barrier to keep the project working*." (Nurse, San Salvador) Centers that were able to obtain necessary material resources, despite initial challenges, reported this facilitated continued PEWS use: "*We had a situation with the electromedical equipment, it didn't come, they it came damaged, but once we had the chance… we started and once we did it we never stopped*." (Nurse, Xalapa)

COVID-19 as an external stressor

During the COVID-19 pandemic, additional barriers to PEWS sustainability emerged. While some centers were able to sustain PEWS despite COVID-19, others struggled. Most centers experienced staffing shortages that increased the nurse-to-patient ratios: *"our workload has doubled… the nursing staff has been reduced"* (Nurse, San Louis Potosi) and created additional challenges training new staff: *"COVID came … and a lot of nurses got medical leave and they sent us new staff and they were not trained so it turned out very difficult"* (Physician, San Louis Potosi). Centers already struggling with material and financial resources before COVID-19 experienced greater resource challenges: *"We always need resources; this country is poorer than it used to be… our needs have increased a lot, and we always need material resources and economic resources"* (Physician, Cuenca). Physicians from hospitals with difficulties sustaining PEWS frequently mentioned a lack leadership support as PEWS was less prioritized compared to other needs during the pandemic.

Despite these barriers, participants at some centers reported little change in the quality of care provided during the pandemic: "*I think that despite of the pandemic, quality is the same*" (Physician, Xalapa). For centers sustaining PEWS, staff noted they were able to isolate patients and transfer patients to the ICU or the COVID unit faster: *"I think it's a tool that helped us with the pandemic too, if we had it before, the entire hospital would have had this advantage that we have in oncology"* (Physician, San Salvador). Organizational readiness and adaptability helped some centers sustain PEWS despite the challenges of the pandemic: "*COVID is another thing. It does influence, but [PEWS] is still working, it's being applied, it has been just an adjustment we had to do against this situation*" (Physician, Xalapa).

Sustainability strategies

PEWS implementation leaders at all centers used multiple strategies to overcome challenges to sustainability, including multidisciplinary staff engagement, education and training, and maintenance of adequate supplies needed for PEWS (Table 4). The majority of identified sustainability strategies were described by participants at high-sustainability (Cuenca, San Salvador) and medium-sustainability (Lima) centers.

Planning and early implementation: Stakeholder engagement

Throughout the planning and early implementation process, PEWS leaders brought together a multidisciplinary team to engage a variety of staff and position PEWS for long-term sustainment: *"The greatest strength of PEWS in our institution is that it has been a team, nurses, doctors, and intensivists"* (Nurse, Lima). Taking a more multidisciplinary approach positively influenced PEWS sustainability through staff and

TABLE 4 Identified sustainability strategies.

Sustainability determinant (and related CCS domain)	Strategy	Examples
Staff and leadership engagement (Engaged Staff and Leadership)	Inclusion of multidisciplinary team	"That has been an achievement of all of us, to be able to ask anyone from the service or the hospital and that person should know what PEWS is." (Nurse, San Salvador)
	Institutional policy	"You continue because it's on the pediatrics protocol and the rest of the services." (Administrator, Cuenca)
	Volunteer participation	"Nurses already assume it as part of the job, they don't see it as an additional work anymore." (Nurse, Lima)
Education and training (Implementation and Training)	Protected time for training	"We do it through the hospital general sessions, through departmental sessions, specifically in that area, through courses, and we also take advantage of the induction courses for interns, that we generally receive every 6 months, in which there's always one topic of the project included." (Physician, Xalapa)
	Group learning and empowerment	"I say it again, that empowerment they had, PEWS is part of them now." (Nurse, San Salvador)
	Refreshers	"The team… had a reinforcement plan, as part of the sustainability of the project." (Nurse, Lima)
	Continuous training	"Because the staff hasn't lowered their guard and the staff continues to train themselves." (Physician, Cuenca)
Resources for PEWS (Organizational Readiness)	Process modification to support PEWS use	"Now the nurses only work six hours, so now the vital signs are taken in different hours" (Nurse, Cuenca)
	Distribution of educational material to remind staff about PEWS	"We generated the educational material and we put it in strategic places so it would be available for the staff." (Nurse, Xalapa)
	Availability of equipment needed to use PEWS	"When you are a nurse, you think that when you ask for material you will get it in 1 month, but it's a process, it takes time and it delays everything. But thank God we are doing great with PEWS now." (Nurse, Lima)

CCS, Clinical Capacity for Sustainability; PEWS, Pediatric Early Warning System.

leadership collaboration. Another method of staff engagement that promoted stainability was creating institutional policies: "*we took it as policy of the institution and the nursing system… this has facilitated a lot*" (Physician, Lima). The third strategy used was voluntary participation that generated interest for the program in a more diffuse, non-directive manner: *"First we asked for volunteers …the one who didn't want to participate were not forced to, but once we had the support of the chiefs, it was part of our daily work and that's how we managed the whole team to participate*" (Physician, Lima). If some staff continued to have poor performance using PEWS, leadership would intervene: "*the chief would call her and ask her what was happening, if you don't like pediatrics, then you just move*" (ICU Physician, Xalapa).

PEWS implementation: Education and training

During implementation, PEWS leaders used strategies focused on education and training to create the groundwork to sustain PEWS. Some centers held trainings during work hours as an incentive to participate: *"When we proposed the training for the staff, the directors had no problem to program hospital time for the colleagues."* (Nurse, San Salvador). Others used group trainings to share PEWS pilot results and allow team members to learn from each other and increase self-efficacy: *"We show the results for how many red [PEWS] were treated; how many went to the intensive care unit. So, showing the results and give the feedbacks with the nurses, the fact that they are part of the results gives them great amount of gratification, and I think now they come voluntarily, with better mood, because they feel they are part of the results and the progress."* (ICU Physician, Cuenca). Ongoing refreshers, or re-training, allowed staff to continuously improve PEWS use, promoting sustainability: "*We have given reinforce for some people that make some mistakes… to maintain our error margin the lowest possible*." (Nurse, San Salvador) Many participants mentioned the importance of continuous training to sustain PEWS: "*Just one training isn't enough but several trainings that leads to a continuous training*." (Physician, Cuenca)

Post-implementation: Maintenance of resources

Obtaining a continuous supply of materials necessary for PEWS was another strategy to promote sustainability. Nursing documentation was permanently changed to facilitate ongoing PEWS use: "*We have a sheet for collecting data, the vital signs, which is part of the clinical record. That cannot be removed until someone decides to change that sheet.*" (Nurse, Lima) Widely available PEWS materials engaged staff in the program and PEWS educational materials were distributed to promote PEWS use: *"it should have high acceptance because we took PEWS to the entire hospital, we posted posters, logos, in the management documents, boards, pins, we would change the PEWS boards constantly"* (Nurse, Lima). While most centers obtained supplies necessary for PEWS from their hospital leadership or affiliated foundations, limited resources meant staff would sometimes buy their own supplies to continue using PEWS: *"nurses… would go and buy them [oximeters], because that made their work easier"* (ICU Physician, Xalapa). All participants, including clinical staff and hospital directors, recognized the need for ongoing availability of material resources to sustain PEWS: "*We use to the maximum and avoid waste and splurge of supplies; we have to be practical to use our resources so we can keep the project going.*" (Physician, Cuenca)

Discussion

Sustainability, or the continued use of an evidence-based intervention resulting in maintained beneficial patient outcomes, is considered one of the most significant translation research problems and the least studied phase of the implementation continuum (1, 2). This study presents empiric evidence about staff perspectives on sustainability of an evidence-based intervention, PEWS, in low-resource clinical settings. We demonstrate that both clinical staff and hospital leadership identify the need to sustain effective interventions. The perceived sustainability of PEWS, however, varied across centers, ranging from high- to low-sustainability. Participants identified multiple challenges to sustainability across all hospitals and, particularly in high- and medium-sustainability hospitals, described several creative solutions leveraged as strategies to promote PEWS sustainability in these settings.

One goal of this study was to evaluate the CCS for conceptualizing sustainability determinants, or factors that served to promote or challenge PEWS sustainability, in a real-world setting. Participant perspectives on the need for ongoing PEWS use (sustainment) to maintain beneficial patient outcomes is consistent with the CCS (5). Similarly, identified sustainability determinants mapped well to the CCS capacity domains (Figure 1) (14, 15), suggesting this model's applicability to these real-world clinical settings. Importantly, identified themes were often interlinked across multiple CCS domains. For example, measuring the impact of PEWS (monitoring and evaluation) was important to demonstrate its benefits to patient outcomes (outcomes and effectiveness), which in turn promoted staff and leadership interest in sustaining PEWS (engaged staff and leadership), including assuring ongoing availability of equipment necessary for PEWS use (organizational readiness). While the CCS suggests discrete capacity domains, this analysis also provides empiric evidence for interaction between determinants indicating that building capacity within one domain is also likely to impact capacity in others. Our team recently integrated serial assessment of clinical capacity for sustainability into the Proyecto EVAT implementation process, with preliminary results suggesting that clinical capacity for sustainability increased over time using PEWS (53). These findings, and the applicability of the CCS, need to be further explored in future work.

Our results also demonstrated that external factors that impact clinical capacity, such as the COVID-19 pandemic, subsequently have a strong influence on sustainability. While the CCS is intended to assess the inner clinical context where interventions are sustained, it may be valuable for practitioners and researchers to be mindful of how external factors like epidemics, political instability, extreme weather incidents, or financial crises might impact internal capacity and whether these impacts are expected to be short-term or long lasting. In alignment with our results, the sustainability literature suggests that maintenance is possible during smaller, more short-term disruptions, but long-term challenges may require adaptation to ensure intervention sustainment (15). More work is needed to better understand upstream, external drivers of clinical capacity to more accurately identify modifiable factors that promote sustainability. Similarly, large-scale prospective studies are needed to quantitatively understand the relationship between capacity factors and sustainability over time.

Another important outcome of our analysis was the identification of several innovative strategies used by local implementation leaders to modify capacity determinants and improve PEWS sustainability in their settings. Thus far, the field of implementation science has focused primarily on conceptualizing and theorizing sustainability in health (11, 12), with a notable lack of empirically-informed sustainability strategies (11). While some determinants of sustainability are similar to those of implementation (e.g., leadership buy-in), others are unique (e.g., staff turnover creating training challenges), and thus require dedicated sustainability strategies (13). This study addresses this knowledge gap by identifying multiple potential strategies to promote intervention sustainability in low-resource hospitals, representing "practice-based evidence" of how to overcome capacity challenges in these settings. More work, however, is needed to better understand best practices for addressing sustainability determinants. Future prospective studies informed by the CCS should

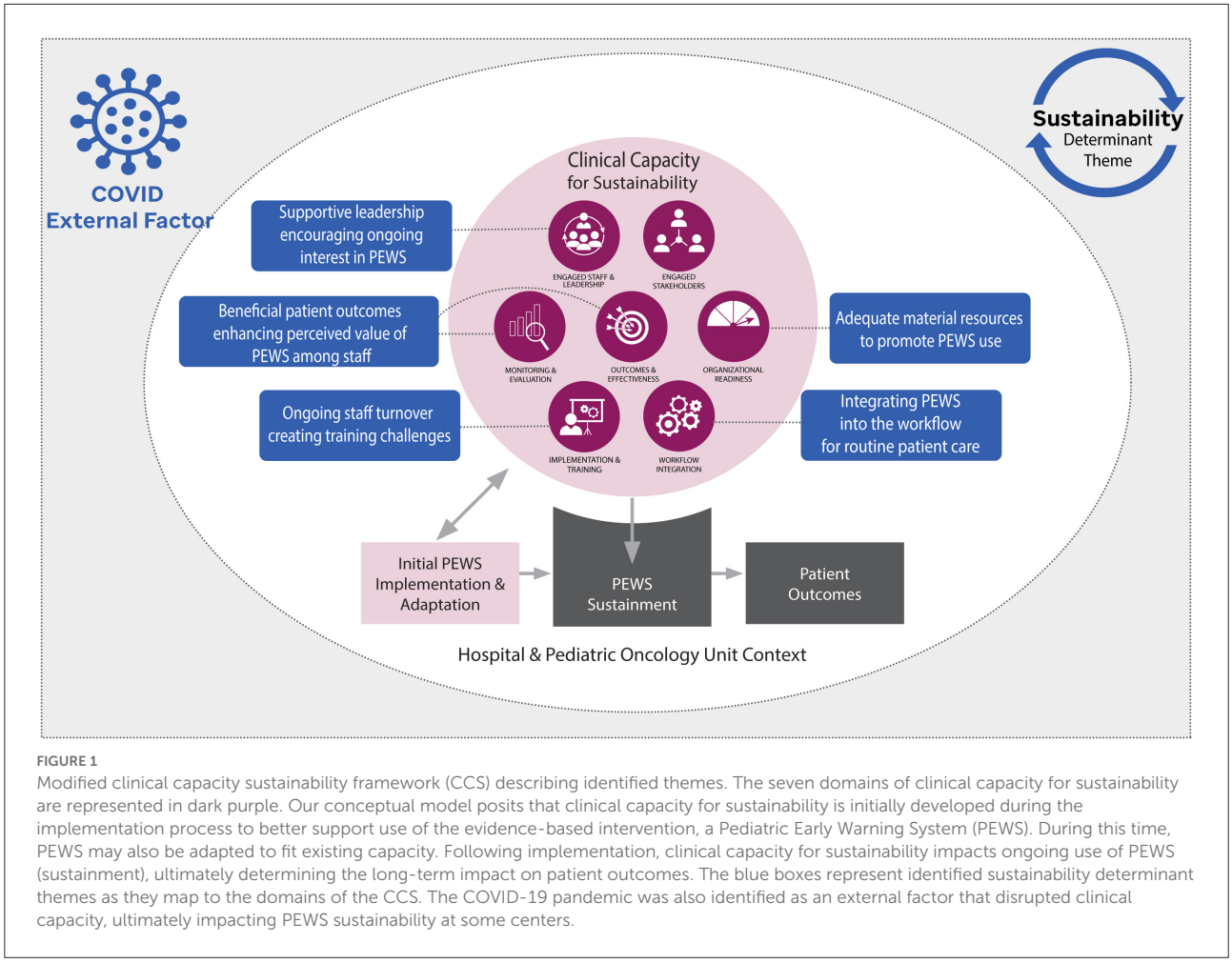

FIGURE 1
Modified clinical capacity sustainability framework (CCS) describing identified themes. The seven domains of clinical capacity for sustainability are represented in dark purple. Our conceptual model posits that clinical capacity for sustainability is initially developed during the implementation process to better support use of the evidence-based intervention, a Pediatric Early Warning System (PEWS). During this time, PEWS may also be adapted to fit existing capacity. Following implementation, clinical capacity for sustainability impacts ongoing use of PEWS (sustainment), ultimately determining the long-term impact on patient outcomes. The blue boxes represent identified sustainability determinant themes as they map to the domains of the CCS. The COVID-19 pandemic was also identified as an external factor that disrupted clinical capacity, ultimately impacting PEWS sustainability at some centers.

more comprehensively identify sustainability determinants and develop empirically-informed sustainability strategies that can be further evaluated using research designs better able to determine their effects on intervention sustainment.

This study has several limitations. The data for this analysis was collected from only 5 Proyecto EVAT centers, which currently represents over 40 hospitals in Latin America with successful PEWS implementation. The identified sustainability determinants and proposed sustainability strategies may not be generalizable to other settings or interventions. Participating centers, however, were purposefully sampled to represent a diversity of regions, hospital organizations, and implementation challenges, and we believe these findings provide important empiric evidence describing intervention sustainability in a variety of low-resource clinical settings. As a secondary analysis, this study mapped identified sustainability determinants to the CCS, however, this framework did not inform the original study design, interview guide, or analysis. The interviews were thus focused primarily on exploring PEWS implementation rather than sustainability and participant discussions of sustainability were spontaneous and not informed by the CCS. One advantage of this analysis is potentially less social desirability bias, as participants were not directly asked about the sustainability of PEWS at their centers. The findings thus describe how sustainability is conceptualized and valued by clinical staff and hospital directors in real-world settings. These findings, however, are likely not inclusive of all possible sustainability determinants or potential strategies, and, as a secondary analysis, important details regarding when, how, and by whom sustainability strategies should be used. A dedicated exploration of these questions should be the focus of future work.

Conclusions

This study describes hospital staff perspectives on the need for sustainable implementation of evidence-based interventions in low-resource hospitals, including identification of sustainability determinants and potential sustainability strategies. Identified determinants mapped well to the CCS, however, external factors, such as the COVID-19 pandemic, may additionally impact clinical capacity for sustainability. This

work highlights an urgent need for rigorous development of theoretically-driven, empirically-informed strategies to support sustainable implementation of evidence-based interventions in a range of clinical settings and resource-levels. Future work must focus on integrating strategies informed by the CCS in the planning and early implementation process to support maintained use of effective evidence-based interventions and achieve long-term beneficial patient outcomes.

Data availability statement

The raw, de-identified 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 St. Jude Children's Research Hospital (St. Jude) Institutional Review Board. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

AA and GS-G were responsible for the analyses. All authors except GS-G and VM were responsible for data collection and reporting. AA and VM were responsible for drafting the introduction, methods, and discussion sections of the manuscript. GS-G was responsible for drafting the results section of the manuscript. All authors reviewed and approved that final manuscript draft.

Funding

The current work was supported by a pilot award provided by the St. Jude Children's Research Hospital and the American Lebanese Syrian Associated Charities (ALSAC), as well as a pilot award provided by the National Cancer Institute grant number P50CA244431 awarded to Colditz and Brownson. Agulnik was funded by the Conquer Cancer Foundation Global Oncology Young Investigator Award for this work. These funders were not involved in the design or conduct of the study; collection, management, analysis, or interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication.

Acknowledgments

We thank the PEWS implementation team at all Proyecto EVAT centers, including those who participated in this study, as well as the Proyecto EVAT Steering Committee for oversight of this work.

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.2022.1004805/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 03 November 2022
DOI 10.3389/frhs.2022.905909

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 28 March 2022
ACCEPTED 30 September 2022
PUBLISHED 03 November 2022

CITATION
Nathan N, Powell BJ, Shelton RC, Laur CV, Wolfenden L, Hailemariam M, Yoong SL, Sutherland R, Kingsland M, Waltz TJ and Hall A (2022) Do the Expert Recommendations for Implementing Change (ERIC) strategies adequately address sustainment?
Front. Health Serv. 2:905909.
doi: 10.3389/frhs.2022.905909

Do the Expert Recommendations for Implementing Change (ERIC) strategies adequately address sustainment?

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Background: Sustainability science is an emerging area within implementation science. There is limited evidence regarding strategies to best support the continued delivery and sustained impact of evidence-based interventions (EBIs). To build such evidence, clear definitions, and ways to operationalize strategies specific and/or relevant to sustainment are required. Taxonomies and compilations such as the Expert Recommendations for Implementing Change (ERIC) were developed to describe and organize implementation strategies. This study aimed to adapt, refine, and extend the ERIC compilation to incorporate an explicit focus on sustainment. We also sought to classify the specific phase(s) of implementation when the ERIC strategies could be considered and applied.

Methods: We used a two-phase iterative approach to adapt the ERIC. This involved: (1) adapting through consensus (ERIC strategies were mapped against barriers to sustainment as identified *via* the literature to identify if existing implementation strategies were sufficient to address sustainment, needed wording changes, or if new strategies were required) and; (2) preliminary application of this sustainment-explicit ERIC glossary (strategies described in published sustainment interventions were coded against the glossary to identify if any further amendments were needed). All team members independently reviewed changes and provided feedback for subsequent

iterations until consensus was reached. Following this, and utilizing the same consensus process, the Exploration, Preparation, Implementation and Sustainment (EPIS) Framework was applied to identify when each strategy may be best employed across phases.

Results: Surface level changes were made to the definitions of 41 of the 73 ERIC strategies to explicitly address sustainment. Four additional strategies received deeper changes in their definitions. One new strategy was identified: *Communicate with stakeholders the continued impact of the evidence-based practice*. Application of the EPIS identified that at least three-quarters of strategies should be considered during preparation and implementation phases as they are likely to impact sustainment.

Conclusion: A sustainment-explicit ERIC glossary is provided to help researchers and practitioners develop, test, or apply strategies to improve the sustainment of EBIs in real-world settings. Whilst most ERIC strategies only needed minor changes, their impact on sustainment needs to be tested empirically which may require significant refinement or additions in the future.

KEYWORDS

sustainability, sustainment, implementation strategies, mechanisms, design and tailoring, implementation science

Introduction

Over the last two decades, research investment in, and application of, implementation science theories, frameworks and methods has resulted in significant improvements in the initial implementation of evidence-based interventions (EBIs) in both clinical and community settings (1–3). Key to advancing the field has been the concerted efforts, particularly in the last few years, to identify effective implementation strategies (and the mechanisms through which they operate) (4–7). Implementation strategies are *"methods or techniques used to improve the adoption, implementation, sustainment and scale-up of interventions."* (3, 8), Systematic reviews of implementation trials have assessed the impact implementation strategies have had on the adoption and implementation of EBIs in real world settings (2, 3, 9–11).

Poor and inconsistent reporting of implementation strategies has been a longstanding issue for the field (8). Historically, the language used to define implementation strategies has been inconsistent and highly variable (12, 13), with different terms used to describe the same strategy or the same terms being used to define different strategies (13, 14). Consequently, descriptions of implementation strategies have lacked the necessary detail required for an adequate understanding of the exact nature, function, and make-up of an implementation intervention (i.e., combination of one or more implementation strategies used to support the delivery of an evidence-based practice, program or intervention) (12, 14–16). Such information is essential for scientific advancement, as it allows for replication in advancing the science and improvements of previous research, as well as for scale-up and translation of effective strategies into practice beyond the initial site (14). These inconsistencies make it difficult to identify core functions of the implementation intervention or the implementation strategies, to synthesize research findings, and ultimately identify the active components of a particular implementation intervention. This problem is especially true for complex, multicomponent implementation interventions such as those typically employed in clinical and public health (14).

The introduction and application of taxonomies or compilations of implementation strategies and behavior change techniques is one approach that has been used to address such issues (12, 13, 17–20). Compilations standardize the naming and definitions of implementation strategies, enabling implementation interventions to be described in a consistent manner. A number of implementation-specific taxonomies and compilations have been developed to standardize and clarify the classification and reporting of implementation strategies (8, 11, 13, 17–19). The *Expert Recommendations for Implementing Change* (ERIC) compilation (8, 13) has been widely used in health and public health and has provided much-needed common terminology for implementation strategies. Developed and refined by implementation experts,

Abbreviations: EBI, Evidence Based Intervention; EBP, Evidence Based Practice; EPIS, Exploration, Preparation, Implementation and Sustainment; ERIC, Expert Recommendations for Implementing Change.

the compilation shows high face validity and consists of 73 strategies grouped into nine categories (see Table 1) (21).

Sustainability research has been identified as a priority area within implementation science (8). Sustainability has been defined as "*(1) after a defined period of time, (2) the program, clinical intervention, and/or implementation strategies continue to be delivered and/or (3) individual behavior change (i.e., clinician, patient) is maintained; (4) the program and individual behavior change may evolve or adapt while (5) continuing to produce benefits for individuals/systems*" (22). A 2020 review by Moullin et al. (23) did however highlight that a number of other conceptual distinctions have been made in the field, particularly in relation to sustainment that is the "sustained use of an EBI" vs. sustainability the "sustained benefits of an EBI." The sustainment of EBIs is critical as premature ceasing of EBIs may mean that the potential public health and clinical healthcare benefits cease or may not be achieved (24). Additionally, if EBIs are not sustained there is a significant waste of public health and clinical resources utilized for initial implementation which may have implications for reducing trust of research/academic institutions (24–26).

Whilst there is growing research focused on sustainment as an outcome (27) including consideration of specific factors (24, 27–31) associated with sustainment that may be distinct from those that matter for implementation (32, 33) the field is bereft of evidence of the most effective strategies to support the sustainment of EBIs (24, 27). A 2019 review of strategies used to sustain public health interventions identified only six studies that purposefully set out to sustain an EBI (27). Overall only nine sustainment strategies were reported with "ongoing funding," "booster training," "supervision and feedback" being the most frequently reported. However, there was insufficient evidence to determine the effectiveness of any one strategy in impacting sustainment. The review reported that most strategies were inadequately described providing very little detail which would enable replication. Such vague and incomplete descriptions of strategies is a limitation of the current evidence base, and highlights the need for a compilation that adequately addresses strategies that support sustainment to ensure they are consistently defined and reported. The review also emphasized the importance of sustainment being considered from the outset of a project and the need for identifying sustainment-focused strategies during the planning of an EBI. Furthermore, strategies relevant to early phases of the initial implementation process are also likely to hold relevance and lay the foundation for longer-term sustainment. However, there is currently no guidance on which strategies should be enacted, and at which phases, to best sustain an EBI.

Given that there are existing compilations for implementation strategies, it is possible that they could be extended or clarified to specifically address sustainment. However key to designing future interventions is the selection of strategies which best addresses the contextual determinants i.e., the barriers and facilitators that impede or promote (4) the sustainment of EBIs (34). While there may be some overlap with the barriers and facilitators to adoption, implementation, and sustainment of EBIs (e.g., organizational culture and resources), it is likely that there are also barriers and facilitators to sustainment of EBIs (e.g., changes in socio-political environment and funding structures) that may be distinct (35). Existing compilations may therefore be lacking in identifying and describing strategies that are specific to and necessary for sustaining an EBI. It is however acknowledged that the sustainment of an EBI is inextricably impacted by strategies selected during the previous adoption and or implementation phases (36, 37). For example, the sustainment of an EBI may be hindered if the adoption and implementation phase has relied on researchers to deliver the intervention, without consideration given to the infrastructure needed to deliver the EBI once research funding ends. Therefore, strategies for the sustainment of EBIs should be considered and planned for in unison with strategies for implementation for any progress to be made in this area. To do this compilations of implementation strategies could specifically incorporate issues relevant to sustainment. This may include updating existing implementation strategies to directly address sustainment or including new strategies that target sustainment-specific barriers and facilitators. Furthermore, whilst frameworks such as the Consolidated Framework for Implementation Research (CFIR) (38) are useful to identify what factors may influence sustainment they do not address how or when change needs to occur (39). Therefore if we are to plan for sustainment at the beginning of implementation efforts, as has been recommended (36), direction on which strategies need to be employed during which phase of the implementation process is needed.

This research is still in its infancy, and there is an opportunity to establish the use of a compilation of sustainment strategies to allow for consistent reporting and, ultimately, empirical testing. As it is likely that sustainment strategies need to be considered during all phases of implementation, extending an existing compilation of implementation strategies that is already widely used, is likely to support the consideration of sustainment at appropriate phases of implementation and avoid unnecessary duplication. Thus, the aim of this study is to adapt, refine and extend an existing compilation of implementation strategies (ERIC) (13, 21) to explicitly incorporate sustainment, as well as specify the phases of implementation that such strategies are likely to be most salient according to the Exploration, Preparation, Implementation and Sustainment (EPIS) (40) framework.

TABLE 1 Sustainment-explicit expert recommendations for implementing change (ERIC) (8–13) glossary.

Conceptual strategy category from original ERIC compilation (20)	Strategy number from original ERIC compilation (20)	Strategy name	Strategy definition (8, 13)	Specific phase(s) when the strategies could be considered and applied
Use evaluative and iterative strategies	4	Assess for readiness and identify barriers and facilitators	Assess various aspects of an organization and the broader context to determine its degree of readiness to implement and sustain, barriers that may impede implementation and sustainment, and strengths that can be used in the implementation and sustainment effort	Preparation, implementation and Sustainment
	5	Audit and provide feedback	Collect and summarize clinical performance data over a specified time period and give it to clinicians and administrators to monitor, evaluate, and modify provider behavior	Preparation, Implementation and Sustainment
	New sustainment strategy	Communicate with stakeholders the continued impact of the EBP	Communicate data to external stakeholders, end-users and consumers to demonstrate the ongoing benefit, cost effectiveness or return on investment of the innovation with continued implementation.	Implementation, Sustainment
	14	Conduct cyclical small tests of change	Implement changes in a cyclical fashion using small tests of change before taking changes system-wide. Tests of change benefit from systematic measurement, and results of the tests of change are studied for insights on how to do better. This process continues serially over time, and refinement is added with each cycle	Implementation and Sustainment
	18	Conduct local needs assessment	Collect and analyze data related to the initial and ongoing need for and fit of the innovation	All phases
	23	Develop a formal implementation blueprint	Develop a formal implementation blueprint that includes all goals and strategies. The blueprint should include the following: (1) aim/purpose of the implementation; (2) scope of the change (e.g., what organizational units are affected); (3) timeframe and milestones; and (4) appropriate performance/progress measures; (5) plan for maintenance and sustainment of the EBI once it has been implemented. Use and update this plan to guide the implementation effort over time	Preparation, Implementation and Sustainment
	61	Stage implementation scale up	Phase implementation efforts by starting with small pilots or demonstration projects and gradually move to a system wide rollout while sustaining delivery of the EBP in the original sites	Implementation, Sustainment
	26	Develop and implement tools for quality monitoring	Develop, test, and introduce into quality-monitoring systems the right input—the appropriate language, protocols, algorithms, standards, and measures (of processes, patient/consumer outcomes, and implementation outcomes) that are often specific to the innovation being implemented and sustained	Preparation, Implementation and Sustainment
	27	Develop and organize quality monitoring systems	Develop and organize systems and procedures that monitor clinical processes and/or outcomes for the purpose of quality assurance and improvement	Preparation, implementation and sustainment
	46	Obtain and use patients/consumers and family feedback	Develop strategies to increase patient/consumer and family feedback on the implementation and sustainment effort	Preparation, implementation and Sustainment

(Continued)

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TABLE 1 (Continued)

Conceptual strategy category from original ERIC compilation (20)	Strategy number from original ERIC compilation (20)	Strategy name	Strategy definition (8, 13)	Specific phase(s) when the strategies could be considered and applied
	56	Purposely reexamine the implementation	Monitor progress and adjust clinical practices and implementation strategies to continuously improve the quality of care	Implementation and Sustainment
	8	Centralize technical assistance	Develop and use a centralized system to deliver technical assistance focused on implementation and sustainment issues	Preparation and Implementation and Sustainment
Provide interactive assistance	33	Facilitation	A process of interactive problem solving and support that occurs in a context of a recognized need for improvement and a supportive interpersonal relationship	All phases
	53	Provide clinical supervision	Provide clinicians with ongoing supervision focusing on the innovation. Provide training for clinical supervisors who will supervise clinicians who provide the innovation	Implementation and Sustainment
	54	Provide local technical assistance	Develop and use a system to deliver technical assistance focused on implementation and sustainment issues using local personnel	Preparation and Implementation and Sustainment
	51	Promote adaptability	Identify the ways a clinical innovation can be tailored to meet local needs and clarify which elements of the innovation must be maintained to preserve fidelity. Continue to assess and adapt the fit of the innovation to ensure that is appropriate and sustained if still relevant.	All phases
	63	Tailor strategies	Tailor the implementation or sustainment strategies to address barriers and leverage facilitators that were identified through ongoing data collection	Preparation, Implementation and Sustainment
	67	Use data experts	Involve, hire, and/or consult experts to inform management on the use of data generated by implementation and sustainment efforts	Preparation and Implementation and Sustainment
	68	Use data warehousing techniques	Integrate clinical records across facilities and organizations to facilitate implementation across systems, continually assess that they are still appropriate	Preparation, Implementation and Sustainment
	6	Build a coalition	Recruit, cultivate and maintain relationships with partners in the implementation and sustainment effort	All phases
Develop staekholder interrelationships	7	Capture and share local knowledge	Capture local knowledge from implementation sites on how implementers and clinicians made something work and continue to work in their setting and then share it with other sites	Implementation and Sustainment
	17	Conduct local consensus discussions	Include local providers and other stakeholders in discussions that address whether the chosen problem is important and whether the clinical innovation to address it is appropriate and continues to be appropriate	Exploration and Sustainment
	40	Involve executive boards	Involve existing governing structures (*e.g.*, boards of directors, medical staff boards of governance) in the implementation and sustainment effort, including the review of data on implementation and sustainment processes	All phases

(Continued)

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TABLE 1 (Continued)

Conceptual strategy category from original ERIC compilation (20)	Strategy number from original ERIC compilation (20)	Strategy name	Strategy definition (8, 13)	Specific phase(s) when the strategies could be considered and applied
	47	Obtain formal commitments	Obtain written commitments from key partners that state what they will do to implement the innovation and how they will support sustainment if it has the intended beneficial effects	Preparation
	Extension of strategy #47 explicit to sustainment	Re-affirm formal commitments	Revisit the written commitments obtained from key partners that state what they will do to implement and sustain the innovation. Assess whether these commitments are being upheld and whether new commitments are required to help sustain the innovation	Sustainment
	52	Promote network weaving	Identify, build and maintain existing high-quality working relationships and networks within and outside the organization, organizational units, teams, etc. to promote information sharing, collaborative problem-solving, and a shared vision/goal related to implementing and sustaining the innovation	All phases
	64	Use advisory boards and workgroups	Create and engage a formal group of multiple kinds of stakeholders to provide input and advice on implementation and sustainment efforts and to elicit recommendations for improvements	All phases
	24	Develop academic partnerships	Partner with a university or academic unit for the purposes of shared and ongoing training and bringing relevant research skills to an implementation or sustainment project	All phases
	25	Develop an implementation glossary	Develop and distribute a list of terms describing the innovation, implementation, and stakeholders in the organizational change	Preparation and Implementation
	36	Identify early adopters	Identify early adopters at the local site to learn from their experiences with the practice innovation	Exploration, Preparation and Implementation
	Extension of strategy #36 explicit to sustainment	Identify successful sustainers	Identify successful sustainer at the local site to learn from their experiences with the practice innovation	Sustainment
	38	Inform local opinion leaders	Inform providers identified by colleagues as opinion leaders or "educationally influential" about the clinical innovation in the hopes that they will influence colleagues to adopt it	Preparation and Implementation
	Extension of strategy #38 explicit to sustainment	Re-engage with local opinion leaders	Periodically re-engage with providers identified by colleagues as opinion leaders or "educationally influential" about the importance of continuing to deliver the practice innovation in the hopes that they will influence colleagues to sustain its use	Sustainment
	35	Identify and prepare champions	Identify and prepare individuals who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may provoke in an organization and continue to support sustainment	Preparation and Implementation and Sustainment
	45	Model and simulate change	Model or simulate the change that will be implemented prior to implementation	Exploration and Preparation

(Continued)

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TABLE 1 (Continued)

Conceptual strategy category from original ERIC compilation (20)	Strategy number from original ERIC compilation (20)	Strategy name	Strategy definition (8, 13)	Specific phase(s) when the strategies could be considered and applied
	48	Organize clinician implementation team meetings	Develop and support teams of clinicians who are implementing the innovation and give them protected time to reflect on the implementation effort, share lessons learned, and support one another's learning	Preparation and Implementation and Sustainment
	57	Recruit, designate, and train for leadership	Recruit, designate, train and retrain as necessary, leaders for the change effort	Preparation and Implementation and Sustainment
	65	Use an implementation advisor	Seek guidance from experts in implementation and sustainability	All phases
	72	Visit other sites	Visit sites where a similar implementation or sustainment effort has been considered successful	Preparation, implementation and Sustainment
	15	Conduct educational meetings	Hold meetings targeted toward different stakeholder groups (e.g., providers, administrators, other organizational stakeholders, and community, patient/consumer, and family stakeholders) to teach them about the clinical innovation	Preparation and Implementation and Sustainment
Train and educate stakeholders	16	Conduct educational outreach visits	Have a trained person meet with providers in their practice settings to educate providers about the clinical innovation with the intent of changing the provider's practice	Implementation and Sustainment
	29	Develop educational materials	Develop and format manuals, toolkits, and other supporting materials in ways that make it easier for stakeholders to learn about the innovation and for clinicians to learn how to deliver the clinical innovation	Preparation
	Extension of strategy #29 explicit to sustainment	Review and update educational materials	Review manuals, toolkits, and other supporting materials on how to deliver the clinical innovation and ensure they continue to be appropriate. Update the resources based on changing scientific evidence as needed	Sustainment
	60	Shadow other experts	Provide ways for key individuals to directly observe experienced people engage with or use the targeted practice change/innovation	Implementation and Sustainment
	19	Conduct ongoing training	Plan for and conduct training in the clinical innovation in an ongoing way, including training of new staff and booster training for existing staff	Preparation and Implementation and Sustainment
	20	Create a learning collaborative	Facilitate the formation of groups of relevant stakeholders or organizations and foster a collaborative learning environment to improve implementation and sustainment of the clinical innovation	Preparation and Implementation and Sustainment
	31	Distribute educational materials	Distribute educational materials (including guidelines, manuals, and toolkits) in person, by mail, and/or electronically	Implementation and Sustainment
	43	Make training dynamic	Vary the information delivery methods to cater to different learning styles and work contexts, and shape the training in the innovation to be interactive	Preparation and Implementation and Sustainment

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TABLE 1 (Continued)

Conceptual strategy category from original ERIC compilation (20)	Strategy number from original ERIC compilation (20)	Strategy name	Strategy definition (8, 13)	Specific phase(s) when the strategies could be considered and applied
	55	Provide ongoing consultation	Provide ongoing consultation with one or more experts in the strategies used to support implementing and sustaining the innovation	Preparation and Implementation and Sustainment
	71	Use train-the-trainer strategies	Train designated personnel or organizations to train others in the clinical innovation	Implementation and Sustainment
	73	Work with educational institutions	Encourage educational institutions to train clinicians in the innovation	Preparation and Implementation and Sustainment
	21	Create new clinical teams	Change who serves on the clinical team, adding different disciplines and different skills to make it more likely that the clinical innovation is delivered (or is more successfully delivered) in an ongoing way	Preparation and Implementation and Sustainment
Support clinicians	30	Develop resource sharing agreements	Develop partnerships with organizations that have resources needed to implement and sustain the innovation	Preparation and Implementation and Sustainment
	32	Facilitate relay of clinical data to providers	Provide as close to real-time data as possible about key measures of process/outcomes using integrated modes/channels of communication in a way that promotes use of the targeted innovation	Implementation and Sustainment
	58	Remind clinicians	Develop, review and update reminder systems designed to help clinicians to recall information and/or prompt them to use the clinical innovation	Preparation and Implementation and Sustainment
	59	Revise professional roles	Shift and revise roles among professionals who provide care, and redesign job characteristics	Preparation and Implementation and Sustainment
	37	Increase demand	Attempt to influence the market for the clinical innovation to increase competition intensity and to increase the maturity of the market for the clinical innovation	Preparation and Implementation and Sustainment
Engage consumers	39	Intervene with patients/consumers to enhance uptake and adherence	Develop strategies with patients to encourage and problem solve around adherence	Preparation, implementation and Sustainment
	41	Involve patients/consumers and family members	Engage or include patients/consumers and families in the implementation and sustainment efforts	All phases
	50	Prepare patients/consumers to be active participants	Prepare patients/consumers to be active in their care, to ask questions, and specifically to inquire about care guidelines, the evidence behind clinical decisions, or about available evidence-supported treatments	All phases
	69	Use mass media	Use media to reach large numbers of people to spread the word about the clinical innovation	Implementation and Sustainment
	1	Access new funding	Access new or existing money to facilitate the implementation and/or sustainment	All phases
Utilize financial strategies	2	Alter incentive/allowance structures	Work to incentivize the adoption, implementation and sustainment of the clinical innovation	Preparation and Implementation and Sustainment

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TABLE 1 (Continued)

Conceptual strategy category from original ERIC compilation (20)	Strategy number from original ERIC compilation (20)	Strategy name	Strategy definition (8, 13)	Specific phase(s) when the strategies could be considered and applied
	3	Alter patient/consumer fees	Create fee structures where patients/consumers pay less for preferred treatments (the clinical innovation) and more for less-preferred treatments	Preparation, implementation and sustainment
	28	Develop disincentives	Provide financial or professional disincentives for failure to implement or use the clinical innovations	Preparation and Implementation and Sustainment
	34	Fund and contract for the clinical innovation	Governments and other payers of services issue requests for proposals to deliver the innovation, use contracting processes to motivate providers to deliver the clinical innovation, and develop new funding formulas that make it more likely that providers will deliver and sustain the innovation	Preparation and Implementation and Sustainment
	42	Make billing easier	Make it easier to bill for the clinical innovation	Preparation, implementation and sustainment
	49	Place innovation on fee for service lists/formularies	Work to place the clinical innovation on lists of actions for which providers can be reimbursed (*e.g.*, a drug is placed on a formulary, a procedure is now reimbursable)	Preparation, implementation and sustainment
	66	Use capitated payments	Pay providers or care systems a set amount per patient/consumer for delivering clinical care	Preparation, implementation and sustainment
	70	Use other payment schemes	Introduce, review and update payment approaches (in a catch-all category) to support implementation and sustainment of the innovation	Preparation, implementation and sustainment
	9	Change accreditation or membership requirements	Strive to alter accreditation standards so that they require or encourage use of the clinical innovation. Work to alter membership organization requirements so that those who want to affiliate with the organization are encouraged or required to use the clinical innovation	Preparation, implementation and sustainment
Change infrastructure	10	Change liability laws	Participate in liability reform efforts that make clinicians more willing to deliver the clinical innovation	Preparation, implementation and sustainment
	11	Change physical structure and equipment	Evaluate periodically current configurations and adapt, as needed, the physical structure and/or equipment (e.g., changing the layout of a room, adding equipment) to best accommodate the targeted innovation	Preparation and Implementation and Sustainment
	12	Change record systems	Change records systems to allow better assessment of implementation or clinical outcomes	Preparation and Implementation and Sustainment
	13	Change service sites	Change the location of clinical service sites to increase access	Preparation and Implementation and Sustainment

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TABLE 1 (Continued)

Conceptual strategy category from original ERIC compilation (20)	Strategy number from original ERIC compilation (20)	Strategy name	Strategy definition (8, 13)	Specific phase(s) when the strategies could be considered and applied
	22	Create or change credentialing and/or licensure standards	Create an organization that certifies clinicians in the innovation or encourage an existing organization to do so. Change governmental professional certification or licensure requirements to include delivering the innovation. Work to alter continuing education requirements to shape professional practice toward the innovation	Preparation and Implementation and Sustainment
	44	Mandate change	Have leadership declare the priority of the innovation and their determination to have it implemented and sustained	Preparation and Implementation and Sustainment
	62	Start a dissemination organization	Identify or start a separate organization that is responsible for disseminating and supporting the ongoing delivery of the clinical innovation. It could be a for-profit or non-profit organization	Preparation and Implementation and Sustainment

NB: Categories, strategies and definitions are per the existing ERIC taxonomy (8, 13) with sustainment wording changes highlighted in red.

Materials and methods

Adapting and extending the ERIC compilation to incorporate sustainment

A two-phase iterative approach to adapt the ERIC compilation to include sustainment was undertaken, based on procedures similar to those previously used in the development (41) or adaptation (42) of ERIC or other taxonomies. This involved:

Adapting and extending through consensus

Consistent with other approaches to developing and extending the ERIC compilation (13, 21, 42), we convened a team of 11 researchers, policy-makers, and practitioners (co-authors of this paper) from Australia, Canada and The United States, who undertook an iterative process of reviewing and adapting the current compilation to incorporate strategies specific to sustainment. For the purpose of this study we defined sustainment as *"the sustained use or delivery of an intervention in practice following cessation of external implementation support"* (26, 36). The team are experts in implementation and or sustainability science, and or health service delivery, and included two of the original authors of the ERIC compilation (BP and TW) an expert on the conceptual distinction of ERIC strategies (13, 21, 34). Both BP and TW have adapted the ERIC for specific contexts (42, 43). In order to adapt and extend the ERIC the following steps were undertaken.

Step 1: Barriers to sustainment

We first identified barriers to sustainment from existing studies. These nine publications (27–29, 44–49) were found through snowballing for literature of "barriers to sustainment" which a research assistant extracted into an excel spreadsheet.

Step 2: Mapping ERIC strategies to address key barriers

To help identify where wording changes may be needed or where additional strategies may need to be created two authors (AH and NN) independently mapped these barriers to existing ERIC strategies. Where the authors felt that a barrier could not be adequately linked to an existing ERIC strategy, they independently drafted proposed wording changes to an existing strategy or identified if a new strategy was needed. The two authors then met to discuss coding, suggested wording changes and or new strategies until they reached consensus. A third author (BP) then reviewed, provided feedback and then met with AH and NN to discuss revisions until consensus was reached.

Step 3: Iterative consensus process

Following completion of Step 2 all team members were asked to independently review the suggested wording changes and the

proposed new strategies developed by AH, NN and BP. They were specifically asked to review and document any edits they believe should be made, or any disagreements they had with the current suggestions, along with detail of their reasoning. After each iteration AH and NN reviewed all feedback. Where there were instances of disagreement between authors they met to develop a proposed amendment and circulated this to all authors for their review. This process of review and updating by the entire team continued for three rounds until consensus was reached.

Preliminary application of the sustainment-explicit glossary

Following the above, the authors undertook a preliminary test of the application and logic of the sustainment-explicit ERIC glossary to determine its ease of application in the field of sustainment, and if any further adaptions or amendments were needed. As this is still an emerging field to identify potential trials which have employed sustainment strategies we reviewed the National Institutes of Health (NIH) database of trials funded in 2019. We also searched the table of contents of the leading implementation science journals, which included: *Implementation Science, Implementation Science Communications,* and *Frontiers in Public Health* for sustainment interventions published between 2018 and 2020. Overall, 12 trials or protocols were identified. As our goal was to check the logic of our proposed adaptation we randomly selected a small number of these studies (n = 6) to test the sustainment-explicit glossary. Two authors (AH and NN) independently coded the strategies described in those publications against those in the sustainment-explicit ERIC glossary. The authors then compared coding to identify areas of confusion, disagreement, or if any additional strategies emerged. This process was designed to identify where updates were needed to improve the content or wording of the glossary and ensure feasibility in its application. The final glossary was reviewed and agreed on by all authors involved.

Implementation phase and strategy utility

To help researchers and practitioners identify when they might consider employing each strategy, we categorized each strategy against the phase(s) of implementation according to the Exploration, Preparation, Implementation and Sustainment (EPIS) Framework (37). To complete this categorization, the same iterative process described above was followed. EPIS was selected as a guiding taxonomy, as it is a widely used and provides clear definitions for each phase. Definitions of the EPIS as defined by the developers (40) were provided to co-authors to help them code the ERIC strategy to the EPIS phase(s).

Results

The sustainment explicit ERIC glossary is presented in Table 1.

Adapting ERIC definitions

Of the 73 ERIC strategies, the definitions of 45 were amended to make sustainment more explicit. For the majority (n = 41) this involved minor surface level changes to include the words "sustainment" or "sustainability." For example, the definition of "Centralized Technical Assistance" was changed to *"develop and use a centralized system to deliver technical assistance focused on implementation and sustainment issues."* Other surface level changes to definitions were more elaborative. For example, the definition of "Promote Adaptability" was changed to *"Identify the ways a clinical innovation can be tailored to meet local needs and clarify which elements of the innovation must be maintained to preserve fidelity. Continue to assess and adapt the fit of the innovation to ensure that it is appropriate and sustained if still relevant."*

The other four strategies where adaptations were made were identified as being in need of slightly deeper level adaptations. These deeper level adaptations were extensions of existing strategies and reflect changes made to the substance of the definition (42), to specifically encompass issues of sustainment, typically because the original definition more explicitly focused on the application of the strategy at an earlier phase of implementation. For example *Obtain formal commitments* (strategy 47) was defined as "*Obtain written commitments from key partners that state what they will do to implement the innovation and how they will support sustainment if it has the intended beneficial effects*" however it was acknowledged that this didn't accurately capture a key barrier to sustainment in regards to ongoing support or decisions around continuation. Accordingly *Re-affirm formal commitments* (an extension of strategy 47) was added which was defined as "*Revisit the written commitments obtained from key partners that state what they will do to implement and sustain the innovation. Assess whether these commitments are being upheld and whether new commitments are required to help sustain the innovation."* The additional strategies are: *Review and update educational materials* (extension of strategy 29); *Identify successful sustainers* (extension of strategy 36); *Re-engage with local opinion leaders* (extension of strategy 38); *Re-affirm formal commitments* (extension of strategy 47). See Table 1 for the detailed definitions of these strategies.

Novel sustainment strategies

One new sustainment focused strategy was identified: *Communicate with stakeholders the continued impact of the*

EBP. This strategy takes the information obtained from *Audit and provide feedback* and/or *Develop and organize quality monitoring systems* strategies and communicates data to external stakeholders, end-users, and consumers to demonstrate the ongoing benefit, cost effectiveness, or return on investment of the innovation with continued implementation. Conceptually, this strategy seems to fit within the ERIC *Use evaluative and iterative strategies* cluster (21).

Preliminary application of the sustainment-explicit ERIC glossary

Application of the sustainment-explicit ERIC identified wide variation in detail and language used to describe the specific strategies employed in the reviewed studies. Consequently, following the initial independent review by the two authors, a thorough discussion and joint application was undertaken to help identify any gaps or areas in need of improvement in the compilation. No new strategies were identified through the coding of published sustainment trials or manuscripts that needed to be considered for inclusion in the glossary. Minor wording changes were made to help clarify some of the strategies and how they relate to sustainment to ensure consistency in interpretation and application.

Implementation phase and strategy utility

Table 1 shows that the majority of strategies ($n = 44$) were identified as being relevant for consideration during three of the four phases of the EPIS Framework, with 43 of the 44 likely to be needed during preparation, implementation and sustainment phases. Only five strategies were identified as being *only* relevant during the sustainment phase, which were the four that received deeper levels of adaptation to focus on sustainment (noted above) as well as the novel strategy (also noted above). Thus, majority of existing ERIC strategies were viewed as relevant for more than one EPIS phase, including sustainment.

Discussion

This is one the first of studies to systematically evaluate an existing compilation of implementation strategies for their relevance for supporting the sustainment of evidence-based programs. The two-phase iterative approach resulted in superficial wording changes to the definitions of 41 of the 73 existing ERIC strategies, slightly deeper wording changes to four ERIC strategies, and the addition of one new strategy. The study also provides guidance to researchers and implementation support practitioners looking to design implementation or sustainment interventions by identifying the phase, according to EPIS framework, when the strategy may need to be considered and employed. It is hoped that a sustainment-explicit glossary based on an existing compilation of implementation strategies will encourage and support those undertaking implementation research to explicitly consider sustainment from the outset and to use a common language when planning and describing their research and practice.

Whilst others have adapted or applied the ERIC compilation to be relevant to a particular setting (42) or class of interventions (50), or to advance understanding of a particular subset of strategies (51), our sustainment-explicit ERIC glossary required minimal changes. We were able to include sustainment concepts by making no changes to strategy names, minimal modifications to definitions and identified only one new strategy. Our extensive mapping exercise of the ERIC strategies to known barriers and facilitators of sustainment from a broad range of studies in clinical and community settings (27–29, 44–49) and sustainability frameworks (24, 36, 52), ensured that we were adequately capturing strategies specific to addressing the main barriers to sustainment.

The preliminary application of the glossary further highlighted the lack of standardized reporting that is already emerging within the sustainment literature. Of the studies reviewed ($n = 6$), many of the strategies utilized were not adequately described in enough detail, or were hard to disentangle from other strategies, which would make it difficult for any future studies wishing to synthesize the effects of these strategies. To avoid the challenges that this has caused historically in the field of implementation science, we implore those planning, or currently undertaking, sustainment research to use consistent terminology to describe their chosen strategies, particularly when multiple strategies are used. Furthermore, as recommended by Michie and Johnston (53) for implementation interventions, we encourage trialists to describe these strategies with sufficient detail in terms of "what," "who," "when," "where" and "how," so these components of each strategy can be sufficiently understood and replicated by others. Frameworks such as those developed by Proctor et al. (8) or Presseau et al. (54) provide useful guidance for specifying this behavior (in the context of implementation and sustainment interventions) (1). If strategies addressing sustainment are consistently described in future research trials this will enable replication studies to be undertaken and study findings synthesized to identify effective strategies or combinations of strategies, and the optimal timing of their delivery, all of which will enhance the design of future sustainment interventions. Whilst the sustainment-explicit ERIC glossary captures all strategies previously identified (27), as evidence in the field continues to grow there may be a need for new strategies to be added. Therefore, this glossary will need to be continuously refined to maintain its utility in sustainment research.

Our application of the EPIS Framework found that a large majority of strategies should be considered during the

design and earlier phases of implementation. This is consistent with others who have advocated that implementation and sustainment are interconnected and therefore need to be planned for in advance (55–58). This is also supported by more recent sustainability frameworks such as the Dynamic Sustainability Framework or the RE-AIM extension for sustainment which posits sustainability is not "static," but rather dynamic, impacted by the changing context in which the intervention is being delivered, the evolving scientific evidence, and the dynamic needs of a population. In a recent study the original developers of the ERIC assessed which strategies experts perceived as being most essential for implementation of three high priority mental health care practices in the US Department of Veteran Affairs (43). The authors found that experts consistently selected a similar set of ERIC strategies as essential for implementation success, regardless of type of EBI (43) or implementation phase. Again, this study highlights the interconnectedness of sustainment with the earlier phases of implementation, and how strategies can be perceived as relevant across the different implementation phases. Shelton et al. (36) suggests that in planning for sustainability, monitoring the reach, adoption, effectiveness and implementation of an EBI is essential to identify early on when challenges are arising and if and how strategies can be adapted, refined, or introduced to support the sustainment of the EBI and address health inequities that may be exacerbated over time.

Robust and valid frameworks or theories specific to sustainability such as the Dynamic Sustainability Framework (52) or the Integrated Sustainability Framework (24) should be employed alongside the sustainment-explicit ERIC glossary, when planning sustainment trials. These frameworks and theories will help identify issues specific to sustainment that should be addressed by any strategies being developed and evaluated (59). Unfortunately, a large proportion of sustainability research is not based on relevant theories, frameworks, or models and for those studies that have, there is wide variation and limited validity in the theories and frameworks commonly applied (59). There is significant need for sustainability research to evaluate the application of sustainability frameworks alongside a compilation such as ERIC (60). This is important if we are to identify how or why strategies impacting sustainment exert their effects (i.e., the mechanisms through which they work) (6). Once this is known we may improve the effectiveness and cost-effectiveness of future interventions by keeping, strengthening, adding or removing strategies that target (or don't) mediators which lead to improvements in sustained implementation (5, 61).

There are several limitations to this study. First, unlike the methods used to develop the original ERIC compilation, we only had a small number of implementation and sustainability experts ($n = 11$) convened to specifically work on this project. Whilst we represented community and clinical perspectives from various countries to gain a broader perspective on this issue, a larger, more diverse, group of experts should further review and revise this glossary for use in sustainment-focused work. Second, we only tested the application of the glossary with a small number of studies. This was undertaken as to test the logic of the amendments; it was not designed to be an extensive application of the sustainment-explicit ERIC or to identify what strategies are being used in sustainment trials. Accordingly, this glossary has not been extensively tested, further application and review of this glossary is needed and welcomed and through its use, it may be evident that further updates are required. Finally, ongoing work is needed to assess the extent to which the sustainment-explicit ERIC glossary is relevant to low- and middle-income countries (62), as this study did not explicitly address this question.

Conclusions

The sustainment-explicit ERIC glossary addresses the need for explicit and clear definitions of strategies to be used in sustainment interventions. The application of relevant strategies during planning and implementation phases may subsequently enhance the evidence-base for the field, and ultimately the sustainment, spread and scale of interventions and improvements in our communities health (63). Future work is needed to empirically test the effectiveness of these strategies in sustaining EBIs in clinical and community settings.

Data availability statement

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

Author contributions

NN obtained funding for the study. NN, AH, BP, and LW conceived the study concept and developed the study design. NN and AH undertook initial adaptations of the ERIC and classification against EPIS. BP and TW provided expert advice as original developers of ERIC. RCS, CL, LW, MH, SY, RS, and MK advised on and undertook the adaption, extension, consensus process, and pilot testing of the tool. NN and AH developed the draft manuscript. All authors contributed to the article and approved the final version of the manuscript.

Funding

This project is funded through the NHMRC as part of NN's Medical Research Future Fund (MRFF) Investigator Grant (GS2000053), BP is supported in part through the U.S. National Institutes of Health (K01MH113806, R01CA262325, P50CA19006, and P50MH126219) and the Agency for

Healthcare Research and Quality (R13HS025632), RS is supported by an NHMRC Medical Research Future Fund (MRFF) Investigator Grant (G2000052), LW is supported by an NHMRC Investigator Grant (G1901360), and SY is supported by an ARC DECRA (G1600359). The funders had no role in the study design, conduct of the study, analysis, or dissemination of findings.

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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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 04 November 2022
DOI 10.3389/frhs.2022.980827

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 29 June 2022
ACCEPTED 17 October 2022
PUBLISHED 04 November 2022

CITATION
Siegel L, Asada Y, Lin S, Fitzgibbon ML and Kong A (2022) Perceived factors that influence adoption, implementation and sustainability of an evidence-based intervention promoting healthful eating and physical activity in childcare centers in an urban area in the United States serving children from low-income, racially/ethnically diverse families. *Front. Health Serv.* 2:980827. doi: 10.3389/frhs.2022.980827

Perceived factors that influence adoption, implementation and sustainability of an evidence-based intervention promoting healthful eating and physical activity in childcare centers in an urban area in the United States serving children from low-income, racially/ethnically diverse families

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Introduction: Early childcare centers offer optimal settings to provide healthy built environments where preschool age children spend a majority of their week. Many evidence-based interventions (EBIs) promoting healthful eating and physical activity for early childcare settings exist, but there is a limited understanding of how best to support adoption, implementation and sustainability in community settings. This study examined how early childcare teachers and administrators from Chicago-area childcare centers serving children from low-income, racially/ethnically diverse communities viewed an EBI called Hip to Health (H^3), and the factors they perceived as relevant for EBI adoption, implementation, and sustainability.

Methods: A multiple methods study including key informant interviews and a brief survey was conducted. Key informant interviews with teachers and administrators from childcare centers located in Chicago, IL were completed between December 2020 and May 2021. An interview guide and coding guide based on the Consolidated Framework for Implementation Research (CFIR) was developed. Interview transcripts were team coded in MAXQDA Qualitative Data Analysis software. Thematic analysis was used to identify findings specific to adoption, implementation, and sustainability. Participants were also asked to respond to survey measures about the acceptability, feasibility, and appropriateness of H^3.

Results: Overall, teachers (n = 20) and administrators (n = 16) agreed that H^3 was acceptable, appropriate, and feasible. Low start-up costs, ease-of-use, adaptability, trialability, compatibility, and leadership engagement were important to EBI adoption. Timely and flexible training was critical to implementation. Participants noted sustainability was tied to low ongoing costs, access to ongoing support, and positive observable benefits for children and positive feedback from parents.

Conclusions: These findings suggest that EBIs suitable for adoption, implementation, and sustainment in childcare centers serving racially/ethnically diverse, low-income families should be adaptable, easy to use, and low-cost (initial and ongoing). There is also some evidence from these findings of the heterogeneity that exists among childcare centers serving low-income families in that smaller, less resourced centers are often less aware of EBIs, and the preparation needed to implement EBIs. Future research should examine how to better support EBI dissemination and implementation to these settings.

KEYWORDS

implementation, preschool, nutrition, adoption, evidence-based, intervention, sustainability

Introduction

Physical inactivity and poor diet quality are major drivers of chronic disease. Intervening early on in life to encourage children's engagement in physical activity and eating healthful foods may protect against non-communicable disease development (1–3). This is particularly important for low-income and racial/ethnic minoritized groups who are disproportionately impacted by chronic disease (4, 5). To address these health disparities and promote greater health equity, prevention efforts that promote healthful eating and physical activity need to have sufficient reach and be disseminated equitably.

Evidence-based interventions (EBIs) promoting physical activity and healthful eating that target preschool children in childcare settings have been shown to be effective in the United States and other high-income countries (6, 7). Embedding EBIs as part of standard programming in existing childcare settings has the potential to expand the reach of EBIs and improve children's health on a population basis. However, in practice, EBIs are not always readily adopted (8) and even if adopted, challenges to implementation and sustainability exist (8–10). A recent systematic review suggests that strategies to support EBI implementation are usually needed, but selection of strategies are largely dependent on the local context (9). Improving EBI translation to real world practice settings requires a greater understanding of why and how childcare centers implement these types of programs. It also requires a greater understanding of the factors needed for such EBIs to be successfully sustained.

This study assessed how teachers and administrators in an urban area in the United States viewed a specific EBI. Hip Hop to Health (H^3) is an EBI that was developed for and previously tested in Head Start classrooms for African American and Latinx preschool children to be delivered by preschool teachers (11, 12). This study examined the factors that teachers and administrators perceived as relevant to this EBI's adoption, implementation, and sustainability in childcare settings serving children from low-income and/or racial/ethnic minoritized families.

Abbreviations: EBI, Evidence based intervention; CFIR, Consolidated Framework for Implementation Research; H^3, Hip Hop to Health; AIM, Acceptability of Intervention Measure; FIM, Feasibility of Intervention Measures; IAM, Intervention Appropriateness Measure; SD, Standard deviation.

Methods

Hip hop to health (H^3) EBI

H^3 is an EBI that was developed to be delivered by teachers in childcare settings serving African American and Latinx children. The randomized effectiveness trial testing H^3 found significant between-group differences in physical activity, screen time, and diet quality that favored the intervention group (11, 12). H^3 consists of eight lessons which feature activities on

topics such as "Go and Grow Foods vs. Slow Foods," "Grains," "Vegetables," and "Drinking Water and Moving Your Body." "Go and Grow Foods" are healthy foods that should be eaten often, whereas "Slow" foods are foods that should be eaten in moderation. Each lesson is 35–40 minutes and consists of 20 mins of physical activity that can be done along with an accompanying musical soundtrack. Lessons also include additional activities such as reading stories, sampling foods, and using puppets (11).

Study design

This is a multiple methods study including a survey and key informant interviews. Both qualitative and quantitative methods were used to obtain a more complete picture of the implementation, adoption, and sustainability factors. Data were gathered from early childcare administrators ($n = 16$) and teachers ($n = 20$) between December 2020 and May 2021. The study was reviewed and approved by the Institutional Review Board at the University of Illinois Chicago (protocol # 2020-0139) which reviewed the ethics and protection of the rights and welfare of the individuals involved in the proposed research.

Study approach

Participants were verbally consented and then asked to watch a brief video describing the H^3 curriculum. Following the video, participants were shown a sample lesson from H^3 and completed a brief survey collecting quantitative data. Qualitative data was then collected *via* a semi-structured interview by a trained staff member.

Sampling, setting, and key informants

Chicago is the third largest city in the United States and has a population of over 3 million people (13). Demographically, Chicago's population is nearly evenly split between white residents (33%), African American residents (29%), and Latinx residents (29%) (13). Over 20% of city inhabitants live below the national poverty line, with this rate varying based on race and ethnicity: 32% of African American residents and 22% of Latinx residents live below the poverty line as compared with 10% of white residents (13).

Forty-five childcare centers were initially identified based on purposive sampling of those (1) located in Chicago or surrounding suburbs; (2) serving a population of 3–5 years of age; and (3) serving a largely low-income or African American or Latinx population. Head Start program participation was noted but not required.

The childcare centers were purposively sampled from (a) a list of Head Start centers that the senior author had generated from a previous study, and (b) online searches of early childhood centers in Chicago or surrounding suburbs that met additional criteria described above. Some sites were no longer active or were not able to be reached.

Teachers and administrators from these centers were identified *via* contact information online, or from the list of contacts of Head Start centers. An email describing the study was sent to these teachers and administrators inviting them to participate in the study. The email contained an attached flyer describing the study in more detail as well as the informed consent document. Teachers and administrators from 22 different centers indicated interest and were scheduled for interviews. Interview materials were only available in English so self-reported comfort with speaking and reading English was a requirement for participation.

Teacher interviews were conducted with early childhood education staff whose job titles were teacher, teacher's aide, or instructional coach. Teachers were interviewed because of their key role in EBI implementation; their perceptions and receptivity to the EBI are critical components to implementation. Administrator interviews were conducted with site directors, coordinators, nutritionists, and education managers at early childcare centers. They represent center leadership and are often involved in decision making; their insights are particularly important for learning about organizational support and capacity of the center.

Interview procedures

All interviews were conducted *via* Zoom by a trained staff member in English. The staff member conducting the interviews identifies as African American, with the majority of the research team identifying as persons of color (Asian/Asian American). Previous studies have cited that mistrust, implicit bias, and lack of cultural competence could serve as barriers to individuals from racially minoritized backgrounds participating in research; these individuals are more likely to participate when they perceive that the researcher is similar in background to themselves (14–17).

A semi-structured interview guide was developed for the key informant interviews, guided by the Consolidated Framework for Implementation Research (CFIR) (18). CFIR is a meta-theoretical framework that can be used to identify barriers and facilitators related to EBI adoption, implementation, and sustainability. The interview guide included select CFIR constructs within the following domains: (1) intervention characteristics, (2) outer setting, (3) inner setting, and (4) characteristics of the individual. A summary of constructs included for each domain is summarized in the Supplementary Table. Key informants were asked to provide

their input about H^3. The questions also captured demographic information and key informants' previous experiences with adopting, implementing, and sustaining similar programs. Before finalizing the interview guide, pilot interviews were conducted with five teachers and administrators from the target population to check for clarity, correct terminology, and flow. The interview guide was revised several times following pilot interviews. Slight variations in the questions used in the interview guides were also included to make the questions more relevant for a teacher or an administrator. Verbal informed consent was obtained from each participant before beginning the interviews. All interviews were audio recorded and professionally transcribed.

Survey procedures

Acceptability, feasibility, and appropriateness of the EBI (i.e., H^3) were assessed using the Acceptability of Intervention Measure (AIM), Feasibility of Intervention Measure (FIM), and Intervention Appropriateness Measure (IAM) developed by Weiner et al. (19). Each measure has four items assessed on a five-point Likert scale with responses ranging from completely disagree to completely agree; higher scores reflect better acceptability, feasibility, and appropriateness. Participants were asked to respond to survey questions after watching the brief video and before beginning the qualitative interview. All participants completed both the qualitative interview and the quantitative survey.

Data analysis and management

Qualitative analysis

An *a priori* draft codebook was created following the CFIR-informed interview guide and revised during several rounds of coding. All transcripts were uploaded into MAXQDA Qualitative Analysis software (20). To begin, coders (LS, YA, SL, AK) independently coded a subset of the transcripts to discuss discrepancies in coding and revise coding definitions as needed. Coders then met weekly to discuss coding progress, further refine the coding guide, and to identify patterns. Once coders reached approximately >85% inter-rater agreement and no additional revisions were required of the coding guide, each remaining transcript was double coded. Coders used MAXQDA functions such as code matrices and summary grids to visualize data and look for cross-cutting patterns. Based on weekly team discussions and iterative revisions to data displays, themes specific to adoption, implementation, and sustainability were developed and documented (21).

TABLE 1 Interview participant and childcare setting characteristics.

Demographics	Administrators ($n = 16$)	Teachers ($n = 20$)
Sex (female)	100%	100%
Mean age in years	48	47
Ethnicity		
Hispanic	6%	21%
Non-Hispanic	94%	73%
Race		
African American	56%	40%
Native American	0%	5%
Two or more races	6%	5%
White	38%	50%
# of years in position		
0–5	19%	20%
6–10	31%	40%
11–20	31%	20%
21+	19%	20%
Highest level of education completed		
High school diploma	0%	10%
Associate's degree	12%	15%
Bachelor's degree	38%	55%
Master's degree	50%	20%
Center location		
Suburban	69%	50%
Urban	31%	50%
Head start?		
N	38%	5%
Y	62%	95%
Center size		
Small (1 site < 50 students)	44%	5%
Mid-size (1 site > 50 students)	6%	25%
Large (Multiple sites < 100 students)	50%	70%

Quantitative analysis

Descriptive statistics, presented as means or percentages as appropriate, were calculated to describe the study sample and to summarize FIM, AIM, and IAM scores.

Results

Demographic characteristics

Table 1 describes characteristics of key informants and the childcare centers where they are employed. Twenty early childcare teachers and 16 administrators were interviewed; most were affiliated with Head Start programs (95% of teachers, 62% of administrators), with the majority of teachers and administrators holding their positions for more than 6 years.

Interview respondents were all female; 56% of administrators and 40% of teachers self-identified as African American, and 6% of administrators and 21% of teachers self-identified as Hispanic. The highest level of education obtained for most administrators was a master's degree (50%); the highest level of education for the majority of teachers was a bachelor's degree (55%). The average age of all respondents was 47.5 years. Fifty percent of administrators and 70% of teachers practiced in *large* centers, defined as centers with multiple locations serving more than 100 children. The remaining practiced in single site settings. *Mid-size* was defined as single site centers with more than 50 children and *small* was defined as single site centers with <50 children.

Quantitative data results: Acceptability, feasibility, and appropriateness of the EBI

Participants provided their impressions of H^3's acceptability, feasibility, and appropriateness by responding to AIM, FIM, and IAM survey items. Table 2 reports AIM, IAM, and FIM mean scores by individual item and category totals. Most teachers and administrators agreed that H^3 was acceptable (mean: 4.24, SD: 0.50), feasible (mean: 4.31, SD: 0.46), and appropriate (mean: 4.21, SD: 0.47).

Qualitative data results: Factors influencing adoption, implementation, and sustainability

Table 3 summarizes main themes that emerged from the key informant interviews and are organized by CFIR domains and constructs along with accompanying quotes. Most themes were related to CFIR constructs within the domains of "*intervention characteristics*" (i.e., cost, adaptability, trialability, complexity) and "*inner setting*" (i.e., compatibility, available resources, leadership engagement) (12). Themes cut across adoption, implementation, and sustainability as shown in Table 3 and are described further in the next sections.

Adoption

Understanding factors that lead to the adoption of an EBI helps researchers to both adapt and design future interventions. Constructs particularly relevant to EBI adoption were cost, adaptability, trialability, complexity (i.e., ease of use), compatibility, and leadership engagement.

Costs: Initial costs are reasonable

CFIR defines the construct of "cost" as "costs of the intervention and costs associated with implementing the intervention, including investment, supply, and opportunity costs" (18). Initial or start-up costs were of particular importance in considering whether to adopt a curriculum. Interview participants were given a sample one-time curriculum price of $65 and asked if they thought that cost was "reasonable." Many participants from *large* centers stated that the cost was reasonable since they'd "*paid far more*" for other curricula materials. Many participants from *small* centers reported that the amount quoted was reasonable because it was lower than the amount they had in mind, even though they did not have other curriculum to compare it to.

Adaptability: Can be adapted to fit into current practices and routines

Adaptability is defined as, "the degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs" (18). Both teachers and administrators described intervention adaptability as important to its adoption. Specifically, they mentioned several characteristics of adaptability, such as (1) having the intervention translated into multiple languages; (2) being able to modify the length or use it as a series of separate modules; (3) adapting it for slightly younger or older children; and (4) being able to modify it to for virtual use (Table 3).

Trialability: Ability to pilot the program and to gather feedback from teachers

Trialability is a CFIR construct that is defined as: "The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted." (18). Teachers and administrators mentioned that being able to pilot the curriculum before deciding whether or not to adopt it was very important. Additionally, it would be important to obtain positive feedback from teachers before committing to a program (Table 3).

Complexity: Curriculum must be easy to use

Complexity is defined as "perceived difficulty of the intervention, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement" (18). Many administrators and teachers expressed the need for the EBI to be easy to use, which considered multiple dimensions. One administrator commented that adopting the curriculum "*should not [be] something that's a burden on the teachers…like it's another task to do in the classroom.*" Curriculum that is disruptive to current workflow and practices or had too many steps would be barriers to adoption (Table 3).

Compatibility: Aligns with priorities, standards, and current practices

Compatibility is defined as "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" (18).

TABLE 2 Mean scores for AIM, FIM, IAM (individual and total).

Item	Description	Mean (SD)	Range
AIM: Approval	Hip Hop to Health meets my approval	4.08 (0.84)	1–5
AIM: Appeal	Hip Hop to Health is appealing to me	4.39 (0.60)	3–5
AIM: Welcome	I welcome Hip Hop to Health	4.31 (0.58)	3–5
AIM: Like	I like Hip Hop to Health	4.19 (0.58)	3–5
	Total	**4.24 (0.50)**	
FIM: Implement	Hip Hop to Health seems implementable	4.11 (0.54)	3–5
FIM: Possible	Hip Hop to Health seems possible	4.36 (0.54)	3–5
FIM: Doable	Hip Hop to Health seems doable	4.39 (0.49)	4–5
FIM: Easy	Hip Hop to Health seems easy to use	4.28 (0.61)	
	Total	**4.31 (0.46)**	
IAM: Fitting	Hip Hop to Health seems fitting	4.28 (0.57)	3–5
IAM: Suitable	Hip Hop to Health seems suitable	4.19 (0.47)	3–5
IAM: Applicable	Hip Hop to Health seems applicable	4.19 (0.58)	3–5
IAM: Match	Hip Hop to Health seems like a good match	4.17 (0.61)	3–5
	Total	**4.21 (0.47)**	

AIM, Acceptability of the Intervention Measure; FIM, Feasibility of the Intervention Measure; IAM, Intervention Appropriateness Measure.
Teachers (n = 20) and Administrators (n = 16).

Teachers and administrators responded that it was important that an intervention fit their organization's values, norms, and policies to be considered. Many participants reported that their organizations placed a priority on student health and that they already implemented activities to promote nutrition and/or physical activity. For teachers and administrators affiliated with Head Start, an EBI that aligned with Head Start standards was of great importance for adoption.

Leadership engagement: Commitment from administrators and those with decision making capabilities

CFIR describes leadership engagement as "commitment, involvement, and accountability of leaders and managers with the implementation" (18). Engagement from leadership is of particular importance in larger centers such as the Head Start affiliated centers. Buy-in from administrators is necessary to support organizational capacity at all phases, but it is of particular importance when deciding to adopt a program. One teacher mentioned *"it's a matter of getting them [administrators] on board and then also creating that time for training the teachers and getting the resources."* Centers affiliated with Head Start had to get approval from different boards before programs were adopted, including an advisory board consisting of parents (Table 3).

Implementation

Many of the constructs relevant to adoption are also relevant to EBI implementation as summarized in Table 3. However, there was a particular emphasis on training (CFIR construct: Available resources) to support EBI implementation.

Available resources: Training needs to be timely and flexible

The construct "Available Resources" is defined as: "the level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time" (18). Both teachers and administrators described training as being critical for implementation; specifically, two main considerations included: (a) timing; (b) delivery/format. First, trainings should be offered when teachers were onboarded for the school year and received trainings for other curriculum/procedures (e.g., in August). This was particularly relevant for Head Start centers.

Second, when teachers were asked about optimal training delivery, many saw advantages to both online offerings and in person. Many expressed a preference for hands-on learning, but they also liked the convenience and permanence of online trainings.

Sustainability

Interview respondents were asked if they could see their center using the H^3 curriculum in the long term, and what factors would influence their center's ability to use the curriculum in the long term. The most common themes related to EBI sustainability were ongoing costs, training support, and evidence that children are positively benefiting from the program.

TABLE 3 Adoption (A), implementation (I), and sustainability (S) of a nutrition and physical activity evidence-based intervention (EBI) in childcare centers: main themes from key informant interviews.

CFIR Domains: Constructs *Themes*	A	I	S	Example quotes
Intervention Characteristics: Costs *Initial and ongoing costs are reasonable*	x	x	x	"I mean, definitely cost because we are funded by grants, so whatever dollar amount is allocated for health and nutrition, education would definitely play a role in implementing the curriculum." (Teacher ID 2010) "Cost. That's the big one." (Administrator ID 1005)
Intervention Characteristics: Adaptation *Can be adapted to fit into current practices and routines*	x	x	x	"That's the part that I was wondering about is with the flexibility and I feel like if the 20 mins are divided, that it could be done...break up program into smaller chunks." (Adminstrator ID 1004) "Maybe having two kits per classrooms in case you want to do it in smaller groups. Instead of a classroom of 20 trying to do it, you know, maybe two teachers are doing it at different times." (Administrator ID 1002) "I mean, because I don't know it thoroughly, I guess I would say maybe the language part, maybe just adding different languages in there. Maybe not for kids so much but for families. Cause we do flyers home and, you know, I think they would appreciate it a lot more if they were able to read it and understand it. So maybe that would be a good to change." (Teacher ID 2011)
Intervention Characteristics: Trialability *Ability to pilot the program and to gather feedback from teachers*	x			"… obviously learning about it and then maybe having the opportunity to try it, like pilot it in a couple of classrooms and then you know, see how it goes and then make the decision as to purchase it for the entire program." (Administrator ID 1009) "She would definitely want the teachers to try it out and then get feedback because she does trust teacher input, you know, after her own evaluation, see if it, she thinks it would be successful in the classroom and then give it that test run and then ask for feedback from the teachers on whether or not it was successful or what could make it successful." (Teacher ID 2012)
Intervention Characteristics: Complexity *Curriculum must be easy to use*	x	x	x	"Again, it just really boils down to it being easy, not something that's a burden on the teachers feeling like it's another task to do in the classroom." (Administrator ID 1008) "And then I would look at how difficult, or how simple it is to, to put together or to, to implement the curriculum. And then I would look at how much work, how much additional work and how many additional supplies would be needed. That's normally what has either caused me to use a curriculum or to let it fall off." (Administrator ID 1016)
Inner Setting: Compatibility *Aligns with priorities, standards, and current practices*	x	x	x	"…we already use food experiences and exercise and stuff like that. I think it would just be ongoing because it'll be a part of our curriculum. That's something we already do anyway." (Teacher ID 2005) "Well, I think it should make sure it fits into the Head Start standards for sure. And other, the PI or the PFA standards. And to just make sure that there's no, I mean, I don't think there's anything that is culturally inappropriate. That it can fit into the program day. I mean, I kind of don't know, but those are things that I imagine are important." (Administrator ID 1004)
Inner Setting: Available Resources: Training is critical to implementation and maintenance. Training needs to be timely, flexible, and ongoing.	x	x	x	"Would definitely require constant training to keep it going. Cause we, you know, often in programs we start things, we stop, we start, stop." (Administrator ID 1002)

(Continued)

TABLE 3 (Continued)

CFIR Domains: Constructs *Themes*	A	I	S	Example quotes
				"The long-term cost availability continued trainings and support…" (Administrator ID 1010) "It would be accepted if it's presented and implemented in a timely fashion. If this were to be something that we were to pilot, it would need to start in August, educate the staff so they can learn it and then bring it in. When the children come in, if it were to be something that was brought in in November or December, it would be more difficult because since we're grant funded, we have several deadlines. So to be most effective, it seems that it's, that a timeline would be implemented in the August early August, teaching the teachers and then them full speed ahead at end of August when the children were to come on, would be the most effective way. It's crucial the timeline, the one you would present it to teachers to be very honest." (Administrator 1005)
Inner Setting: Leadership Engagement *Commitment from administrators and others with decision making capabilities*	x	x	x	"it's a matter of getting them [administrators] on board and then also have a creating that time for, for training the teachers and getting the resources. Important to leadership on board and providing training and resources to support teachers in implementation" (Teacher ID 2012) "Yes, the parents I mean, in the office of Head Start there's a parent board. So they have also with budgets, they have to get it approved by the parent board." (Teacher ID 2004)
Positive benefits to children *Maintenance of the EBI is strengthened if there is evidence that children are benefiting from the program.*			x	"Well, because if it proves to be beneficial, it benefits the program. I guess there's some more success stories about, you know, the overall wellbeing of families and children" (Teacher ID 2009) "Long-Term? I think again, I think the child's outcomes, so if children are, retaining the information and the curriculum is successful in getting that, I think that we would not have a reason to change." (Administrator ID 1009)

Cost: Ongoing costs need to be manageable and to support ongoing training

Both teachers and administrators stated that low ongoing costs were extremely important in sustaining EBI implementation. Specific costs mentioned were for printing, fuel, food, and replacing program components.

Ongoing support or continued training was also mentioned as a crucial factor for EBI sustainability. In large centers in particular, there is a consistent need to offer training to current staff in the form of booster sessions and to train new teachers since staff turnover is common.

Positive benefits to children: Need to see evidence that the EBI is working

Both teachers and administrators reported the importance of seeing children's positive reactions and benefits from the program in observable ways. In addition, many teachers would consider the program successful if the benefits also extended to parents.

Differences by center size and type

In general, larger or multi-site centers, such as Head Start centers, had adopted EBI programs in the past. Participants from these centers reported more familiarity and readiness, as well as cited existing regulations and policies that support nutrition and physical activity curricula. One administrator stated: "*Some months we have a focus, it could be portion sizing, it could be a healthy eating activity. And we do this program once a year; they come in and they teach the kids. It's not the teacher's doing it. It's this organization doing it. And then the children get to take something home with them, for example, like the plates, little*

dividing of the plate for the serving sizes. So that's currently what we do." In contrast, none of the participants from *small* centers in this study had implemented a formal EBI previously. Many expressed "creating" their own program by pulling together resources or using those that were given to them. One teacher said: "*Our director, every week she sends recipes about healthy nutrition so we can show [them] to the kids and share [them] with the parents. Every week we do that. And for the physical activity, other than going to the playground in the shade or simple activities in the classroom, like dancing, that's it. That's all.*"

Discussion

These findings highlight factors related to EBI adoption, implementation, and sustainability in childcare centers within an urban area in the United States serving low-income, racially/ethnically diverse families. Successfully adopting, implementing, and sustaining an EBI promoting positive health behaviors in early childhood can be one strategy to promote greater health equity in these populations. In this study, teachers and administrators responded favorably to the EBI (i.e., H^3) presented to them and agreed that it was acceptable, appropriate, and feasible. In considering EBI adoption, implementation, and sustainability, respondents stressed the need for the EBI to fit into what they were already doing. It also needed to be low-cost (start-up, ongoing), easy to use, and have training supports that were flexible to the needs of the center and would be ongoing. However, there were notable differences between small and large centers in their readiness and capacity for EBI adoption that warrant further attention.

Teachers and administrators interviewed were largely in favor of the EBI proposed as reflected in both qualitative and quantitative findings (e.g., AIM, FIM, IAM scores) (19). In most cases, centers were already promoting physical activity and healthful eating in some form; therefore, many viewed the EBI as compatible with existing practices and could reinforce what they were already doing. Compatibility has been recognized as a facilitator to program adoption based on previous studies of physical activity and nutrition interventions delivered in childcare settings (22–30). For example, EBIs that "fit well within existing curricula"), "enhanced the classroom," or were aligned with existing "preschool and government health objectives" were considered facilitators to implementation (23, 24, 27).

There was also consensus among teachers and administrators that EBIs needed to be easy to use and could be easily adapted to a center's routine or practices. The adaptations most often mentioned by key informants in the current study included breaking up sessions into shorter lessons to accommodate daily routines and adapting lesson plans to accommodate varying class sizes, age groups, and language needs (e.g., translation of parent handouts). Similar adaptations have been identified in previous studies. These studies included settings with predominantly white populations (e.g., Sweden and Scotland); however, the income status of families with children enrolled in the centers was not reported (23, 27, 31, 32) as is often the case in many of these studies. The theme of adaptability was also found in studies conducted in Head Start centers which serve low-income families (26, 33, 34), which is more similar to the target population in our study. Implementation also occurs more smoothly when interventions are perceived as easy to use, require little to no preparation (e.g., ready to use), and are not overly burdensome. This facilitator to implementation (ease of use) has been largely reported in centers with predominantly white populations (income status not reported) (23, 24, 31, 35, 36). When this theme (ease of use) was reported in racially/ethnically diverse settings and/or Head Start centers (22, 25, 37), it was more common to perceive interventions in terms of its complexity rather than ease of use. For instance, interventions viewed as too complex and therefore difficult to implement were those with too many activities, had excessive paperwork, or required too much planning. In contrast to our findings, these themes were gathered after an intervention was implemented and therefore, centers could speak better to the challenges they encountered with implementation.

Cost was important to both EBI adoption and sustainability. Both administrators and teachers mentioned that the cost of the intervention was an essential factor for deciding to use the curriculum and being able to continue to use it over time. Specific cost-factors that were mentioned were the initial cost of the curriculum, ongoing costs such as replacing materials that became lost or worn out, and food costs. This highlighted the importance of considering the cost to maintain the curriculum over time (beyond startup costs). This finding was addressed by Eismann et al. (38), who reported that organizations often fail to successfully implement EBIs in part because they do not realize up front what costs will be needed to sustain the intervention. Burton et al. (39) noted that participants perceived the cost of their EBI (including "investment, supply, and opportunity cost") was prohibitive and a barrier to implementation. Consideration of cost and cost effectiveness is not often reported in studies examining healthy eating and physical activity practices or programs in childcare settings as noted by previous systematic reviews on physical activity and healthy eating interventions in childcare settings (40, 41).

Another key finding was the importance that both administrators and teachers placed on being well-trained to implement the intervention, which is critical for the success of any EBI. This was consistently found in studies across contexts including centers serving populations that were predominantly white, racially/ethnically diverse, and low-income (22–25, 27, 30, 32–34, 36, 42). As emphasized in this current study, trainings should be planned with the partner organizations to adequately consider their needs and preferences. Specifically, the type of training, whether online, in-person or a hybrid, as well as the timeline of training were mentioned as being critically

important. Due to the calendar of the school year, having trainings begin shortly after teachers arrive back at school in August was mentioned as a key factor to implementation success. Also, the availability of resources, ongoing trainings and support from the university, and a designated contact person that teachers and administrators can contact for help or with questions were listed as being extremely important for sustaining an EBI. A 2021 paper by Combs et al. reported that training is a key part of EBI implementation, but that training must be conducted in a manner that is most useful to the center in terms of scheduling and mode (43). Teachers in the current study reported both pros and cons to online training—while it offered additional convenience it lacked a hands-on component that many early childhood teachers reported was very helpful when learning a new curriculum. Combs et al. also found that while online training did not lead to lower levels of adherence to the curriculum or dosage, it was associated with lower reports of quality of delivery (43). Their recommendation was to include some experiential component to online training; the findings of this paper support that recommendation.

Finally, it is important to note some differences by center type/size that could have implications for EBI adoption and dissemination. In general, centers affiliated with Head Start were larger and/or part of multi-site centers. When interviewing administrators and teachers from Head Start centers, most had implemented EBIs or similar programs in the past so there were mechanisms in place and organizational capacity to support EBI adoption and implementation. In contrast, key informants from small, single site centers were not at all familiar with EBIs; however, they too, prioritized promoting physical activity and healthful eating in their centers. This suggests that EBI dissemination may favor centers that are larger, have greater organizational capacity (e.g., leadership, available resources, etc.), and are more likely to be networked with external organizations (e.g., academic institutions). Researchers have a role in perpetuating this bias since the development and testing of EBIs usually originate from grant funded studies carried out by academic institutions. A gap in the current research is the equitable dissemination of EBIs (44). Addressing this gap means better dissemination of EBIs through potential systems and policy changes, as well as developing implementation strategies to support EBI adoption and implementation in smaller, less resourced and networked centers.

Limitations

These findings have some limitations. This study used purposive sampling methods that recruited teachers and administrators from childcare centers based on characteristics (e.g., centers serving low-income, racially/ethnically diverse families) that were representative of the target population of this study and could speak to the phenomenon under investigation. One limitation of purposive sampling is that it can be prone to researcher bias, since the researcher is making a decision about who to sample (45). Another possible limitation is that these results may not be representative of EBI facilitators and barriers outside of the studied population (46). However, this approach was still used as it provided the most time and resource-effective means of recruiting the targeted population due to challenges during the COVID-19 pandemic. A purposive sampling approach also provided additional insight into EBI implementation within this specific population.

This was also a cross sectional study that captured perceived views, thoughts, and insights from key informants at one point in time, prior to EBI implementation. Cross sectional designs are limited in their ability to deduce a causal relationship between the variables being studied and to describe a phenomenon over a period of time (47). However this design allowed for a relatively timely and straightforward study. A cross sectional design also allowed for the study of multiple possible implementation factors concurrently (47). Lastly, a third possible limitation is the relatively prospective nature of these findings; however, assessing the EBI prior to implementation may save valuable time and resources when H3 is fully implemented, and ultimately lead to a more impactful intervention.

Conclusions

Overall, the study findings indicate that EBIs should be easy to implement, low-cost (initial and ongoing), have proper training supports, and be compatible with the practices and policies of early childcare centers to be successfully adopted, implemented, and sustained. Further attention should also be given to more equitable dissemination of EBIs and understanding how to support the adoption, implementation, and sustainability of EBIs in smaller, less-resourced centers.

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 Institutional Review Board of the University of Illinois Chicago (Protocol # 2020-0139). Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

AK, LS, MF, and YA contributed to the design of the study. LS collected the data and wrote the first draft of the manuscript. YA directed the qualitative analysis. LS, YA, AK, and SL analyzed and interpreted data. LS and AK developed the figures and tables. All authors reviewed the manuscript, provided critical feedback, and approved the final manuscript.

Funding

Research reported in this publication was supported in part by the University of Illinois Cancer Center Pilot Project Program funds.

Acknowledgments

A special thanks to all of the teachers and administrators that shared their time and input with us during challenging times to make this study possible.

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.2022.980827/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 09 November 2022
DOI 10.3389/frhs.2022.1010305

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 02 August 2022
ACCEPTED 17 October 2022
PUBLISHED 09 November 2022

CITATION
Swindle T, Bellows LL, Mitchell V, Johnson SL, Shakya S, Zhang D, Selig JP, Whiteside-Mansell L and Curran GM (2022) Predictors of sustainment of two distinct nutrition and physical activity programs in early care and education.
Front. Health Serv. 2:1010305.
doi: 10.3389/frhs.2022.1010305

Predictors of sustainment of two distinct nutrition and physical activity programs in early care and education

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Introduction: The goal of the present study was to investigate factors associated with sustainment of two evidence-based programs for nutrition promotion in early care and education (ECE) settings – Food Friends (FF) and Together, We Inspire Smart Eating (WISE).

Materials and methods: In a cross-sectional study design, ECE directors (N = 55) from centers that had previously been trained in WISE or FF completed a survey. Program-specific measures included Steckler's Perception of Innovations, the Program Sustainability Assessment Tool (PSAT), and the Organizational Readiness for Change Assessment (ORCA). For our primary outcomes, two measures of sustainment were examined: Nutrition Continued Practice (i.e., the use of or general focus on nutrition programs) and Program Fidelity (i.e., how well centers used specific evidence-based practices of WISE or FF). Multiple regression was used to determine the association of these outcomes with program, years since last implementation, and overall scores on predictors. Follow-up correlation analyses were used to investigate outcome relationships with context submeasures due to high intercorrelations between predictor submeasures.

Results: Nutrition Continued Practice was significantly predicted by program and overall PSAT score. WISE programs had significantly higher Nutrition Continued Practice scores than FF program (p = 0.03). All subscales of the PSAT (e.g., environmental support, funding stability, organizational capacity, program adaptation, communications, and strategic planning) were significantly correlated with Nutrition Continued Practice (all rs > 0.30, all ps < 0.03). Program Fidelity was significantly predicted by PSAT and Steckler Perception of Innovation scores. All subscales of the PSAT were strongly positively correlated with Program Fidelity (all rs > 0.48, all ps < 0.001); relative advantage (r = 0.54, p < 0.001) and level of institutionalization (r = 0.61, p < 0.001) were positively correlated with Program Fidelity.

Conclusion: This study suggests that factors associated with the continued practice of program principles are partially distinct from those that are associated with the sustainment of specific practices driving program fidelity. Results suggest capacity building strategies may be important for both continued attention to nutrition and physical activity as well as sustaining fidelity to specific evidence-based practices.

KEYWORDS

implementation research, sustainability, early care and education, childcare, nutrition, physical activity, implementation science

Introduction

Healthy eating (1–3), regular physical activity (3–5), and maintaining a healthy body weight (3, 6, 7) are established preventive measures to curb risk for a range of diseases including cardiovascular diseases, non-alcoholic liver diseases, metabolic syndrome, diabetes, and several cancers. However, most children do not meet recommendations for healthy diet and physical activity (PA) (8–14). Establishing early nutrition and PA habits are important for lifelong health and healthy weight (3, 15). Early care and education (ECE) environments are promising settings for promoting nutrition and PA for children. In the United States (U.S.), 12.5 million of children under 5 years spend approximately 30 hours in ECE centers per week (16, 17). In other high-income countries, usage rates are similarly high; 45% of children under 5 years of age in Australia are in childcare (18), and over 80% of children in the European Union receive formal childcare before attending compulsory school (19). Establishing and sustaining effective programs in ECE settings may have a significant, positive effect on child health.

Sustainability is the endurance of a program after a defined program period and after the ending of external implementation support, which is characterized by (a) the integration of the program in an existing institutional or community system (20, 21) (b) the continuation of the intervention (14, 20), and (c) progress in target behavior, yielding continued gains to the target population (20). Sustaining programs for promoting child health has proved more challenging than establishing initial implementation of such programs (22, 23). Specifically, there have been many public health efforts implemented to prevent and control childhood obesity, but lack of sustainment of program/intervention efforts is a major translational issue in public health (23–25). In fact, 40 to 60% of interventions are not sustained after external funding ends (22, 25–29). Implementation science recognizes that closing such gaps in sustainment of programs is crucial to achieve continued benefits for the target population (20, 30) and to maintain community engagement (25, 30).

Reflecting the growing emphasis on sustainability in implementation, there are several theories, models, and frameworks dedicated to understanding this topic (31). One of the most prominent models, the Dynamic Sustainability Framework (DSF), posits that characteristics that influence program sustainment include internal context (e.g., staff availability, program budget), external context (e.g., political support for a program or for the needs a program serves), and program-specific components (e.g., how fun or engaging a program is perceived to be), and the interaction among these (32). Recent systematic reviews (23, 25, 33), although not informed by the DSF in their framing and design, have supported the framework by identifying factors that align with key DSF constructs for predicting sustainment in educational settings. Internal contextual barriers to sustainment included lack of staff and staff turnover, time, training, and general financial resources; external contextual barriers included community, political engagement, and parental involvement; program-specific barriers included teacher perceptions of how interesting or fun the program was and how adaptable the program was to individual center needs.

Across these reviews, only two studies were identified that examined sustainment of obesity prevention or nutrition promotion programs in ECE. Whether the general pattern of key factors for sustaining programs holds in the ECE setting is unknown. Ward and colleagues used a mixed methods approach to assess factors related to sustainment of the Healthy Start-Départ Santé intervention program after 2 years of the initial training in 140 ECEs in Canada (34). Qualitative interviews suggested lack of time, resistance among childcare staff, and low parental involvement as barriers while facilitators included support from policy to implement the program, budget-friendly menu, and staff engagement. In Illinois, U.S., Allar et al. (35) investigated the use of a physical activity program (I am Moving, I am Learning) approximately 10 years after initial implementation in Head Start, a government-funded program that serves children from families with low incomes. These authors identified that low equipment requirements, and the fun, flexible nature of the movement program were perceived

as contributors to the sustainment of this program by teachers and parents (35). Additionally, the integration of this program into the regular classroom routine was also identified as being important for sustainment. Despite the importance of sustaining childhood obesity intervention programs and the potential for ECE as a target setting for sustaining such programs, there are limited studies that examine the sustainability of childhood obesity prevention programs in ECE. Investigating factors associated with sustainment in the context of ECE offers opportunity to test empirical theories such as the DSF.

The current study addresses this research gap by identifying barriers and facilitators of the sustainability of two intervention programs in ECEs in the United States: (1) Food Friends® (FF), which includes Fun with New Foods and Get Movin' with Mighty Moves and (2) Together, We Inspire Smart Eating (WISE)®. Both programs have a focus on nutrition; FF also has a PA component. Specifically, the purpose of the present study was to understand sustainment factors associated with continued use of FF and WISE over time, as well as any factors that might be unique to the sustainment of each program. To that end, directors of centers that had or were currently implementing FF and WISE completed a survey that assessed (a) continued attention to nutrition and physical activity support at their center and (b) current FF and WISE fidelity, (c) internal and external contextual factors related to sustainment and program-specific components (e.g., how successful they perceived the program to be at their center, how the program compared to alternative options, how often the program was used at their center).

Materials and methods

Interventions

Food Friends is a preschool program implemented mainly in Colorado, U.S. that was designed to address healthful eating behaviors and PA patterns in preschoolers (i.e., children ages 3 to 5). FF includes offering new foods and taste tests over 18 weeks; teachers are trained to role model trying the new foods. There are 8 FFs mascots that introduce children to each food group. FF has a companion program, Mighty Moves, focused on supporting development of motor skills through structured activities, music, and classroom enhancements (e.g., scarves). It was implemented successfully for over 20 years and has been shown to both increase children's willingness to try and consume novel foods (food preference) and improve gross motor performance in the short-term (36, 37) and longitudinally (38, 39).

WISE was similarly designed to increase healthy eating habits in early childhood in children aged three to eight years old across a 9-month school year, although it does not include a physical activity component. WISE includes weekly food experiences and supporting activities that align with ECE educational standards and has been shown to create positive changes in both child and family eating behaviors. These include incorporation of more fruit and vegetables into the diet after experiencing WISE and decreased intake of nutrient-poor foods (e.g., chips, cookies, candies) compared to children not exposed to WISE (40, 41). WISE has been disseminated since 2012 and continues to be disseminated primarily in Arkansas, US.

Participant recruitment

Both FF and WISE maintain databases of previously trained ECE centers, which provided the sampling pool for the survey. In total, the WISE database included 209 centers, and the FF database included 212 centers. All centers in the training databases were eligible for survey participation. Directors from each center were invited to complete the survey *via* email invitation first; these invitations were followed with phone invitations if the email did not receive a response. Our target sample size was 112 ($n_{WISE} = 49$ and $n_{FF} = 63$) to provide 80% power to detect medium sized effects and reflect the imbalance of trained centers in each state to date (17). However, due to recruitment challenges experienced during the COVID-19 pandemic, actual recruitment numbers differed.

Prior to sending email invitations, study staff confirmed email contact information for the site director *via* website or phone call. Each center director received an initial email invitation to the survey. Centers that did not respond to the initial email invitation or two reminder emails were contacted by phone by trained study staff. Data collection took place between January and September 2021.

The survey was divided into sections that assessed general use of nutrition practices at the center (i.e., first portion) and a section that assessed specific use of either FF or WISE (i.e., second portion). Participants had the option to continue to the FF and WISE specific portion of the survey. Only participants who completed the second portion of the survey were included in the following analysis.

Survey

The survey was divided into 5 sections: (1) Your Role at the Center (2) Nutrition and Physical Activity at the Center, (3) FF/WISE Programming at the Center, (4) Factors Influencing the Use of FF/WISE at the Center, and (5) What It Is Like at the Center. These sections reflected adaptations of three key measures: Steckler's Perception of Innovations (42), the Organizational Readiness for Change Assessment (ORCA) (43), and the Program Sustainability Assessment Tool (PSAT) (44). The Steckler measure, consistent with the DSF construct of Intervention, was chosen to measure attitudes toward the innovations broadly (i.e., nutrition and physical

TABLE 1 Survey content, source, and reliability of all measures included in the director survey.

Survey section	Item content	Number of items	Source	Reliability
Your role at the center	Participant/Center characteristics	15	Self-developed	NA
Nutrition and physical activity at the center	Continued attention to nutrition/PA at the center	5	Self-developed	$\alpha = 0.83$
	Concern about nutrition/PA	8	Adapted from Steckler (42) Awareness Concern about Prevention scale placeholder 0	$\alpha = 0.61$
	Nutrition/PA training	15	Self-developed	NA
	WISE/Food Friends or equivalent use	2	Self-developed	NA
	Use of program resources	7	Self-developed	NA
WISE/Food Friends programming at the center	Program Fidelity	7	WISE fidelity (45) checklist placeholder 1 (adapted and mirrored for Food Friends sites)	
	Level of use	2	Steckler (42) Perceptions of the Innovation.	NA
	Level of success	3	Steckler (42) Perceptions of the Innovation.	NA
	Relative advantage	4	Steckler (42) Perceptions of the Innovation.	$\alpha = 0.69$ FF, 0.93 WISE
	Level of institutionalization	7	Steckler(42) Perceptions of the Innovation.	$\alpha = 0.90$ FF, 0.87 WISE
	Environmental support	3	Program Sustainability Assessment Tool (44)	$\alpha = 0.91$ FF, 0.91 WISE
Factors influencing the use of WISE/Food Friends at the center	Funding and resource stability	3	Program Sustainability Assessment Tool (44)	$\alpha = 0.90$ FF, 0.87 WISE
	Organizational capacity	3	Program Sustainability Assessment Tool (44)	$\alpha = 0.96$ FF, 0.93 WISE
	Program adaptation	3	Program Sustainability Assessment Tool (44)	$\alpha = 0.91$ FF, 0.88 WISE
	Communications	3	Program Sustainability Assessment Tool (44)	$\alpha = 0.89$ FF, 0.94 WISE
	Strategic planning	3	Program Sustainability Assessment Tool (44)	$\alpha = 0.92$ FF, 0.95 WISE
	Staff culture	3	Organizational Readiness for Change Assessment (43)	$\alpha = 0.83$ FF, 0.94 WISE
What it is like at the center	Opinion leaders	3	Organizational Readiness for Change Assessment (43)	$\alpha = 0.93$ FF, 0.77 WISE
	General resources	4	Organizational Readiness for Change Assessment (43)	$\alpha = 0.74$ FF, 0.78 WISE
Participant demographics	Gender, age, race, ethnicity	6	US Census Bureau	NA

activity) and adapted for each program to measure attitudes about FF/WISE specifically. The ORCA measure captured issues relevant to the DSF construct of Practice Setting (e.g., culture, leadership), and the PSAT captured constructs relevant to both the Practice Setting (e.g., organizational capacity) and the Ecological System (e.g., external environmental support). The complete survey is included in Supplementary materials; the survey was estimated to take 30 to 45 minutes to complete. Participants were asked to think about their center when it was operating normally (before COVID-19). A summary of the survey content is provided in Table 1 including the constructs measured in each section of the survey, the number of items per construct, and relevant reliability and validity information. Correlations between measured variables, mean scores and standard deviations can be found in Table 2.

Director role at the center

In this section, items assessed characteristics of the center and the person completing the survey including: (1) level of involvement in decisions about nutrition and physical activity at the center, (2) years of experience in ECE and at the center, (3) role at the center and years in the role, (4) other roles at the center, (5) whether the program was a Head Start, (6) the center's total capacity and hours of operation, (7) tax status of the center, and (8) school district (if applicable). These items were used to describe survey participants and to screen for eligibility for completing the survey. Individuals with no role in making decisions about nutrition and physical activity at the center were asked to provide an alternate email for the person involved in those decision. At the end of this section, respondents were asked if they wanted to continue the survey.

TABLE 2 Means, standard deviations, and correlations of all variables.

Variable	*M*	*SD*	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1. Program	0.53	0.50														
2. Lag	3.42	2.19	0.43**													
3. Funding stability	3.33	1.98	−0.26	−0.26												
4. Environmental support	3.46	1.78	−0.18	−0.36**	0.77**											
5. Organization capacity	4.25	1.90	−0.03	−0.25	0.79**	0.71**										
6. Program adaptation	3.63	1.81	−0.13	−0.11	0.56**	0.52**	0.66**									
7. Communications	3.25	1.66	−0.13	−0.10	0.73**	0.76**	0.79**	0.69**								
8. Strategic planning	3.29	1.93	−0.14	−0.27	0.86**	0.74**	0.87**	0.66**	0.81**							
9. Level of use	0.93	0.47	−0.05	−0.25	0.19	0.22	0.31	0.33*	0.29	0.36*						
10. Level of success	62.16	12.73	0.12	0.15	0.40*	0.41**	0.42**	0.17	0.43**	0.37*	0.26					
11. Relative advantage	3.28	0.48	−0.09	−0.27*	0.45**	0.50**	0.48**	0.37**	0.44**	0.55**	0.14	0.33*				
12. Level of institutionalization	2.67	0.73	−0.14	−0.12	0.73**	0.72**	0.76**	0.61**	0.72**	0.80**	0.27	0.48**	0.52**			
13. Staff culture	4.50	0.53	0.11	0.07	0.16	0.15	0.28	0.16	0.23	0.28	0.10	0.36*	0.26	0.05		
14. Opinion leader	4.41	0.60	−0.05	−0.14	0.24	0.16	0.39**	0.17	0.22	0.30*	0.24	0.37*	0.27	0.22	0.48**	
15. General resources	3.78	0.70	0.13	0.15	0.27	0.11	0.39**	0.03	0.24	0.22	0.13	−0.06	0.10	0.24	0.19	−0.07

M and SD are used to represent mean and standard deviation, respectively. *Indicates $p < 0.05$. **Indicates $p < 0.01$.

Nutrition and physical activity at the center

Items in this section focused on Continued Attention to Nutrition/PA at the center, Concern about Nutrition/PA, Program Component Usage, and Nutrition/PA Training. Continued Attention is sustaining attention to the issue (i.e., nutrition/PA through policy and/or resource allocation), even if specific programs/interventions are not sustained *per se* (e.g., Rate the level of focus for your program for providing children opportunity to try new or unfamiliar foods). Continued Attention items were self-developed based on salient aspects of the training and evidence-base of FF and WISE (e.g., intentional exposures to new foods). Items on Concern about Nutrition/PA were adapted from the Steckler and colleagues measure of Awareness Concern about Prevention scale (42). Nutrition/PA Training items assessed how frequently in the last 5 years that staff had received training in specific nutrition/PA topics (none to a lot). Nutrition/PA Training items were akin to a checklist, which would preclude internal consistency as an appropriate assessment of reliability. To note, self-developed responses for FF and WISE were developed to capture similar aspects of the programs, and thus the same questions were asked for each program, allowing for data to be aggregated across programs. Sum scores were created for these constructs with higher scores reflecting greater use and training levels.

At the end of this section, participants indicated if they had used FF and WISE in the prior 7 years. Survey items also branched to ask for the number of years the program was used, the most recent year of use of each program, and their role with the program. We also include an open-ended response on reason for discontinuing use. Based on participants' response to the question about use of FF/WISE, the remainder of the survey was specific to their experience with either FF and WISE (i.e., branching logic replaced program names as applicable throughout the remainder of the survey). If the program indicated no use of FF and WISE in the past 7 years, the survey ended.

Food Friends/WISE programming at the center

In this section, participants provided responses to items about Program Fidelity, as well as Level of Use, Level of Success, Relative Advantage, and Level of Institutionalization which were adapted items from the Steckler Perception of Innovations Measure (37). Program Fidelity items were designed to mirror that of the published WISE fidelity measure (45) and a corresponding and adapted item set for FF. Items were averaged to get an overall fidelity score. All remaining scales were based on Steckler measures on Perceptions of the Innovation (42). Level of Use included yes/no questions about integration of the programs into routine and standing curriculum. Level of Success included items rated on a sliding scale from Not at All (0) to Completely (100; e.g., The program met your goals). Relative advantage items ask about perceived effectiveness and quality of the programs and were averaged to create a scale score. Finally, the Level of Institutionalization scale assessed factors associated with integrating the programs into center activities (e.g., weekly classroom schedules, overall curriculum) with ratings on a 4-point scale (Strongly Disagree to Strongly Agree). Scale scores were created by averaging across items; for subscale means and standard deviations, see Table 2.

Factors influencing the use of Food Friends/WISE at the center

This section included items adapted from the Program Sustainability Assessment Tool (PSAT) (44). Specifically, items were selected and adapted from the constructs of Environmental Support [e.g., FF/WISE had champions or advocates who garnered additional resources (e.g., food, community, donations)], Funding and Resource Stability [e.g., FF/WISE had sustained funding at your center (e.g., food costs, replacement materials)], Organizational Capacity (e.g., Our center had adequate staff to complete FF/WISE goals.), Program Adaptation [e.g., Our center adapted to changes in the environment for FF/WISE (e.g., turnover, leadership change)], Communications (e.g., Our center promoted FF/WISE in a way that generated interest [e.g., wall displays, parent communications)], and Strategic Planning (e.g., Our center had a long-term sustainability plan for FF/WISE beyond our initial year of implementation). Each of these constructs was captured with 3 items each on a 1 (To Little or No Extent) to 7 (To a Very Great Extent) scale.

What it is like at the center

The final section of the survey included items from the Organizational Readiness for Change Assessment (ORCA) including items on Staff Culture, Opinion Leaders, and General Resources (43). These questions were rated on a 1 (Strongly Disagree) to 5 (Strongly Agree) scale.

Cognitive interviewing

The research team conducted 5 cognitive interviews to refine and adapt survey items, three with prior participants in the FF program and two prior participants in the WISE program. For the interviews, one study Principal Investigator (PI) and one research assistant held a video conference with each participant. The participant opened the survey on their personal computer and shared their screen as they completed the survey. The research team invited the participants to talk aloud as the completed the survey, explain the rational for their responses, ask questions about the items and/or instructions, and note any aspects that were confusing or unclear. The researchers documented the items on which participants had comments and questions and asked the participants to suggest improved wording. In addition, the researchers prompted the participants at the end of each page to give feedback about the format, item response options, and instructions. The researchers also monitored for signs of confusion (e.g., excess scrolling, mouse movements) to prompt participants to explain their thought processes. Finally, the researchers asked participants to review the initial survey instructions both before and after completing the survey to improve clarity about the survey's purpose and contents. Improvements were made to the survey iteratively to test changes in wording with subsequent interview participants. The PSAT Partnership and Program Evaluation sub-scales were excluded from the full survey because of confusion and poor performance during cognitive interviews.

Analyses

Careless responding

Four measures were used to investigate levels of careless responding to identify problem cases in the data: Mahalanobis Distance, long-string analysis, survey duration, and even-odd consistency (46). If a participant response was flagged under at least two of the above conditions, their responses were investigated for concordant responding (e.g., their responses to conceptually similar items were checked for consistent responses). Mahalanobis Distance is a measure of multivariate normality. Participant response sets (i.e., their pattern of responses to every survey question) were compared to the average response set using a Mahalanobis Distance value, and p-values were generated identifying participants whose response sets were multivariate outliers. Long-string analysis looks for consistent identical responding within surveys (e.g., selecting "Slightly Agree" for ten items in a row), and acceptable cut-off values are determined based on survey design. An even-odd consistency correlation can assess the extent to which participants chose similar answers to even and odd questions within a given survey, with inconsistent responses indicated by low correlation scores (see Supplementary materials for more information on this process).

Program sustainment

The key outcomes of program sustainability were conceptualized in two ways: Continued Practice (i.e., the use of or general focus on nutrition programs or PA programs at the center) and Program Fidelity (i.e., how well centers used specific evidence-based practices of FF or WISE). Continued Practice was calculated by summing up scores from four measures, described in the Nutrition and Physical Activity at the Center portion of the survey, that capture the extent to which program elements were being used at centers. These included a measure of continued attention to nutrition and PA at the center (e.g., "Rate the level of focus for your program: teaching children about nutrition"), concern about nutrition and physical activity at the center (e.g., "How true are the following statements at your center?: I am concerned with the level of activity children get"), the use of nutrition program components (e.g., "How often do children at your site engage in the following activities: Teacher/adult-led physical activities during outdoor play (like recess)"), and nutrition and PA training (e.g., "How much training content have staff at your center received in the following: portion

sizes for children; creating positive mealtimes"). From these items, composite scores for Nutrition Continued Practice and Physical Activity Continued Practice were calculated separately. FF consisted of two programs that were targeted at changing nutrition and physical activity practices in ECE contexts, whereas WISE is only targeting nutrition in ECE. Therefore, central comparisons of continued practice are made on the continued practice of nutrition, and physical activity continued practice is a secondary variable/outcome measured only for FF.

Program Fidelity

Program Fidelity was calculated by a set of seven items that measure the extent to which each center was following key components of FF or WISE. Participants indicated the extent to which their centers were using key elements of FF or WISE in the last year each program was implemented (e.g., "Used the Food Friends puppets and characters with the lessons" or "Used the Windy Wise mascot with WISE lessons). Responses to the seven items are summed to create the Program Fidelity score.

Analysis plan

The original analysis plan for this survey data indicated that measures of sustainability would be determined based on continued practice and attention to best practices in nutrition education and adherence to specific program elements. Responses to the PSAT, Steckler Perceptions of Innovation, and the ORCA would be used as predictors of these measures of sustainability, as well as the interaction between the subscales of the PSAT measure and lag. The previous analysis plan (17) was altered due to two main factors that emerged from the current data set: lower than anticipated sample size and high intercorrelation between theorized predictors of sustainment. Due to our final sample of $N = 55$, regression analysis with the initial number of predictors (all subscales of each measure, lag, program, and interaction between lag and PSAT subscales) were no longer adequately powered. Additionally, both the adapted PSAT ($\alpha = 0.97$) and Steckler Perception of Innovation ($\alpha = 0.89$) measures had high internal consistency across items regardless of subscale. When correlations between subscales were investigated, the intercorrelations among subscales within these scales caused substantial multicollinearity issues (i.e., VIF values > 5 and reversal of the direction of bivariate correlations directions vs. beta-weights, see Table 2 for correlations of all variables used in current analysis). For instance, the six subscales of the PSAT measure had intercorrelations ranging from $r = 0.51$ to $r = 0.87$.

Therefore, it was determined multiple regression models with sustainment variables as outcomes, and the overall average scores of the PSAT, Steckler Perceptions of Innovations, and ORCA subscales, program type, and lag entered as predictors would be used to determine which overall measures were predictive of sustainment outcomes. Following these regressions, any overall scale that was predictive of a sustainment outcome would be investigated further by looking at the bivariate correlation between corresponding subscales and the sustainment outcome. Distribution of scores for all subscales and overall measures were investigated to determine if there were significant outlier scores or issues with normality. There were no individual averages for the PSAT, Steckler, or ORCA that were greater than three standard deviations away from the mean, and the Mahalanobis Distance analysis described above to investigate careless responding did not identify multivariate outliers among participant response sets. Program (FF or WISE) differences in PSAT, Steckler Perceptions of Innovations, and ORCA subscales were also assessed using MANOVAs in order to determine if there were program-specific differences in these variables. All analyses were conducted in SPSS 27 (Windows, Version 27.0. Armonk, NY: IBM Corp).

Results

Sample demographics

A total of 105 participants ($n = 51$ WISE participants, $n = 54$ FF participants) began the survey. Of the 105 individuals that began the survey, 82 (78%) completed the first portion of the study, 58 (55%) proceeded to the end, and three were later removed from the sample due to careless responding. Thus, there were a total of 55 participants ($n_{WISE} = 26$, $n_{FF} = 29$) whose responses about their centers were included in the final analysis. Most participants were female ($n = 52$, 94.5%), White ($n = 48$, 87.3%; Black = 4, 7.3%; American Indian or Alaskan Native = 1, 1.8%; missing = 2, 3.6%) and non-Hispanic ($n = 51$, 92.3%; Hispanic = 3, 5.5%; missing = 1, 1.8%). The average participant age was 49.3 years ($SD = 8.9$, minimum (min) = 32 years, maximum (max) = 65 plus years; missing = 19). Participants had worked an average of 21.0 years in ECE ($SD = 9.4$, min = 32 years, max = 45 years; missing = 2) and had worked at their current center for an average of 14.0 years ($SD = 8.2$, min = 4 years, max = 37 years; missing = 2). Most participants had been in their current role for 0-5 years ($n = 16$, 29%). Most of the participating centers were not Head Starts $n = 40$ (72.7%); served fewer than 100 children; were open 4 or 5 days a week; and were mainly metropolitan (> 50,000 population) and micropolitan (10,000-50,000 population), as determined by U.S. Department of Agriculture Rural-Urban Community Area codes (47). See Table 3 for a breakdown of center-level demographics by state.

Lag was determined as the number of years since FF or WISE has been implemented at a center. For WISE centers, the mean number of years it had been since implementation was 1.4 years ($SD = 1.3$ years, min: 0 years, max: 6 years). For FF

TABLE 3 Center–level demographics ($N = 55$) for WISE ($n = 26$) and Food Friends centers ($n = 29$).

	Overall (*N*, %)	Food Friends (*n*, %)	WISE (*n*, %)
Type of program			
Head Start	13 (23.6%)	4 (13.8%)	9 (34.6%)
Non–Head Start	40 (72.7%)	25 (86.2%)	15 (57.7%)
Missing	2 (3.6%)	0 (0%)	2 (7.7%)
Number of children served			
1–25 children	12 (21.8%)	6 (20.7%)	6 (23.1%)
26–50 children	10 (18.2%)	5 (17.2%)	5 (19.2%)
51–100 children	17 (30.9)	12 (41.4%)	5 (19.2%)
101–200 children	9 (16.4%)	4 (13.8%)	5 (19.2%)
Over 200 children	5 (9.1%)	2 (6.9%)	3 (11.5%)
Missing	2 (3.6%)	0 (0%)	2 (7.7%)
Number of hours open			
6 h or less per day	3 (5.5%)	1 (3.4%)	2 (7.7%)
7 to 12 h per day	49 (89.1%)	27 (93.1%)	22 (84.6%)
13 to 18 h per day	1 (1.8%)	1 (3.4%)	0 (0%)
Missing	2 (3.6%)	0 (0%)	2 (7.7%)
Days per week center is open			
2 days	1 (1.8%)	1 (3.4%)	0 (0%)
3 days	0 (0%)	0 (0%)	0 (0%)
4 days	11 (20.0%)	9 (31.0%)	2 (7.7%)
5 days	41 (74.5%)	19 (65.5%)	22 (92.3%)
Missing	2 (3.6%)	0 (0%)	2 (7.7%)
Tax status			
Non–profit	39 (70.9%)	21 (72.4%)	18 (69.2%)
For–profit	7 (12.7%)	5 (17.2%)	2 (7.7%)
Don't Know	7 (12.7%)	3 (10.3%)	4 (15.4%)
Missing	2 (3.6%)	0 (05)	2 (7.7%)
USDA rural–urban community area classification			
Metropolitan	16 (29.1%)	8 (27.6%)	8 (30.8%)
Micropolitan	16 (29.1%)	6 (20.7%)	10 (38.5%)
Small town to rural	9 (16.4%)	7 (24.1%)	2 (7.7%)
Missing	14 (25.5%)	8 (27.6%)	6 (23.1%)

centers, the mean number of years since last implementation was 3.3 years ($SD = 2.4$ years, min = 0 years, max = 8 years). The mean difference in lag between FF and WISE was significant ($t(53) = 3.51$, $p < 0.001$). Chi-square tests did not indicate that center demographics or director demographics were significantly associated with survey completion.

Program differences in predictors of sustainment

Two-way MANOVAs were used to investigate if PSAT, Steckler Perceptions of Innovations, and ORCA subscale measures differed by program type (FF/WISE) after controlling for lag. There were no differences in PSAT scores by program ($F_{(6,33)} = 2.05$, $p = 0.087$, $\eta_p^2 = 0.27$). Neither the Steckler Perceptions of Innovations ($F_{(4,28)} = 1.33$, $p = 0.285$, $\eta_p^2 = 0.16$) or ORCA ($F_{(3,43)} = 0.195$, $p = 0.899$, $\eta_p^2 = 0.013$) subscales differed significantly by program.

Predictors of sustainment continued practice

The regression model with program, lag, overall ORCA, Steckler Perception of Innovation, and PSAT scores accounted for a significant proportion of variance in Nutrition Continued Practice scores ($F_{(5,45)} = 4.13$, $p = 0.004$, $R^2 = 0.24$; see Table 4). Program was a significant predictor of Nutrition Continued Practice scores ($\beta = -0.32$, $t = -2.28$, $p = 0.028$). WISE programs reported higher Nutrition Continued Practice ($M = 11.47$, $SD = 1.83$) compared to FF programs ($M = 10.27$, $SD = 2.13$). Overall PSAT score was also a significant predictor of Nutrition Continued Practice ($\beta = 0.423$, $t = 3.11$, $p = 0.003$). Because of issues with multicollinearity among PSAT subscales, follow-up analyses looking at the relationship between PSAT subscales and Nutrition Continued Practice were performed with simple bivariate correlations. Nutrition Continued Practice was significantly positively correlated with all PSAT subscales: communications ($r = 0.51$, $p < 0.001$), funding stability ($r = 0.49$, $p < 0.001$), strategic planning ($r = 0.45$, $p < 0.001$), organizational capacity ($r = 0.43$, $p = 0.001$), environmental support ($r = 0.39$, $p = 0.004$), and program adaptation ($r = 0.34$, $p = 0.01$). The regression model with program, lag, and overall ORCA, Steckler Perception of Innovation, and PSAT scores did not predict a significant portion of variance in FF-only Physical Activity Continued Practice scores ($F_{(4,22)} = 0.28$, $p = 0.89$, $R^2 = 0.05$).

Program Fidelity

The regression model predicting Program Fidelity indicated that program, lag, and overall ORCA, Steckler Perception of Innovation, and PSAT scores accounted for a significant amount of variance in Program Fidelity scores ($F_{(5,45)} = 13.31$, $p < 0.001$, $R^2 = 0.55$). Both the overall PSAT score ($\beta = 0.626$, $t = 6.00$, $p < 0.001$) and overall Steckler Perception of Innovation ($\beta = 0.219$, $t = 2.10$, $p = 0.041$) were significant, positive predictors of Program Fidelity scores. Program Fidelity scores were significantly and positively correlated with all PSAT subscales: organizational capacity ($r = 0.73$, $p < 0.001$), program adaptation ($r = 0.66$, $p < 0.001$), communications ($r = 0.66$, $p < 0.001$), strategic planning ($r = 0.58$, $p < 0.001$), environmental support ($r = 0.57$, $p < 0.001$), and funding stability ($r = 0.46$, $p < 0.001$). Program Fidelity was significantly correlated with only two of the four Steckler Perceptions of Innovation measures: level of institutionalization ($r = 0.61$, $p < 0.001$) and relative advantage ($r = 0.54$, $p < 0.001$).

TABLE 4 Results of regression models predicting sustainment outcomes (Nutrition continued capitalization is inconsistent practice, physical activity continued practice, and program fidelity).

Sustainment outcome	*t*	*p*	*β*	*F*	*df*	*p*	adj. R^2
Nutrition Continued Practice							
Overall Model				4.13	5, 45	0.004	0.24
Program	−2.28	0.03	−0.32				
Lag	0.21	0.16	0.21				
PSAT	3.11	0.003	0.42				
Steckler Perception of Innovations	0.51	0.61	0.07				
ORCA	0.84	0.40	0.11				
Physical activity continued practice (CO Only)							
Overall model				0.28	4, 22	0.89	0.05
Lag	−0.68	0.50	−0.15				
PSAT	0.55	0.59	0.13				
Steckler Perception of Innovations	0.07	0.95	0.014				
ORCA	−0.40	0.69	−0.09				
Program Fidelity							
Overall model							
Program	0.63	0.53	0.07	13.31	5,45	<0.001	0.55
Lag	−1.21	0.23	−0.14				
PSAT	6.00	<0.001	0.63				
Steckler Perception of Innovations	2.10	0.04	0.22				
ORCA	0.61	0.54	0.06				

Discussion

This study contributes to the limited literature on sustainment of nutrition/PA programs in ECE (25) by examining predictors of sustainment across two nutrition/PA programs in two U.S. locations. Specifically, we examined how indicators of the Dynamic Sustainability Framework constructs were associated with sustainment in the presence of other DSF constructs, answering recent calls to use theory to evaluate the sustainment of interventions (30). Specifically, our study was able to identify evidence to support the importance of each DSF construct in understanding sustainment, both for sustaining attention to nutrition/PA broadly and to sustaining the programs as designed. Overall, our data suggest that contextual and system factors may be more important for sustainment than characteristics of the intervention.

For the construct of Intervention, perceptions of the innovation were a significant predictor of sustained Program Fidelity but not Continued Attention (either nutrition on PA), providing evidence that program-specific attitudes influence program-specific outcomes. The Steckler constructs of Institutionalization and Relative Advantage were most highly associated with sustained Program Fidelity. That is, perceiving FF/WISE as better than alternative program options and integrating FF/WISE into center schedules, routines, and norms was correlated with programs' continued use of specific program elements (i.e., Program Fidelity). This finding is consistent with a recent review finding perceived benefits and program integration as key factors for sustained implementation of health behavior programs in schools and ECEs (25). It is also consistent with qualitative research on sustaining IMIL in ECE settings, which identified integration into the curriculum and routine as key for sustainment (35).

We also examined program differences in outcomes to further examine the association of Intervention characteristics with sustainment outcomes. Only one difference between FF/WISE programs was observed; Nutrition Continued Practice was significantly higher for WISE compared to FF after controlling for lag and other predictors. This may be because of the singular focus of WISE on nutrition compared to the dual focus of FF on nutrition and PA. For example, Ward and colleagues found that ECE centers were more likely to maintain healthy eating than physical activity components of their intervention, stating that focusing on both may be a challenge for centers (35). Overall, the similarities in findings for FF/WISE suggest either true overlap in sustainment related outcomes and predictors despite the program type, lack of power to detect differences, or similarities due to measurement characteristics. Future in-depth qualitative research will explore these possibilities.

Beyond the DSF construct of Intervention, some findings support the association of the Practice Setting and Ecological System with sustainment outcomes. In fact, the overall PSAT score was the most important predictor in the presence of other predictors for both outcomes. Specifically, both Nutrition Continued Practice and Program Fidelity were significantly predicted by overall PSAT scores with high correlations will all PSAT sub-scores. Indicators of the importance of the Practice Setting included moderate to strong correlations between sustainment outcomes and communication, strategic planning, the center's adaptation of programs, and organizational capacity. While communications and planning are potentially malleable targets for supporting sustainment, organizational capacity may be less so. Consistent with a 2020 review by Herlitz et al. of sustainment of public health programming in schools (34), our study suggests that some organizations may be disadvantaged from the outset for achieving sustainment. Specifically, program capacity was an important predicator of sustainability across both programs and both targeted outcomes, consistent with the importance of capacity in prior reviews of sustainment of community-based public health interventions (48) and of health behavior interventions in schools and ECE settings (25). Prior research has also suggested that adaptation to the local context is key for sustainment of a program as well as sustained impact if fidelity to components are maintained (48). The self-report nature of our study did not allow us to determine if adaptations were fidelity consistent or inconsistent. In-depth observations at study sites in subsequent research will shed light on this issue. Despite these indicators of the importance of the practice setting, organizational readiness (as measured by the ORCA) was not related to either sustainment outcome in the presence of other predictors in our sample. This is counter to a recent review of health behavior interventions in schools and ECE settings (25), which found organizational readiness to be among the most frequently identified inner context factors important for sustainment.

The importance of the Ecological System was supported with a strong correlation between PSAT Environmental Support and Program Fidelity, a moderate association between PSAT Environmental Support and Nutrition Continued Practice, and moderate associations between PSAT Funding Stability and Program Fidelity and Nutrition Continued Practice. Our findings on the importance of funding are consistent with a review of studies on sustainment of obesity prevention programs in community settings, which identified resources as the most frequently identified factor for sustainment (24). Shoesmith et al. also identified funding availability as the most frequently cited outer context barrier to sustainment in their review of school and ECE-based health behavior interventions (25). Funding stability for an ECE program may have direct impact on use of a nutrition/PA program (e.g., purchase of supplies) or indirect impact (e.g., under-staffed, under-resourced work climates). Future research should explore these potential mechanisms. Our data suggest that support beyond funding is also needed. Although our study did not examine nuance in types of environmental support, prior research has identified parent engagement as key to sustainment in the ECE setting (35). Center leadership and teachers may benefit from an external "pull" from parents to provide this type of programming. Sustainment strategies targeting the ECE Ecological System are limited in the literature and may have value.

Taken together, these results support the importance of all levels of the DSF in understanding sustainment. Specifically, intervention characteristics (e.g., program type, perceptions of innovation), practice setting traits (e.g., organizational capacity, communications), and the ecological system (e.g., environmental support) were important predictors in our study. Although not tested in our study, elements identified by the DSF may be interlinked in complex manners. For example, evidence-based practice integration and continued training over time have been identified as important predictors of sustainment (25, 33), but these activities are more difficult to implement for institutions where financial stability and staffing constraints are more prominent, perhaps linking certain sustainment predictors together *via* institutional revenue and monetary resources. We were not able to test interactions as expected because of challenges with measuring factors related to sustainment.

Challenges, limitations, and strengths

The primary challenge we faced in measurement were high intercorrelations between sub-scales of the PSAT in our sample. Specifically, all sub-scales were correlated at or beyond $r = 0.52$, contributing to high variance inflation factors in the proposed analyses and a need for a revised analysis approach. This was a somewhat unexpected finding because original confirmatory factor analyses of the PSAT in over 250 public health programs (e.g., tobacco control, diabetes prevention) supported a factor structure with 8 distinct domains (44). However, a recent examination of the PSAT in school settings demonstrated an overarching Cronbach's alpha for internal consistency of 0.95 (33), suggesting high overlap between scales much like our sample. Together with the findings of our study, data suggest that the PSAT may need further revision and testing to have appropriate discriminant validity between sub-scales for educational settings. Further, the lack of association between the ORCA constructs and outcomes in our study may suggest need for further measure development/adaptation around organizational readiness for the ECE setting. In future work, a sufficiently powered sample could be used to perform confirmatory factor analyses (CFA) and invariance testing

to establish similar performance over various samples for these measures.

The study has additional limitations and strengths. A key limitation is that study recruitment and data collection was conducted during the COVID-19 pandemic. Programs that were able to be reached and participate during this time may differ in systematic ways from programs that were non-responsive. Specifically, it is possible that only more resourced and/or engaged centers were able to respond, which may have truncated the range of variables in our study. This concern is somewhat attenuated by the findings on program capacity's influence on sustainment outcomes, which indicates useful variability was present in the sample. A related limitation is that our sample size did not reach desired numbers for the previously proposed moderation analysis. Based on initial recruitment predictions, it was estimated that approximately 40% of the potential recruitment pool would respond to the director survey ($n = 150$; WISE programs = 45, FF programs = 105). We did not reach these numbers, and many programs that started the survey did not complete it in its entirety (45%). Thus, our study was slightly under-powered compared to our original design. Several strengths offset these limitations. First, we were able to collect information about two distinct programs across two U.S. locations. This increases the generalizability of our findings about the key factors associated with sustaining nutrition/PA programs in ECE. We were also able to model wide variation in lag since implementation, despite surprising null findings regarding its predictive power. Finally, our study was able to simultaneously examine multiple domains theorized by the DSF to be associated with sustainment outcomes in an ECE setting. This approach revealed that, for the present sample, contextual and systems characteristics were the most predictive of continued attention to nutrition/PA and specific program practices.

Implications for future research and practice

Similar to prior systematic reviews (49), our results indicated that organizational capacity and centers' adaptation of programs were strongly correlated with Program Fidelity. Targeted capacity building and intentional local adaptation during the pre-implementation phase may better prepare programs to self-sustain evidence-based practices over time. Partnered approaches to building local capacity are emerging as examples to inform further research in this area (33, 50, 51). Future research could explore the value of sustainment strategies targeting contextual factors in the pre-implementation and implementation phases for long-term outcomes. Implementation practitioners may see more benefit from advocating for systems changes and addressing contextual challenges than working directly with implementers and the innovation. Additionally, intentional efforts to support centers as they adapt programs may support long-term fidelity and sustainment.

In the presence of a supportive system and stable context or adjacent to addressing these factors, our data particularly support the importance of local perceptions of innovation as an area for future research and practice. In our study, perceiving FF or WISE as being better or more advantageous than other alternatives was related to higher Program Fidelity. Future research could explore the unique value of sustainment strategies that target adopter perceptions of innovations as well as technical assistance or facilitation approaches that provide structured support for ECE centers to integrate innovations into their program goals and schedule, both at the outset and as an ongoing effort. Practitioners may support implementers by directly addressing their thoughts, attitudes, and motivations related to the targeted innovation. These factors should be considered from the outset of program development and initial training.

Conclusions

Our study supports the importance of each DSF construct in understanding sustainment, both for sustaining attention to nutrition/PA broadly and to sustaining the programs as designed. Further, our data demonstrate that contextual and system factors may be more important for sustainment than characteristics of the intervention. This study also suggests that factors associated with the continued practice of program principles are partially distinct from those that are associated with the sustainment of specific practices driving program fidelity. Thus, capacity building strategies may be important for both continued attention to nutrition and PA as well as sustaining fidelity to specific evidence-based practices.

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 UAMS Institutional Review Board, University of Arkansas for Medical Sciences. Written informed consent for participation was not required for this study in accordance with the National Legislation and the Institutional Requirements.

Author contributions

TS led the drafting and revision of this manuscript. TS and LB led the conception and design of this study in addition to obtaining funding. GC conducted the analyses for the study, contributed to drafting the manuscript, and coordinated the initial submission of this manuscript. DZ contributed to the drafting and editing of this manuscript. SJ contributed to the design of this study and editing of this manuscript. GC and JS contributed to the conception and design of the study and editing of this manuscript. All authors approved the manuscript before submission.

Funding

The project was funded by NIH R21CA237984 (TS and LB). TS was also supported by the National Institute of General Medical Sciences of the National Institutes of Health under Award Number 5P20GM109096. TS and GC have salary support from NIH UL1 TR003107. TS, GC, DZ, VM, SJ, and JS have salary support from R37CA252113.

Conflict of interest

Authors LW-M and TS have a financial interest in the technology (WISE) discussed in this presentation/publication. These financial interests have been reviewed and approved in accordance with the UAMS conflict of interest policies.

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

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.1010305/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 10 November 2022
DOI 10.3389/frhs.2022.1005802

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 28 July 2022
ACCEPTED 24 October 2022
PUBLISHED 10 November 2022

CITATION
Malone S, Newland J, Kudchadkar SR, Prewitt K, McKay V, Prusaczyk B, Proctor E, Brownson RC and Luke DA (2022) Sustainability in pediatric hospitals: An exploration at the intersection of quality improvement and implementation science. *Front. Health Serv.* 2:1005802. doi: 10.3389/frhs.2022.1005802

Sustainability in pediatric hospitals: An exploration at the intersection of quality improvement and implementation science

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Background: Although new evidence-based practices are frequently implemented in clinical settings, many are not sustained, limiting the intended impact. Within implementation science, there is a gap in understanding sustainability. Pediatric healthcare settings have a robust history of quality improvement (QI), which includes a focus on continuation of change efforts. QI capability and sustainability capacity, therefore, serve as a useful concept for connecting the broader fields of QI and implementation science to provide insights on improving care. This study addresses these gaps in understanding of sustainability in pediatric settings and its relationship to QI.

Methods: This is a cross-sectional observational study conducted within pediatric academic medical centers in the United States. Clinicians surveyed worked with one of three evidence-based clinical programs: perioperative antimicrobial stewardship prescribing, early mobility in the intensive care unit, and massive blood transfusion administration. Participants completed two assessments: (1) the Clinical Sustainability Assessment Tool (CSAT) and (2) a 19-question assessment that included demographics and validation questions, specifically a subset of questions from the *Change Process Capability Questionnaire*, a QI scale. Initial descriptive and bivariate analyses were conducted prior to building mixed-effects models relating perceived QI to clinical sustainability capacity.

Results: A total of 181 individuals from three different programs and 30 sites were included in the final analyses. QI capability scores were assessed as a single construct (5-point Likert scale), with an average response of 4.16

(higher scores indicate greater QI capability). The overall CSAT score (7-point Likert scale) was the highest for massive transfusion programs (5.51, SD = 0.91), followed by early mobility (5.25, SD = 0.92) and perioperative antibiotic prescribing (4.91, SD = 1.07). Mixed-effects modeling illustrated that after controlling for person and setting level variables, higher perceptions of QI capabilities were significantly related to overall clinical sustainability.

Conclusion: Organizations and programs with higher QI capabilities had a higher sustainability capacity, even when controlling for differences at the individual and intervention levels. Organizational factors that enable evidence-based interventions should be further studied, especially as they relate to sustainability. Issues to be considered by practitioners when planning for sustainability include bedside provider perceptions, intervention achievability, frequency of delivery, and organizational influences.

KEYWORDS

implementation science, clinical sustainability, quality improvement, pediatrics, sustainability capacity

Introduction

Implementation science and sustainability capacity

While recent implementation science work has focused on improving how programs and interventions get initially implemented within complex settings, the impact of an evidence-based intervention is not fully realized without appropriate sustainment over time. Studies have consistently shown that fewer than half of practice changes are sustained, with one review finding only 4% of practices in healthcare reporting sustainment (1–3).

Sustainability has been defined as "the extent to which an evidence-based intervention can deliver its intended benefits over an extended period of time after external support… is terminated" (4). While research on sustainability is increasing, it is still relatively poorly understood (5–7). One important research opportunity is identifying the determinants of sustainment of evidence-based interventions (8, 9). Some examples of relevant determinants include individual interested parties, multi-professional relationships, and organizational culture (10–13). While there has been work initially conceptualizing some of these determinants as sustainability capacity, there is still much to be done before we can understand all the factors that influence sustainability. To understand how to intervene to ensure sustainment of evidence-based practices, it is crucial to advance the study of sustainability determinants and theory in clinical settings.

The relevance of quality improvement for studying clinical sustainability

Health care systems have developed with an emphasis on continual improvement, resulting in numerous theories and methods being developed and refined (14–19) focusing on how healthcare delivery can be improved, resulting in better patient safety and more positive health outcomes. While there are different histories and approaches to improvement, quality improvement and implementation science are aligned in their focus on improving care delivery and outcomes. *Quality improvement (QI)* is focused on identifying local, context-specific problems and rapid correction. While having a scientific and theoretical basis, QI is a more applied science within the hospital system (20). There are opportunities to improve our understanding of implementation science in clinical settings by bringing in QI science.

QI is aimed at realizing improvement within specific metrics, which makes it helpful in project management and execution in busy and under-resourced settings. Some QI studies have demonstrated an ability to sustain their practices (21, 22). However, other literature has cited difficulties with sustaining changes (23). Some research has begun to target determinants of sustainment of practice change (24).

Implementation science, which also focuses on improving healthcare services, according to Mittman, "generally seeks to develop and rigorously evaluate fixed implementation strategies to address implementation gaps across multiple sites" (25). This has created a dichotomy where implementation scientists focus on information that can be scaled and generalized, while QI work has aimed its interventions at individual needs and

corrections. However, the fields overlap, with their common focus on improving the delivery of evidence-based practices to benefit patients.

The importance of context in clinical sustainability

One important class of determinants of sustainability are characteristics of the *context* within which the intervention is carried out. Context has been defined by May et al. as "the physical, organizational, institutional, and legislative structures that enable and constrain…people and procedures" (26). It follows, then, that understanding outcomes requires knowledge of the environmental context within which the system is embedded (e.g., staffing, organizational climate) (27). Since these contexts vary by setting, there is a need for "unpacking" these contextual factors within clinical care to enumerate key contextual variables, prioritize those most salient, and measure these variables across settings (28, 29).

The clinical healthcare environment consists of unique provider dynamics, workflow challenges, and complexities to overcome when evaluating sustainment of practices over time (30). Clinical care is best understood through practices and procedures that occur, relying heavily on frontline providers who are conducting activities highly integrated with the rest of the workflow. The time horizon for implementation and impact is often shorter in clinical sustainability than in public health, allowing patient and system-level changes to be seen more immediately by those providing care. To understand these differences, clinical sustainability must be distinguished from sustainability more broadly. Clinical sustainability has been defined as "the ability of an organization to maintain structured clinical care practices over time and to evolve and adapt these practices in response to new information (31)."

The workflows, team composition, and relationship to patients and families are some of the factors that make pediatrics a unique care delivery setting. For example, children's hospitals require multidisciplinary expertise focused on the experiences of childhood. While medical specialists have different training for pediatrics, there are also different professional roles regularly involved in pediatric settings, including clinical social work and child life specialists. Additionally, pediatric hospitals must focus on the parents and caregivers, whereas adult settings are less concerned about caregivers and less frequently have individuals other than the patient providing consent for treatment (32). The research base for children is more limited due to ethical and practical issues with recruitment and testing (33). Providers often express concern with the available evidence due to origination in adults and concerns about the imperfect translation of evidence to pediatric settings (34). All these differences require special attention to be paid to pediatric health settings.

Goals and research questions

This study addresses some of these gaps in understanding sustainability in pediatric settings and its relationship to QI. More specifically, this study assesses different individual and intervention characteristics, including quality improvement capabilities, and their association with clinical sustainability capacity. By examining the ability of a healthcare organization to implement and continue to deliver high-quality care, the study aims to answer the following questions:

(1) What specific individual and organizational factors are related to clinical sustainability capacity?
(2) How does quality improvement capability correspond to sustainability of clinical programs?

Results from this study will help us to understand if there are any individual, intervention, or quality improvement determinants that contribute to sustainability capacity and could point toward future areas of intervention. This will help advance the science of sustainability through the development of links between determinants and sustainability capacity.

Methods

This is a cross-sectional observational study conducted within pediatric academic medical centers in the United States. The study included healthcare professionals affiliated with one of three evidence-based clinical programs and uses multilevel modeling to assess hospital-level contextual factors and their associations with sustainability capacity.

Settings

Three multicenter national hospital clinical programs were included in this study. Thirty sites participated in the study amongst the three programs. All thirty sites were engaged in evidence-based practice change that involve multi-professional teams. These are all programs that emphasize delivering evidence-based interventions in different units and teams. While some sites had multiple programs that were eligible for the study, they were treated as separate sites due to the unique resources and personnel in each clincial unit. Each site had been delivering the program for a different length of time.

The three evidence-based interventions that the sites were focused on were: antibiotic prescribing in clean/clean-contaminated surgeries (35), early mobility within the pediatric intensive care unit (36), and massive transfusion blood

TABLE 1 Description of three pediatric interventions.

	ASP[a]	Early mobility	Massive transfusion
Description	Appropriate antibiotic prescribing practices in clean and clean-contaminated surgical cases	A care bundle focused on reduction of delirium and sedation to begin early rehab for children that are critically ill	Practices that allow for rapid distribution and administration of blood product
Professions	Pharmacist, physician, physician assistant, nurse practitioners	Nurse, physician, respiratory therapy, physical therapy, occupational therapy	Physician, pharmacist, blood banker
Disciplines	Infectious disease, surgery	Critical care	Emergency medicine, blood bank, intensive care

[a]Antimicrobial stewardship program (ASP) perioperative antibiotic prescribing program.

administration (36, 37). These are all internationally recognized guidelines and evidence-based practices (38–40). Table 1 outlines each intervention and the multi-professional team involved. For ease of describing the practices, the surgical antibiotic practice will be referred to as an antimicrobial stewardship program (ASP) throughout.

Participants and recruitment

Data were collected during October 2020—July 2021 from 181 multi-professional clinicians involved in the pediatric evidence-based practices described above. A group of institutions participating in delivery of these interventions was generated through collaboration amongst the study team. National program leads were used to identify team leads at each site for each of the three practices, with a total of 40 sites originally identified. Site leads were then contacted and asked about their site participation. If team leads agreed, a list of site participants was provided to the study team, which was defined as any individual involved in the relevant clinical care practice in their setting. These individuals were then recruited to complete the survey over email and were invited to forward the email to anyone else in their organization that participated in delivery of the intervention. Known participants were contacted twice *via* email and asked to participate in an online survey that was conducted using Qualtrics (Qualtrics, Provo, UT). Overall, 30 sites participated in the study (Table 1). All participating sites were US based academic medical centers with either (1) dedicated pediatrics care or (2) a freestanding children's hospital. From these sites, 181 individuals responded to the survey. There were no incentives provided for participating in the study. The study protocol was reviewed and approved by Washington University Human Research Protection Office (202102017).

Data sources

The survey instruments were:

- Clinical Sustainability Assessment Tool (CSAT) (41)—This measure assesses clinical sustainability capacity and includes seven domains: engaged stakeholders, engaged staff and leadership, organizational readiness, monitoring and evaluation, implementation and training, outcomes and effectiveness, and workflow integration. There are 35 questions, all completed on a seven-point Likert scale with options ranging from: not at all—to a great extent. There is also a "not able to assess" option for each question. This instrument has demonstrated reliability and is one of the few instruments developed to assess sustainability in clinical settings (42).
- *Validation questions*—This is an additional set of questions that gathers information about the nature of the evidence-based intervention as well as other organization characteristics that assist in understanding the validity of the CSAT. The questions were grouped into two categories: questions about the organization and those about the intervention. A subset of the organization questions were taken from the Change Process Capability Questionnaire, a QI assessment utilized by the Agency for Healthcare Research and Quality (AHRQ) (43). Additional organizational, intervention, and individual questions are described below.
- Demographic questions—A set of questions provided information about the individual taking the assessment. These include the role, profession, and the environment within which the individual usually practices (e.g., adult vs. pediatrics, inpatient vs. outpatient).

The full instruments can be found in Supplementary material A and B.

Variables, data management, and analysis

The variables of interest for this project can be found listed in Table 2. In addition to data collected to understand quality improvement capability, other data were collected to assess organizational and individual determinants that could

TABLE 2 Variables included in study.

Variable	Variable type	Source
Dependent variables		
Sustainability capacity [CSAT]	Continuous [averaged across 7 domains]	Clinical sustainability assessment tool
Independent variables		
Quality improvement capability[a]	Continuous [average of 6 questions]	Validation survey
Covariates: individual		
Role	Categorical	Demographics
Profession	Categorical	Demographics
Position	Categorical	Demographics
Service environment	Categorical	Demographics
Covariates: organizational		
Organization type	Categorical	Demographics
Size	Ordinal [3 levels]	Demographics
Urban/Rural	Categorical	Demographics
Covariates: intervention		
Length of practice	Ordinal [5 levels]	Validation survey
Strength of evidence	Ordinal [5 levels]	Validation survey
Importance	Ordinal [5 levels]	Validation survey
Achievability	Ordinal [5 levels]	Validation survey
Frequency of delivery	Ordinal [5 levels]	Validation survey

[a]This is a calculated score, comprised of five items from the Change Process Capability Questionnaire (45).

influence the sustainability of pediatric clinical programs. This is further explained below within the description of mixed-effects modeling.

Sustainability capacity

Sustainability capacity was the main dependent variable for this study. Capacity was represented as the CSAT score for each domain as well as an overall sustainability capacity score. The seven domain scores were calculated as a simple average of the five items within each subscale. Scores can range from 1 to 7, where a higher score indicates a higher sustainability capacity. The total CSAT score was calculated as an average of the seven domain scores, again ranging from 1–7. This total score represents the perceived sustainability capacity for the specific clinical setting, where higher numbers indicate a greater capacity.

Quality improvement capability

Quality improvement capability was the main independent variable for this study. Six questions were chosen from the Change Process Capability Questionnaire as a proxy for QI work conducted at the site level (43). This score reflected the overall site relationship to QI and use of QI strategies. Scores could range from 1 to 5, where higher scores indicated a higher extent of quality improvement capabilities within their setting. All six questions included in the quality improvement capability construct were assessed individually and as a scale. One of the six items was re-coded, as it was initially reverse coded.

One item performed poorly during reliability testing, indicating it was not measuring the same latent construct of QI capability. This item was ultimately removed to create a 5-item scale of quality improvement capability. This included history of use of QI methods, assessment of QI culture, and strategies that were used in the setting. This scale was utilized in the rest of the study as an average. The value for Cronbach's alpha for the construct was $\alpha = 0.83$, indicating very good reliability (44).

Other covariates

Other covariates of interest were assessed at the individual, intervention, and organization level.

Participants reported three organizational characteristics: the type of organization, staff size, and location. Organizational variables were assessed for distribution and some responses were collapsed. Environment was re-coded to a binary variable, assessing those who worked at primarily at an academic medical center compared to those who also deliver care in other settings, such as community hospitals or urgent care. All individuals identified their organization as located in an urban area with many employees, so these two variables were eliminated from further analyses.

Individuals were asked to assess their perception of the intervention in five different ways. First, people reported the length of time, in years, that they believed the intervention had been implemented in their setting. Next, they were asked to identify the strength of evidence supporting the intervention or practice (5 options, from very weak to very strong). Third, participants reported their perception of how important the intervention was to provide quality care within their setting (5 options, from not at all important to very important). Participants also assessed their perception of how easy the practice was to implement within the setting, described as achievability (5 options, from very difficult to very easy). Finally, they were asked about the frequency of delivery, or how often those in their care received the intervention (from not at all to all the time).

Four questions were asked to understand characteristics about the participants. All four individual-level variables were assessed and three were re-coded to assist with distribution across the data. The participant role remained a categorical variable as collected, with individuals reflecting all types of involvement in the implementation team. The setting was recoded to a binary variable, with individuals identified as

those practicing in one setting vs. more than one setting (inpatient *and* outpatient). Position was recoded due to the frequency of bedside clinicians included in the sample, and the other three positions of leadership, administration, and research were collapsed into a single response category. Finally, the individual profession was collapsed into nurses, physicians, and all others (i.e., respiratory therapy, physical therapy, social work, and pharmacists).

Data analysis

The data were recoded, cleaned, and analyzed in R. Both the CSAT scores and a Quality Improvement Capability Score were calculated, derived from the questions taken from the AHRQ Change Process Capability Questionnaire (45). The data were analyzed in three phases. First, descriptive statistics were generated to assess each individual variable as well as begin to understand sustainability across the programs. Next, bivariate statistical analysis was conducted to understand the relationship between some of these variables and sustainability. Finally, multi-level models were built to answer questions about the relationship of quality improvement capability to clinical sustainability capacity.

A multilevel analysis was conducted to identify associations of individual-level and contextual factors with clinical sustainability capacity. A two-level multilevel structure was utilized, where healthcare staff was nested with clinical care sites. Using multilevel analysis helped address clustering and account for contextual information at the organizational level (46).

The multilevel modeling equation for this two-level structure was:

$$Level\ 1:\ Sustain_{ij} = \beta_{0j} + \beta_{1j}QIC_{ij} + \beta_{2j}Individual_{ij} + r_{ij}$$

$$Level\ 2:\ \beta_{0j} = \gamma_{00} + \gamma_{01}Org_j + u_{0j}$$

$$\beta_{1j} = \gamma_{10} + \gamma_{11}Org_j + u_{1j}$$

$$\beta_{2j} = \gamma_{20} + \gamma_{21}Org_j + u_{2j}$$

In this equation, level one represented the participant level differences in their sustainability capacity score. The second-level represents the differences at the organization or site level. *The* dependent variable of interest is sustainability capacity (Sustain). Sustainability capacity was modeled as a function of quality improvement capability scores measured at the person-level (*QIC*) and other person-level covariates (Individual). The covariates at the second-level variable, Org, included the program type and perceptions about the interventions evidence, achievability, and frequency of delivery.

This allowed for a model that can answer one of the main questions of interest requiring a multi-level model, which is how perceived quality improvement capabilities predicts sustainability after controlling for other individual and intervention level characteristics. This model also assisted in answering questions about other relevant determinants of sustainability capacity. This model was built in a block fashion, with intermediate models produced before the final model focusing on the role of quality improvement capability. This block model-building approach allows us to examine the role of QI capability on sustainability after controlling for the other individual and site-level covariates.

The models were built sequentially, starting with a null model to test ICC and then adding level one and level two variables in sequentially to subsequent models. Finally, the QI capability score was added, forming the final model.

Results

Describing sustainability across programs

Participant and setting descriptive statistics

A total of 181 individuals from three different programs and 30 sites were included in the final analysis. Individual demographics of interest are included in Table 3. Individuals most frequently worked in a single practice setting (e.g., inpatient) (74%) and were involved in direct patient care (70%). About half of the participants were physicians (48%), although all professions were recruited to participate within each setting.

Individuals within the study primarily identified their practice group as pediatrics across all three programs. Individuals reported their practice environment largely as academic medical centers (84%). Most people described the intervention as existing at their site for <5 years and believed the evidence for the intervention to be strong, with a mean score of 4.22 (SD = 0.74). Participants demonstrated bimodal

TABLE 3 Participant characteristics and clinical role.

	ASP[a]	Early mobility	Massive transfusion
Total # of sites in sample	10	8	12
Total # of people in sample	53	88	40
Setting			
Single setting	34	80	20
Two + settings	18	8	20
Profession			
Physician	34	28	26
Nurse	1	26	6
Other	18	34	8
Position			
Direct patient care	32	77	18
Other	21	11	22

[a] Antimicrobial stewardship program (ASP) perioperative antibiotic prescribing program.

10.3389/frhs.2022.1005802

TABLE 4 Intervention level descriptive statistics by program.

	Program		
	ASP[a]	Early mobility	Massive transfusion
Length of practice			
Less than 1 year	4	5	0
1–5 years	4	73	14
6–10 years	15	1	13
>10 years	7	1	10
Strength of evidence			
Very weak	0	0	0
Weak	1	0	2
Neither weak nor strong	8	6	8
Strong	29	33	15
Very strong	0	0	0
Importance of intervention			
Very unimportant	5	12	0
Somewhat unimportant	0	0	0
Neither important or unimportant	0	0	0
Somewhat important	9	9	4
Important	40	67	36
Achievability of implementation			
Very difficult	0	0	1
Somewhat difficult	27	18	7
Neither easy nor difficult	6	20	12
Somewhat easy	12	29	11
Very easy	0	3	2
Frequency of delivery			
None of the time	1	0	0
Some of the time	7	18	23
Most of the time	24	45	2
All of the time	19	25	14

[a]Antimicrobial stewardship program (ASP) perioperative antibiotic prescribing program.

reporting for importance, reporting the intervention to be either very unimportant or important. Those participating in ASP (M = 3.20, SD = 0.74) and early mobility (M = 3.08, SD = 0.69) reported individuals receiving the intervention more frequently than those in massive transfusion programs (M = 2.77, SD = 0.96). Table 4 presents the intervention level descriptive statistics.

CSAT scores

Table 5 presents the subscale and overall CSAT scores in total and by each program. The overall CSAT was highest for massive transfusion programs (5.51). Each program had different high-performing domains. The standard deviation highlights variability within each of the scores.

Overall, the scores indicate there was variation by program across each of the domains. Transfusion programs had higher scores in five of the domains, with the mobility programs having the highest domain averages in the other two.

Quality improvement capability scores

The quality improvement capability scores were calculated using the average of the five items that were included after calculating Cronbach's alpha. Table 6 presents the item and scale averages and standard deviation for each practice as well as across the three programs. The lowest item mean was for QI in the past year and the highest was for using QI skills. The ASP and massive transfusion programs had the highest overall QI capability scores, with ASP being slightly higher. Like with CSAT scores, the standard deviation indicates there was variability within the QI capability scores.

Association of quality improvement capability and clinical sustainability

Figure 1 shows the relationship between total QI capability score and total CSAT scores. There is a moderately strong, positive association between these two variables ($r = 0.49$, $p < 0.001$). This relationship illustrates that an increase in QI capability is associated with higher CSAT scores.

Model relationships between individual, site-level, and quality improvement covariates with clinical sustainability

After assessing both univariate and bivariate statistics, multilevel mixed-effects modeling was conducted. The models are summarized in Table 7. Four models are presented, starting with a null model (no covariates), an initial substantive model with individual-level covariates, a multilevel model with both individual and site-level covariates, and then a final model with QI capability scores.

Null model

The ICC calculated from the null model was 0.12, indicating some variability that is accounted for by the different sites. This non-zero value supports the approach of using mixed-effects modeling to account for clustering of individual-level scores within the specific sites (46).

Model with level 1 variables

All level one variables were added to the model at the same time. While level one variables enhanced the model, only one

TABLE 5 CSAT subscale and total score by program.

CSAT Subscales	ASP[a] ($n = 53$)	Early mobility ($n = 88$)	Massive transfusion ($n = 40$)	Total across programs
Engaged staff and leadership	5.21 (1.29)	5.41 (1.14)	5.71 (1.08)	5.43 (1.18)
Engaged stakeholders	4.62 (1.19)	5.56 (1.02)	5.26 (1.31)	5.22 (1.20)
Organizational readiness	5.13 (1.17)	4.98 (1.17)	5.65 (0.97)	5.40 (1.15)
Workflow integration	5.01 (1.17)	5.38 (1.04)	5.6 (0.98)	5.40 (1.09)
Implementation and training	4.53 (1.46)	4.84 (1.31)	5.33 (1.22)	5.00 (1.36)
Monitoring and evaluation	4.64 (1.58)	4.68 (1.52)	5.31 (1.55)	5.00 (1.56)
Outcomes and effectiveness	5.46 (1.21)	5.93 (0.89)	5.60 (0.91)	6.00 (1.02)
Total CSAT score	4.91 (1.07)	5.25 (0.92)	5.51 (0.91)	5.20 (0.98)

[a]Antimicrobial stewardship program (ASP) perioperative antibiotic prescribing program.
Cells contain averages and standard deviations.

TABLE 6 Quality improvement items from Change Process Capability Questionnaire.

Question	ASP[a]	Early mobility	Massive transfusion	Total
Our clinical team understands and uses quality improvement skills effectively.	4.43 (0.69)	4.18 (0.77)	4.35 (0.80)	4.29 (0.76)
Our clinical team has changed or created systems in the organization that make it easier to provide high quality care.	4.40 (0.69)	4.16 (0.83)	4.33 (0.83)	4.27 (0.79)
We choose new processes of care that are more advantageous than the old to everyone involved (patients, clinicians, and our entire clinical team).	4.06 (0.79)	3.93 (0.80)	4.23 (0.86)	4.03 (0.82)
The working environment in our clinical team is collaborative and cohesive, with shared sense of purpose, cooperation, and willingness to contribute to the common good.	4.25 (0.87)	4.13 (0.84)	4.30 (0.76)	4.20 (0.83)
Our clinical team has greatly improved quality of care in the past year.	4.11 (0.75)	3.91 (0.79)	4.00 (0.75)	3.99 (0.77)
Total score	4.25 (0.55)	4.06 (0.61)	4.24 (0.67)	4.16 (0.61)

[a]Antimicrobial stewardship program (ASP) perioperative antibiotic prescribing program.

was a significant predictor of sustainability scores within the three programs. Individuals who identified as being primarily in positions other than bedside providers perceived higher sustainability capacity (Coef. = 0.40, $p < 0.05$).

Model with level 2 variables

Level two variables were added in two phases to the model. First, organizational variables of program and environment were added. Subsequently, the intervention characteristics were added. The AIC values decreased with the addition of these variables and lower AIC values indicate better fit. The transfusion program staff reported higher CSAT scores relative to the ASP programs (Coef. = 0.64, $p < 0.05$). Higher perception of strength of evidence for a program also resulted in higher CSAT scores (Coef. = 0.45, $p < 0.05$). Individuals that reported higher frequency of delivery, meaning the intervention was delivered more frequently, also reported higher overall CSAT scores (Coef. = 0.34, $p < 0.05$). The perceived ease of implementation and length of time in practice were not significant.

Final model

Finally, the five-item quality improvement capability construct was added to the overall model. The AIC decrease suggests that the model was improved through the addition of this construct. The quality improvement capability variable was also significant (Coef. = 0.65, $p < 0.05$). In this model, intervention frequency, the strength of evidence, and transfusion program remained significant. This final model is a significant improvement over the level-2 model (LR Chi-square = 38.9, $p < 0.01$).

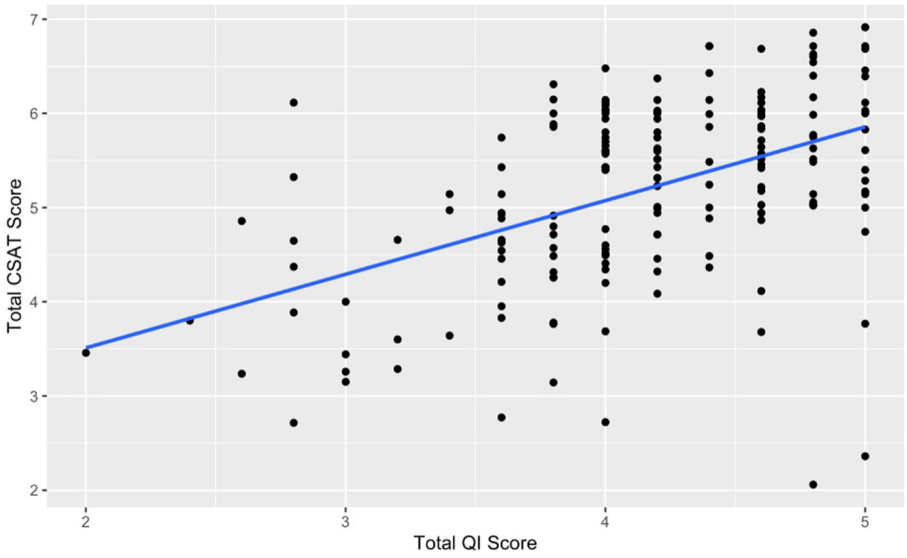

FIGURE 1
Relationship between total CSAT score and total QI score.

How quality improvement influences sustainability capacity

After the final model was completed and assessed, further analyses were conducted to understand more about the direction and strength of the relationship between quality improvement capability score and CSAT total score. To understand how quality was operating through the sustainability score, the entire model was run with each of the seven CSAT subscale scores as the dependent variable. The final model with all covariates was run, and the parameter estimates for the QI variable for each of the seven models are presented in Table 8. Quality improvement capabilities were positively and significantly associated with CSAT subscale scores for every domain. Quality improvement capability functioned most strongly through monitoring and evaluation and organizational readiness and least through engaged stakeholders and outcomes and effectiveness. However, an increase in quality improvement capability scores led to a significant increase in CSAT domain scores in all the seven domains.

Discussion

Sustainability and quality in pediatric hospital care

The construct of QI capability is especially important in pediatric hospital care due to its extensive engagement with the field of quality (47). This study assessed the relationship of various individual and organizational constructs to sustainability capacity. These results show that after controlling for the person and setting level variables, perceptions of higher QI capabilities are significantly related to overall clinical sustainability scores. Our research suggests that QI capability within the hospital is related to the capacity to sustain evidence-based practices after implementation, highlighting a way to consider the relationship of QI theory with implementation science.

The measure of quality improvement capability within the hospital was found to be related to overall sustainability capacity. This study responds to foundational calls within the field of sustainability. Additionally, this study highlights quality improvement processes within healthcare that can serve as a bridging factor, or enabling condition, between larger health delivery organizations and individual high-performing healthcare delivery teams (48, 49). Future work should focus on the systems that facilitate or hinder both QI and sustainability. While this study offers information related to how these constructs are measured in pediatric hospital settings, this research is limited by the sample size and only provides data focused in a single practice environment. Given that other types of programs and practices certainly have different characteristics within the hospital and in other settings, there would be benefit to conducting a larger study both in pediatrics and in other contexts.

Various other factors related to the intervention were significantly related to higher sustainability capacity. Implementors should focus on how different clinicians assess the quality of evidence during implementation and sustainment. The frequency of delivery was consistent with anticipated delivery of these different interventions in

TABLE 7 Sustainability capacity modeled with individual, intervention, and organizational predictors.

	Null model		Level 1 (person) variables			Level 2 (setting) variables			Final model with QI		
	Coef.	95% CI	Coef.	(95% CI)	*p*-value	Coef.	95% CI	*p*-value	Coef.	(95% CI)	*p*-value
Intercept	5.15	(4.95, 5.35)	4.91	(4.43, 5.40)		1.25	(0.07, 2.46)		−0.29	(−1.44, 0.86)	
Setting (reference: single)											
Setting: multiple			0.12	(−0.23, 0.47)	0.50	0.04	(−0.27, 0.35)	0.80	0.07	(−0.21, 0.36)	0.64
Position (reference: bedside)											
Position: other			**0.40**	**(0.04, 0.76)**	**0.03**	0.19	(−0.13, 0.52)	0.28	0.18	(−0.11, 0.48)	0.26
Profession (reference: nurse)											
Profession: physician			0.09	(−0.35, 0.52)	0.70	0.30	(−0.09, 0.71)	0.16	0.24	(−0.11, 0.60)	0.22
Profession: other			0.15	(−0.28, 0.59)	0.51	0.36	(−0.03, 0.78)	0.10	0.36	(0.02, 0.73)	0.07
Role (reference: team leader)											
Role: administration			0.05	(−0.52, 0.63)	0.87	0.13	(−0.38, 0.65)	0.64	0.19	(−0.27, 0.66)	0.44
Role: participating			−0.07	(−0.45, 0.32)	0.73	0.00	(−0.34, 0.34)	0.98	−0.05	(−0.35, 0.26)	0.75
Role: evaluator			−0.46	(−0.45, 0.31)	0.30	−0.45	(−1.16, 0.30)	0.26	−0.37	(−1.00, 0.31)	0.30
Role: clinical staff			−0.04	(−1.30, 0.39)	0.84	−0.12	(−0.47, 0.22)	0.50	−0.09	(−0.39, 0.23)	0.60
Program (reference: ASP)											
Program: early mobility						0.33	(−0.09, 0.74)	0.16	0.37	(0.03, 0.70)	0.06
Program: massive transfusion						**0.64**	**(0.23, 1.06)**	**0.01**	**0.65**	**(0.31, 0.99)**	**0.002**
Environment (reference: academic)											
Environment: other						0.14	(−0.25, 0.66)	0.50	0.11	(−0.21, 0.50)	0.55
Int. Importance (reference: not important)											
Int. importance: important						−0.21	(−0.78, 0.33)	0.48	−0.28	(−0.80, 0.20)	0.29
Int. importance: very important						−0.29	(−0.75, 0.15)	0.23	−0.35	(−0.76, 0.04)	0.10
Intervention: strength of evidence						**0.45**	**(0.26, 0.65)**	**<0.001**	**0.40**	**(0.24, 0.58)**	**<0.001**
Intervention: length of implementation						0.05	(−0.13, 0.20)	0.54	−0.05	(−0.21, 0.07)	0.43
Intervention: achievability						0.15	(−0.00, 0.31)	0.07	0.10	(−0.03, 0.24)	0.17
Intervention: frequency of delivery						**0.34**	**(0.17, 0.51)**	**<0.001**	**0.21**	**(0.05, 0.36)**	**0.02**
Quality improvement capability									**0.65**	**(0.46, 0.85)**	**<0.001**
Model fit			**AIC**	509.7		**AIC**	471.0		**AIC**	434.1	
Model improvement (LR Chi-squared)					56.7 ($p < 0.01$)			38.9 ($p < 0.01$)			

Bolded parameters indicate significance at $p < 0.05$.

routine care. Results highlighting the frequency of delivery creating more capacity for sustainability could potentially function through the domain of workflow integration and is supported by other literature highlighting the importance of routinization into the workflow (50, 51). Future research ought to consider how to sustain interventions in relationship to intervention differences (i.e., acuity, frequency, etc.) (52).

Implications for healthcare delivery

This study has implications for implementation practice. First, the CSAT should be considered as a useful tool during QI and/or implementation efforts. Second, this relationship between QI and implementation provides insight into strategies and methodologies that should be considered for training and implementation.

Our findings rely on the use of the Clinical Sustainability Assessment tool. The CSAT scores were consistent, regardless of individual-level characteristics. This study reinforces that the CSAT is a pragmatic tool that can be used by clinicians for evaluation and planning to sustain programs and practices. Additionally, this understanding of how QI initiatives bolster sustainability indicates that utilizing QI methodologies should be considered with planning strategies for implementation efforts.

TABLE 8 Mixed effect models for each subdomain, focused on QI variable.

CSAT domain	Quality improvement variable in final model	
	Coef.	SE
Engaged stakeholders	0.38	0.16
Outcomes and effectiveness	0.43	0.13
Engaged staff and leadership	0.49	0.15
Workflow integration	0.64	0.14
Implementation and training	0.70	0.17
Organizational readiness	0.87	0.13
Monitoring and evaluation	0.93	0.19

All parameters were significant at $p < 0.05$.

Implementation science and quality improvement

This study responds to a theoretical question that has been posed within improvement sciences about the relationship between implementation science and QI. Easterling et al. found implementation science and QI literature to be separate bodies of work when they were assessing learning health system literature (49). QI has been described as an applied science that provides tools and theories to assist in rapid improvement at a local level (53) while implementation science has focused more broadly on the processes for change, context alignment, and outcomes related to both implementation as well as patient health (54–56).

Sustainability may be better understood and enhanced by more closely linking QI and implementation science to provide insights on how to improve care delivery. This study highlights how using theories and tools from both QI and implementation science can enhance our understanding of how to best ensure sustainability of our efforts to improve healthcare quality. Specifically, drawing from these two fields allows for a better understanding of the needs to assess impact to the practitioner (QI), system level care outcomes, as well as the integration into the practice environment and process of implementing change (implementation science). To be successful, research on sustainability determinants in healthcare must address the existence of QI as a relevant influence in the field. This research responds to calls to advance research on sustainability and sustainment (8, 30), and future studies should be focused on organization and intervention level determinants of sustainability as well as their sustainment.

Limitations

This study draws it strength from being a survey of frontline clinicians engaged in the delivery of these programs. A combination of recruitment strategies was utilized, resulting in an inability to track overall response rate and understand a potential selection bias for those who self-selected to complete the assessment. This survey also reports individual perceptions of these constructs, which are subjective measures. Future research should focus on objective measurement of these constructs and outcomes. By using perception of these constructs, we can assess how clinicians understand the intervention in their clinical environment, which is relevant and can highlight differences in understanding practice delivery within a single setting.

Conclusion

This study sought to understand the influence of QI on sustainability in pediatric healthcare settings. We found that sustainability capacity is influenced by the following: the perception of evidence, individual roles, frequency of delivery, and QI capabilities of the setting. This is one of these first studies to show a strong relationship between QI and intervention sustainability. This work helps bring together theory and research from QI science and implementation science. By doing this, we highlight the opportunity to improve healthcare delivery by integrating these relevant fields of study.

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 Washington University in St. Louis, HRPO. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

SM led the process of designing, collecting data, and the writing of the manuscript. JN and SK both assisted with the design of the study, facilitated data collection, and edited the manuscript. VM and KP assisted with data collection, study design, and edited the manuscript. BP, EP, and RB assisted with planning the study, supervision of the project, and drafting of the manuscript. DL assisted with planning the study, data analysis, supervision of the project, and drafting of the manuscript. All authors reviewed and approved the final manuscript.

Funding

This study was supported in part by the National Institute of Aging K01AG071749 (BP). This study was supported in part by the National Cancer Institute (P50CA244431), the National Institute of Diabetes, and Digestive and Kidney Diseases (P30DK092950 and P30DK056341), the Centers for Disease Control and Prevention (U48DP006395), and the Foundation for Barnes-Jewish Hospital. This study was supported in part by AHRQ R01HS026742-03 (Newland, Malone). The findings and conclusions in this paper are those of the authors and do not necessarily represent the official positions of the National Institutes of Health or the Centers for Disease Control and Prevention.

Acknowledgments

This research would not have been possible without the participation of all the programs working to provide excellent care to children every day—thank you all for all your support and engagement. Special thanks to Philip Spinella.

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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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.1005802/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 25 November 2022
DOI 10.3389/frhs.2022.1031628

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 30 August 2022
ACCEPTED 09 November 2022
PUBLISHED 25 November 2022

CITATION
Love P, Laws R, Taki S, West M, Hesketh KD and Campbell KJ (2022) Factors contributing to the sustained implementation of an early childhood obesity prevention intervention: The *INFANT Program*.
Front. Health Serv. 2:1031628.
doi: 10.3389/frhs.2022.1031628

Factors contributing to the sustained implementation of an early childhood obesity prevention intervention: The *INFANT Program*

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Background: The *INFANT Program* is an efficacious, group-based program for first-time parents, delivered at three-monthly intervals when *INFANT* are aged 3–18 months through an existing universal care service in Victoria, Australia. Many lessons have been learnt from its origins as a cluster randomized control trial to its small-scale, community-level implementation. This study aimed to describe factors contributing to its sustained implementation to inform large-scale implementation across Australia.

Methods: This study used a multi-site qualitative exploratory approach. *INFANT* facilitators trained between 2013 and 2017 were sent an online survey, with optional telephone interviews. The Consolidated Framework for Implementation Research (CFIR) was selected as the underpinning theoretical framework as it offered the opportunity to explore a breadth of possible barriers and enablers across patterns of implementation (never, discontinued, ongoing).

Results: All participants were female ($n = 31$), the majority were Maternal and Child Health Nurses (48%), representing five regional and nine metro local government areas (LGAs), across all patterns of implementation (never implemented $n = 4$; discontinued implementation $n = 5$; ongoing implementation $n = 5$). All consenting participants were interviewed ($n = 11$) representing four regional and seven metro LGAs, across all patterns of implementation (never implemented $n = 3$; discontinued implementation $n = 4$; ongoing implementation $n = 4$). The main reason for attending *INFANT Program* training was to become skilled to implement the program. Mapping identified barriers and enablers to the CFIR revealed the inner and outer settings and implementation process to be of greatest influence. Main differences between LGAs with ongoing and discontinued implementation related to funding availability, organizational management support and endorsement, organizational resourcing and capacity, integration into routine practice and

establishing role clarity with partner organizations, and planning for sustained implementation from the start.

Conclusion: This study provides important insights into the barriers and enablers to the sustained implementation of an evidence-based intervention (the *INFANT Program*) during small scale community-level implementation. The authors therefore contend that the pre-requisite for scale-up of a population health intervention is not just proof of effectiveness but also proof of sustained implementation at the local/organizational level. Study findings have broad transferability given their similarity to those identified for health promotion interventions implemented globally, in healthcare, education and community settings.

KEYWORDS

implementation, sustainability, maintenance, early childhood, obesity prevention, health promotion

Introduction

The first 1,000 days (conception to 24 months) are acknowledged as a crucial period for growth and development in early childhood, laying the foundation for life-long health behaviors and the prevention of chronic disease (1, 2). The early establishment of healthy behaviors (3), such as prolonged breastfeeding (4), reduced consumption of energy-dense, nutrient-poor foods/beverages (5), limited screen time and sedentary behavior (6), and prevention of rapid infant weight gain (7), is considered critical for the prevention of childhood obesity and overweight which affects an estimated 38.3 million children under the age of 5 years globally (8). In Australia, 25% of children aged 2–4 years are already experiencing overweight/obesity (9), with a minority meeting the recommended dietary and movement guidelines (10), and those living in lower socioeconomic or regional areas most affected (11). It is predicted that if current rates of childhood weight gain continue, prevalence of these conditions among Australian children will reach 33% by 2025 (12).

Research indicates that early intervention at or within a few months of birth can benefit obesity prevention in the first 1,000 days (2, 13–15). The World Health Organization's Commission on Ending Childhood Obesity (16) describes a continuum of care for the prevention, management and treatment of obesity among infants and children using a multi-strategy approach targeting the individual, family, community and public policy. Recent reviews support this approach, suggesting the use of interventions that include multicomponent (healthy eating, sleep, sedentary or screen-time, and physical activity or active play) guidance and support (17), and targeting system-level determinants of a child's diet and movement behaviors, such as caregiver behaviors, household and external environments, and food supply chains (18). The main influence of health behaviors in the early years is the family and home environment (19), therefore family-focused health services are well placed to provide this multicomponent support. In Victoria, Australia, this opportunity is available through the universal free Maternal and Child Health (MCH) service which provides 10 consultations between birth and age 3.5 years, with an uptake of 83–97% in the first 12 months (20).

While still an understudied area, expert consensus is emerging regarding the conceptualization of sustained implementation, especially clarifying the definition, developing an underpinning framework, and advancing measurement/assessment criteria (21–30). Sustained implementation is considered to have occurred when, *"after a defined period of time, the program/intervention/strategies continue to be delivered and/or individual behavior change (i.e., clinician, patient) is maintained, either as originally planned or with some degree of adaptation, while continuing to produce benefits for individuals/systems*" (27, 31). Sustained implementation, originally described as "institutionalization" (32) and more recently as "routinization" (33), "maintenance" (30) and "continuation beyond financial security" (28) is less frequently investigated in comparison to adoption and initial implementation, often due to budgetary and timeframe constraints (34).

Barker et al. (35) propose sustained implementation be a consideration during program development, small-scale replication, and real-world "at scale" implementation. This proposition appears justified given the number of programs/interventions/strategies implemented "at scale" that fail to be sustained long-term. In one of the earliest publications to examine the sustained implementation of public health programs, Scheirer (36) reported 40–60% were being implemented to some extent 1–6 years post program adoption. A multi-stage international literature search by Indig et al. (37) identified 40 public health interventions in high income countries (USA, Australia, Netherlands, Canada, UK, New

Zealand, Finland) that showed reliable evidence of being implemented "at scale" between 1990 and 2014, of which 80% were still being implemented "to some extent" largely through institutionalization (55%) or commercialization (20%). A recent realist review (38) of nutrition and/or physical activity interventions implemented "at scale" (at a State or National level) within Australia since 2010, found four of the identified seven interventions (57%) were still being implemented 8 years post program adoption (one national and three in New South Wales).

As highlighted by Glasgow et al. (39) more than 20 years ago, numerous evaluated interventions are "lost in translation" because implementation is not sustained in real-world settings. Further, the "Determinants of Diet and Physical Activity" (DEDIPAC) Knowledge Hub study (40), informed by two umbrella reviews, reported a lack of research providing detail of implementation processes from the perspective of the health professional, practitioner or policy-maker, especially after completion of research projects. Understanding what factors impact sustained implementation is therefore essential to inform the, often significant, investments made by public health and government entities in developing and implementing programs "at scale" in real-world settings (41). While there is a sense of urgency to implement programs "at scale" in order to maximize their reach (42), it would appear that selection of programs is often based on availability and opportunity rather than proven efficacy or ability for sustained implementation (43).

The present study explored barriers and enablers influencing sustained implementation of the *INFANT Program* following the cessation of the state-wide prevention initiative, Healthy Together Victoria. Sustained implementation was defined as delivery of the *INFANT Program* (six three-monthly program sessions with first time parents of infants aged 3–18 months using a group-based format) between 2016 and 2017. Perspectives were obtained from trained *INFANT* facilitators, providing important insights into implementation processes, barriers and enablers experienced by health practitioners tasked with program implementation in "real-world" settings. Ethical approval for this study was obtained through Deakin University (HEAG-H 183_2014).

Methods

Program context

The *INFANT Program* is believed to be the first of its kind to address obesity risk behaviors in the first 1,000 days of life using a universally delivered service. Delivered in Australia, this is an efficacious, group-based program for first-time parents, comprising six 1.5-hour sessions delivered at three-monthly intervals when their infant is aged approximately 3, 6, 9, 12, 15 and 18 months (44) with positive health outcomes evident for mother and infant (45). The evolution of the *INFANT Program* from randomized controlled trial to small-scale community-level implementation (46) and the varying models of program implementation used (47) have been reported elsewhere. In 2014, the *INFANT Program* was included as a strategy within the state-wide prevention initiative, Healthy Together Victoria (HTV) (48). HTV operated across Victoria (2011–2016) to deliver a package of programs and strategies using a systems approach, with specific health promotion workforce funding and support provided to 14 local government areas (LGAs),[1] based on socio-demographic indices and chronic disease risk factor prevalence. Due to national governance changes, funding ceased in 2015 (ahead of its scheduled 2018 end date) with the resultant cessation of HTV. Despite this early withdrawal of funding, a few LGAs continued to implement some of their activities, including the delivery of the *INFANT Program*. This provided an opportunity to investigate factors influencing the uptake and sustained implementation of the *INFANT Program* by LGAs, especially those previously receiving HTV funding.

Study design

This study used a multi-site qualitative exploratory approach to facilitate an in-depth understanding of barriers and enablers to the sustained implementation of the *INFANT Program* within Victoria, Australia (49). This was considered a pragmatic and appropriate approach given the intent was to explore constructs to inform future examinations of the area. The researchers followed the Consolidated criteria for reporting qualitative studies (COREQ) checklist (50).

Theoretical framework

The Consolidated Framework for Implementation Research (CFIR) (51) was selected as the underpinning theoretical framework as it offered the opportunity to explore a breadth of possible barriers and enablers across patterns of implementation (never, discontinued, ongoing). The CFIR comprises 37 constructs across 5 domains, each considered important for the adoption, implementation and embedding of interventions into routine practice (51) (Table 1). At the time of this study the CFIR was considered the most contemporary model available, underpinned by implementation research with practical application across diverse settings. Since this study was concluded, specific sustainability models have emerged, such as Integrated Sustainability Framework (ISF) (29). The use of the CFIR model to reflect elements of sustainability is however

1 Victoria, Australia, comprises 79 local government areas (LGAs) [municipalities] with elected councils providing governance in relation to local laws across a range of community services.

still considered relevant given the strong alignment between the constructs of the CFIR and ISF. The CFIR Guide Tool (CFIR Booklet (cfirguide.org) was used to develop survey and interview questions. (Table 1, Supplementary material 1). While the CFIR can be applied using a quantitative approach (52, 53), this study applied a qualitative approach as commonly used by others (54, 55).

Data instrumentation

Open-ended questions within the surveys were used to explore barriers and enablers to the sustained implementation of the *INFANT Program* following facilitator training, with follow-up interviews to explore findings in more depth (Supplementary material 1). Participants completed a 15-minute online survey regarding their perspectives of the *INFANT Program* training, reasons for attending training, intentions of program delivery after training, and tailored questions depending on the pattern of program implementation (never, discontinued, ongoing). The survey was structured according to pattern of implementation, with tailored questions framed by the CFIR domains (51) to identify enablers and barriers to ongoing (sustained) implementation. Questions comprised open-ended and 7-point Likert scale (completely disagree-completely agree) responses. Follow-up 30–45 min audio-recorded telephone interviews were conducted with consenting survey participants to explore survey responses further. Interview questions asked participants to reflect on organizational decision-making about the planning process, resourcing and support for the implementation of the *INFANT Program* after completing the face-to-face training.

Data collection

All Victorian-based staff who had completed the *INFANT Program* facilitator training between 2013 and 2017 ($n = 88$) were contacted, using email contact details provided during training registration. Those contacted were invited to complete an online survey and an optional telephone interview. Those consenting to an interview were contacted directly by PL to schedule a convenient date and time for the interview. All interviews were conducted by PL using a semi-structured interview guide, ranging in duration from 21–47 min. Audio-recorded interviews were transcribed verbatim by an external agency. No incentives were offered to participate in the study.

Of the 88 Victorian-based *INFANT Program* trainees, two were not contactable, four were on leave and 16 had moved to other positions, resulting in a final sample size of 63 participants, representing 16 LGAs (six regional and 10 metro) at various stages of implementation (never implemented $n = 6$; discontinued implementation $n = 5$; ongoing implementation $n = 5$). Thirty-one participants completed the online survey, with 11 consenting to follow-up interviews, representing 14 LGAs across all patterns of implementation (never implemented $n = 4$; discontinued implementation $n = 5$; ongoing implementation $n = 5$).

Data analysis

Qualitative data analysis was underpinned by a contextualist epistemology, where knowledge emerges from and is situated within the context of the data (56). As the interpretation of qualitative data can be influenced by the roles and backgrounds of the researchers, these are made explicit. All researchers have a health qualification and work within a research context. At the time of the study MW was a research assistant with nutrition experience, and PL, RL, and ST were postdoctoral researchers with experience in the implementation of public health nutrition interventions at a community level. MW, ST, PL, and RL had no involvement in the development of the *INFANT Program*. RL had specific involvement in evaluating the small-scale community implementation of the *INFANT Program*. KDH and KJC are chief investigators of the *INFANT Program*, responsible for its development, randomized control trial, small-scale community implementation, and ongoing evaluation.

A reflexive thematic analysis approach, as described by Clarke et al. (57), was undertaken using open-ended survey responses and interview transcripts to determine shared meaning underpinned by the CFIR domains (51). Data were coded deductively (informed by the CFIR framework) and inductively (to identify other codes) using NVIVO v12 (QSR International, Melbourne, Australia (58). A sub-sample of interviews was coded independently by three co-authors (PL, ST, and MW), followed by discussion regarding interpretation and application of the coding framework. All coding was completed by MW. NVIVO coding summaries were used for case comparison analysis to identify similarities and differences between barriers and enablers for different patterns of implementation across the LGAs, namely, never, discontinued, and ongoing (sustained) implementation. Consensus on final theming was developed in agreement between PL, RL, KDH, and KJC. As an exploratory study with a small sample size, data saturation was not a consideration.

Results

Description of participants

Thirty-one participants completed the online survey, with 11 consenting to follow-up interviews. All participants were female, mainly between the ages of 40–59 years (71%). Most participants were Maternal and Child Health Nurses (48%), followed by dietitians (2.5%), and

TABLE 1 Consolidated framework for implementation research (CFIR) (51).

Domain	Construct	Example questions used for surveys (S) /interviews (I) (see Supplementary material 1 for detail)
Intervention characteristics	• Intervention source development and implementation decision-making process • Strength and quality of evidence to support choice of intervention • Relative advantage of implementing intervention versus an alternative • Adaptability of intervention to meet local needs • Trialability of intervention prior to implementation • Complexity and difficulty of implementation • Design quality and packaging of intervention • Costs associated with implementation	• What were the reasons why you attended the facilitator training? (S; I) • What did you know about the *INFANT Program* (if anything) before you attended the facilitator training? (I) • In your opinion, why do you think it was decided that the *INFANT Program* should/not be implemented in your area? (S; I)
Outer setting	• Patient needs and resources met in relation to implementation barriers/enablers • Cosmopolitanism (organization networks with other external organizations) • Peer pressure to implement intervention • External policy and incentives (mandates, strategies) to spread intervention uptake	• In your opinion, why do you think it was decided that the *INFANT Program* should/not be implemented in your area? (S; I) • What factors do you think helped /hindered the implementation of the *INFANT Program* in your area? (S; I) • How was the decision made that the program would/not be implemented in your organization? (I)
Inner setting	• Structural characteristics of the organization, such as maturity, age and size • Networks and communications (informal or formal) within organization • Culture, norms, values and basic assumptions of the organization • Implementation climate (receptivity, compatibility, relative priority, incentives) • Readiness for implementation (leadership engagement and commitment, available resources, access to knowledge, information incorporated into work tasks)	• Was the decision influenced by any other organizations implementing the *INFANT Program*, and if so, how? (I) • How does the *INFANT Program* fit within existing services within your organization? (I)
Implementer characteristics	• Knowledge and beliefs about the intervention and value placed on intervention • Self-efficacy/belief in own capabilities to implement intervention to achieve goals • Individual stage of change (level of preparedness to implement intervention) • Individual identification with the organization (commitment to organization) • Other personal attributes (learning styles, capacity, competency, motivation, etc.)	• What did you know about the *INFANT Program* (if anything) before you attended the facilitator training? (I) • How well did the training prepare you to implement the *INFANT Program* in your area? (I)
Implementation process	• Planning processes for implementation • Engagement strategies (with opinion leaders, champions, key stakeholders) • Executing according to implementation plan • Reflecting and evaluating (qualitative and quantitative feedback on progress)	• How was the *INFANT Program* planned and implemented in your area? (I) • How have you gone about evaluating the *INFANT Program* in your organization? (I)

in part-time roles (68%). Across all LGAs, the main reason for attending *INFANT Program* training was to become skilled to implement the program. The majority of participants attended training to take on the role of program facilitator (88%), and "mostly" and "completely" agreed that training provided the necessary knowledge (81%) and confidence (74%) to implement the *INFANT Program* (Table 2).

TABLE 2 Descriptive data of study participants by pattern of implementation.

Study participant descriptor		Pattern of implementation ($n = 31$ survey responses)			
		Total	Ongoing	Discontinued	Never
Gender	Female	31	15	11	5
Age	20–29 years	3	3	0	0
	30–39 years	4	3	1	0
	40–49 years	12	5	6	1
	50–59 years	10	4	3	3
	60+ years	2	0	1	1
Profession	Maternal child health nurse	15	8	5	2
	Dietitian	8	6	0	2
	Health promotion officer	2	1	1	0
	Early childhood professional	2	0	1	1
	Social worker	1	0	1	0
	Early intervention worker	1	0	1	0
	Children and family resource officer	1	0	1	0
	Bicultural families and children officer	1	0	1	0
Full/Part-time	Full time	10	5	3	2
	Part-time	21	10	8	3
Years in role	<5 years	7	5	2	0
	5–10 years	9	6	3	0
	11–15 years	4	2	1	1
	>15 years	11	2	5	4
Reason for attending training (multiple options)	Intention to deliver	16	7	8	1
	Gain additional knowledge	11	6	3	2
	Learn about the program	19	10	4	5
	Personal professional development	10	5	3	2
	Organization already delivering	10	8	2	0
Program LGAs	HTV-funded (7 LGAs)	21	11 (2 LGAs)	9(4 LGAs)	1 (1 LGA)
	Non-HTV funded (7 LGAs)	10	4 (3 LGAs)	2(1 LGA)	4 (3 LGAs)

Patterns of implementation

Online survey participants represented 14 LGAs across all patterns of implementation (never implemented $n = 4$; discontinued implementation $n = 5$; ongoing implementation $n = 5$). Of these LGAs, 11 participants consented to interviews representative of all patterns of implementation (never implemented $n = 3$; discontinued implementation $n = 4$; ongoing implementation $n = 4$). All patterns of implementation were evident across regional and metro LGA locations. Regional LGAs ($n = 5$) reported $n = 1$ as never implemented; $n = 2$ with discontinued implementation; and $n = 3$ with ongoing implementation. Metro LGAs ($n = 9$) reported $n = 3$ as never implemented; $n = 3$ with discontinued implementation; and $n = 2$ with ongoing implementation. Of the 14 LGAs, seven (3 regional; 4 metro) had received specific health promotion workforce funding through the HTV initiative (never implemented $n = 1$; discontinued implementation $n = 4$; ongoing implementation $n = 2$), and seven were non-HTV funded (never implemented $n = 3$; discontinued implementation $n = 1$; ongoing implementation $n = 3$) (Table 2).

Barriers and enablers to sustained implementation

Mapping identified barriers and enablers to the CFIR (Supplementary material 2) revealed the inner and outer settings and implementation process to be of greatest influence.

Inner setting

Organizational implementation climate and readiness for implementation were most frequently described by participants. LGAs that had never implemented the *INFANT Program* felt

that the *"timing was not right"*, with a lack of agreement between organizations regarding the implementation approach. These LGAs also reflected on limited leadership engagement and the lack of a program "champion". A lack of management support was the main barrier cited by the HTV-funded LGA that had never implemented the *INFANT Program* whilst a lack of funding and availability of staff to coordinate and deliver the program were main barriers cited by non-HTV funded LGAs with no implementation—*"I'm sure it can be done it was just too hard for us without resources at our disposal" [Never implemented, metro LGA].*

LGAs with discontinued or ongoing implementation felt the *INFANT Program* was highly compatible with existing services and a priority. LGAs with discontinued implementation reflected that the program was competing with other priorities, and in some cases, other programs. The main barrier cited by all four HTV-funded LGAs that had discontinued implementation was the cessation of funding—*"(HTV) funding ceased, and management deemed it [the INFANT Program] was no longer needed" [Discontinued implementation, metro LGA].* The non-HTV funded LGA that had discontinued implementation cited a lack of management support and poor program attendance as the main barriers.

Only LGAs with ongoing implementation described consideration of sustained implementation at the start—*"We made the decision at the start that it [INFANT Program implementation] was going to keep going beyond the funding time… we needed to embed it into services that we have already" [Ongoing implementation, regional LGA].* LGAs with ongoing implementation also mentioned the importance of establishing organizational connections prior to undertaking the training to achieve early buy-in. For both HTV-funded and non-HTV funded LGAs, management support was cited as the main enabler to implementation.

Available implementation capacity and resources was described as a limiting factor by LGAs across all patterns of implementation, especially when attendance rates were low, and even if program delivery was incorporated into staff roles as *"once (HTV) funding stopped, the positions stopped" [Discontinued implementation, regional LGA].* LGAs with ongoing implementation described how staff capacity had been created through the allocation of health promotion hours within existing staff roles, clarifying role responsibilities between partner organizations (such as referrals by maternal child health, and scheduling by community health), and establishing designated administration support to streamline enrolment, reminder notifications, and securing venues. LGAs with discontinued or ongoing implementation described strong organizational engagement, especially between dietetic and maternal child health services.

Outer setting

Across all patterns of implementation, LGAs described the *INFANT Program* as meeting a community need, complementing and strengthening the universal Maternal and Child Health (MCH) Service offered across Victoria. LGAs that had never implemented suggested that the program be promoted more as *"people haven't any idea of what it is or the benefits" [Never implemented, metro LGA]* and commented on the need to consider more contemporary approaches to program delivery in line with current technology -*"introducing the electronic form of it… because most people have smartphones" [Never implemented, metro LGA].*

All LGAs expressed a desire to be connected with local organizations to assist with program recruitment, implementation and to provide *"positive feedback from another organization already running the program" [Ongoing implementation, regional LGA].* Access to the *INFANT Program* research team for implementation guidance was a valued support by LGAs with discontinued or ongoing implementation.

LGAs with discontinued or ongoing implementation suggested better alignment between funding and policy directives, with recurrent funding, resourcing and monitoring to enable sustained implementation—*"It would be lovely to just be able to do it in a fully funded, dedicated way… through state or federal funding… in the same way that other services are provided then you can dedicate staff to it" [Discontinued implementation, regional LGA].*

Across all LGAs, two main models of program implementation were apparent, one led by the MCH team (based within local government) and the other a partnership between the MCH team and dietitians (based within community health). All LGAs with ongoing implementation had a partnership model in place.

Implementation process

While LGAs across all patterns of implementation described the *INFANT Program* as aligning to existing services and having the potential to replace ad hoc group information sessions, only LGAs with ongoing implementation spoke about integration of the program into service provision. Examples included delivery of the first *INFANT Program* session as part of existing New Parent Groups, enrolling participants into all sessions with automated reminder notifications and opt-out consent (rather than individual session enrolment) and offering "open" groups so participants could attend any missed sessions. LGAs with discontinued and ongoing implementation both made adaptations to program delivery, predominantly delivering four of the six sessions (3, 6, 9, and 12 months) given the high attrition rates at the 15 and 18 month sessions. LGAs all described undertaking some form of program evaluation, expressing concerns about unrealistic targets, what data to collect, and participant burden.

The importance of engagement and involvement of key partner organizations and stakeholders was evident across all patterns of implementation. LGAs that had never implemented the *INFANT Program* echoed their feedback regarding a lack of consensus by partner organizations about the appropriate implementation approach, with no opinion leaders or program champions. LGAs with discontinued implementation spoke of the need for a designated implementation team so that implementation was not in addition to existing workloads—*"… to do it properly… get all the admin done… all that really needs a designated team. We were a bit caught between what we were already doing…" [Discontinued implementation, regional LGA].* LGAs with ongoing implementation described the partnership between dietetic (community health) and maternal child health (local council) as ideal for the implementation of the *INFANT Program*, but that this required a shared understanding and clarity regarding implementation roles and responsibilities. Engagement with "external change agents" was suggested across all patterns of implementation and included the promotion and/or extension of the *INFANT Program* into childcare centers, playgroups, and ante-natal groups.

Intervention characteristics

Across all patterns of implementation, LGAs were aware of the *INFANT Program* prior to attending training, through professional conferences, colleagues and management, and as an endorsed HTV program. All LGAs considered the program to be evidence-based with strong research outcomes, offering a relative advantage to the organization in terms of alignment with current MCH services, and providing consistency of information to parents. LGAs with ongoing implementation regarded the program as "value-adding" by providing a more structured approach, replacing ad hoc group information sessions *"to allow time to deliver INFANT Program which covers these topics plus more" [Ongoing implementation, metro LGA].* LGAs with discontinued or ongoing implementation described similar complexities in relation to scheduling of sessions with similar aged infants, and venue availability and costs. Regional LGAs in particular were challenged by small birth rates and large geographical distances which limited attendance rates and group size. Costs associated with the *INFANT Program* were described in terms of implementation capacity, and not in relation to accessing training or program resources.

All LGAs described the need to consider flexibility with implementation of the *INFANT Program* to meet community needs, such as providing more visual images or using an interpreter for different cultural groups, tailoring delivery for groups with mixed age groups, and most commonly, providing fewer sessions given the low attendance rates at the 15 and 18 month sessions. One non-HTV funded LGA that had never implemented the program was concerned about how much flexibility and adaptation could be applied before impacting on program fidelity—*"[I'm} concerned that adapting the program by combining sessions or offering them in other formats does not have the evidence base" [Never implemented, metro LGA].*

LGAs across all patterns of implementation considered the training and website resources to be of high quality. LGAs with ongoing implementation described the training as enhancing group facilitation skills. LGAs with discontinued implementation felt the training had reinforced existing knowledge, enhancing levels of confidence to deliver program sessions. LGAs that had never implemented expressed a need for specific implementation guidance and examples of how LGAs had implemented the program, especially where this had occurred without additional funding.

Implementer characteristics

Across all patterns of implementation, study participants considered themselves to possess the appropriate knowledge and beliefs to implement the *INFANT Program*, describing the delivery of infant feeding and active play information to parents as *"our bread and butter"* and *"part of our core work" [Ongoing implementation, metro LGA].* LGAs with both discontinued and ongoing implementation described the training as enhancing levels of confidence to present the content and facilitate the group discussion in a different way, with *"a greater focus on active listening" [Ongoing implementation, regional LGA].*

Discussion

This study explored barriers and enablers to sustained implementation of an early childhood health behavior program for parents, the *INFANT Program,* during small scale implementation in Victoria, Australia, from the perspective of trained *INFANT* facilitators. Challenges regarding complexities of program implementation were apparent across all patterns of implementation, with requests for specific implementation guidance and connections with other LGAs achieving successful implementation. The main differences between LGAs with ongoing and discontinued implementation related to the "inner and outer setting" and "implementation process", specifically, funding availability, organizational resourcing and capacity, organizational management support and endorsement, integrating implementation into routine practice, establishing early buy-in and role clarity with partner organizations, and planning for sustained implementation from the start.

The enablers and barriers identified in this study are similar to those reported in the literature and can therefore be considered to have relevance to other health promotion interventions. Muellmann et al. (40) describe five main enablers, relevant to multi-level interventions and policies promoting healthy eating and physical activity, namely, stakeholder networks, structures in settings, continued funding and

political support, standardized training of staff with detailed implementation protocols, and socio-cultural tailoring of content to fit the needs and context of the targeted population. In addition to these enablers, Mikkeslen et al. (59) report the need for capacity building of health professionals across health, education and community settings, including pre-service and in-service training, so that implementation activities continue after any research support concludes. Similarly, systematic reviews of health promotion (28), community-based obesity prevention (23), healthcare (22), schools and childcare services (60) and public health (61) interventions highlight the importance of several recurring enablers, namely: strategic planning, program alignment, integration into existing programs and policies, accessing new/existing money to facilitate sustainment, leadership prioritization and support to mobilize implementation, adequate human resourcing, workforce development and capacity building regarding implementation planning and evaluation, systematic adaptation to enhance compatibility of the intervention with the organization, monitoring progress and demonstrating effectiveness, and establishing organizational partnerships.

The provision of external funding through the HTV initiative was a key catalyst for *INFANT Program* implementation, however four of the seven HTV-funded LGAs discontinued implementation once HTV funding ceased. LGAs with ongoing implementation of the *INFANT Program* utilized strategies that were not reliant on external funding support, in particular, creating staff capacity through the allocation of health promotion hours within existing staff roles, and establishing a partnership model for implementation between community health dietetic and maternal child health services. Cross-disciplinary and cross-organizational partnerships, with a shared agenda, can frequently add tangible resources to the implementation process (62). Investment in organizational capacity and infrastructure creates a foundation for the intervention activities to continue if/when external resources, such as a research team or government agency, are discontinued (59).

For both HTV-funded and non-HTV funded LGAs, management support was cited as the main enabler to ongoing implementation. The role of leaders and transformational leadership in supporting sustained implementation is well documented (23, 52, 63, 64) in the form of policy and reward systems, organizational decision-makers, and community champions. Effective leaders can mobilize capacity and collaboration, frequently overcoming organizational indifference or opposition to a new intervention. Leaders are also instrumental in generating program awareness and securing ongoing investment. The uptake of the *INFANT Program* by HTV-funded LGAs is indicative of the leadership endorsement of the program as part of the HTV initiative. With the cessation of the HTV initiative, the loss of this endorsement and the removal of funding resulted in many HTV-funded LGAs discontinuing their implementation of the *INFANT Program*.

Early consideration of sustained implementation was identified as a common strategy by LGAs with ongoing implementation of the *INFANT Program*. This view complements the growing consensus that sustained implementation should be considered from the beginning of the implementation process, with dedicated planning to define program components and determinants to inform appropriate implementation strategies (28). An integral part of this early planning phase includes dedicated exploration of an organization's readiness in terms of commitment and capability for implementation, which has now been incorporated as a consideration during *INFANT* facilitator training. When organizational readiness for change is high, organizations display greater initiation, persistence and cooperation to achieve successful implementation (53, 65). In a recently updated systematic review, Miake-Lye et al. (66) mapped organizational readiness assessment instruments to the CFIR, and identified "readiness to implementation" as the most commonly reported construct.

The challenge of fidelity and adaptation was identified as a barrier by LGAs that had never implemented the *INFANT Program* post facilitator training. These LGAs described being unsure what degree of adaptation would be possible without impacting program fidelity and were seeking specific implementation guidance. The assumption that intervention effects lessen if implemented "at scale" without careful adherence to research protocols has been challenged by Chambers et al. (34) who suggest that this constrains the intervention "fit" (compatibility) within the given context and positions sustained implementation as "the endgame". They propose that sustained implementation be a consideration throughout the implementation process to accommodate adaptation so that the intervention becomes integrated into the local context (34). To facilitate a more precise understanding of adaptations made to the *INFANT Program* when implemented in real-world settings, comprehensive documentation using the Framework for Reporting Adaptations and Modifications-Enhanced (FRAME) (67) has subsequently been incorporated into the *INFANT* Effectiveness-Implementation Trial (68) to inform the timing, context and process for adaptation to facilitate sustained implementation. Capturing intervention adaptation is a key inclusion to establish the degree to which intervention components are modified for organizational compatibility without jeopardizing intervention outcomes.

De-implementation strategies are likely to become an important consideration for the sustained implementation of the *INFANT Program*, as LGAs all commented about competing organizational priorities and the need for flexibility to meet community needs, such as tailoring session content and/or delivery mode. Acknowledging that intervention adaptation, whether organic or planned, occurs and is beneficial to

sustained implementation, elicits an additional consideration of de-implementation of intervention strategies /components considered no longer compatible or effective (30). De-implementing detrimental or redundant practices is distinct from implementing evidence-based practices, and is considered more difficult, requiring more intense strategies. Norton and Chambers (69) propose four types of de-implementation actions—removing, replacing, reducing or restricting the use of a specific intervention strategy /component. They suggest that future research identify and map specific sustainment barriers to appropriate de-implementation strategies, as is done for implementation strategy development, as well as optimal timeframes and pace at which de-implementation should occur, to mitigate potential harm or unintended negative consequences.

Implications for the *INFANT Program*

This study has provided the opportunity to investigate sustained implementation of the *INFANT Program* during small scale community-level implementation. The factors influencing sustained implementation of the *INFANT Program* highlight a number of organizational (inner) and system-level (outer) barriers and enablers that are interconnected around prioritization and endorsement, leadership and management support, human and financial resourcing, and capacity building.

These study findings have contributed important insights in preparation for large scale implementation across Victoria and its associated effectiveness-implementation trial (68). Findings have informed the refinement of intervention characteristics, namely, online facilitator training and refresher training and a community of practice (collaborative online forum), and delivery as four group sessions (3–12 months) supplemented with app-based messages (birth to 18 month). Post COVID-19 and the emergence of telehealth, virtual (online) group delivery has also become a consideration for future exploration. Findings have also informed the selection of specific implementation strategies to support adoption and sustained implementation of the *INFANT Program* across local government areas. Using the Expert Recommendations for Implementing Change (ERIC) compilation (70), key strategies have been selected to address barriers to sustainability, namely:

- Accessible, incentivised online training, an online community-of-practice, and a Statewide training coordinator role to build capacity of organizational implementers
- Statewide implementation coordinator role to facilitate implementation planning with local organizations, and capture intervention modifications
- Early assessment of organizational implementation readiness and timely provision of appropriate implementation support, such as implementation case studies available on the *INFANT Program* website [Deliver *INFANT* | *INFANT* (infantprogram.org)]
- Leveraging key state and local level policy opportunities to embed *INFANT Program* delivery, such as the Victorian government's *Healthy Kids, Healthy Futures* 5-year action plan (71), and the *Victorian Public Health and Wellbeing Plan 2019–2023* (72).

Furthermore, the *INFANT* effectiveness-implementation trial (68) will include an evaluation timepoint at 24-months post facilitator training which will assess program sustainability using the Program Sustainability Assessment Tool (self-administered surveys) (73) with follow-up in-depth interviews.

Implications for research

Since completion of this study, Shelton et al. have developed the Integrated Sustainability Framework (ISF) (29) which proposes key multilevel factors needed for sustained implementation of interventions across settings and contexts, namely, outer contextual characteristics (policy environment and funding, organizational partnerships), inner contextual characteristics (organizational infrastructure and support, leadership and program champions, funding), implementation processes (e.g., recruitment, training, strategic planning and communication, evaluation), characteristics of interventionists (role commitment and motivation, self-efficacy, payment), and intervention characteristics (perceived benefit/need for program, program fit and adaptability). The ISF factors are similar to those identified in the CFIR used in this study (51). Future research utilizing the ISF would be useful to advance the application of a specific framework to guide implementation sustainability research.

Strengths and limitations

This study used a recognized theoretical framework within the field of implementation science, the Consolidated Framework for Implementation Research (CFIR) (51). Described as a determinant framework, mapping identified barriers and enablers to the CFIR advances understanding of how and why sustained implementation occurs across multiple levels of influence using a systems approach (74). While a relatively small sample size, the response rate was high (49.2%) for this type of research with almost equal representation of LGAs across all patterns of implementation (never, discontinued and ongoing), reducing the risk of social bias. The online survey questions were informed by the literature. Closed response options may have limited participant responses, however, open-ended response fields were also provided to elaborate on survey

responses, and participants were offered an optional interview opportunity to expand on responses. This study collected data in 2017 from *INFANT Program* facilitators who completed their training between 2013 and 2017 with training completion dates evenly distributed across patterns of implementation, therefore any effects of potential participant recall bias would have been similarly distributed.

Conclusion

This study provides important insights into the barriers and enablers to the sustained implementation of an evidence-based intervention (the *INFANT Program*) during small scale community-level implementation. The opportunity to gain insights on real-world implementation prior to delivery at-scale is rare, with decisions to scale-up interventions frequently occurring without adequate evidence of effectiveness and/or sustainment (43). The authors therefore contend that the pre-requisite for scale-up of a population health intervention is not just proof of effectiveness (75) but also proof of sustained implementation at the local/organizational level. In addition, assessment of implementation readiness should occur beyond the stages of adoption and early implementation to inform strategies that support sustained implementation. The use of hybrid type 2 effectiveness-implementation trials is therefore strongly recommended to achieve such concurrent evaluation (68, 76).

The factors influencing sustained implementation of the *INFANT Program*, predominantly organizational and system-level barriers and enablers, have broad transferability given their remarkable similarity to those identified for health promotion interventions implemented across the world, in healthcare, education and community settings. This study is a reminder that sustained implementation requires investment, effective governance, partnerships and supportive systems. These should be fundamental inclusions when planning "at scale" intervention delivery to optimize opportunities to integrate intervention components into routine practices and policies thereby sustaining implementation.

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 Deakin University Human Ethics Advisory Group-Health (HEAG-H 183_2014). The patients/participants provided their written informed consent to participate in this study.

Author contributions

PL, RL, and KJC conceived and designed the study. PL obtained study ethics and undertook recruitment and study interviewees. ST and MW analyzed the data with cross-checking by PL. PL led the manuscript writing with input from all authors. All authors approved the manuscript for submission.

Funding

The *INFANT* RCT trial was funded by a NHMRC grant (APP425801). Additional funds were supplied by the Heart Foundation Victoria and Deakin University. The *INFANT* Follow-up Study of outcomes at 3.5 and 5 years was funded by a NHMRC grant (APP1008879). RL held an NHMRC ECR Fellowship (#1089415) when conducting the small-scale implementation study. During this current study, PL and ST were funded through the NHMRC CRE for Early Prevention of Obesity in Childhood (EPOCH). KDH is supported by a Heart Foundation Future Leader Fellowship (#105929). The *INFANT* Effectiveness-Implementation Trial is funded by a NHMRC Partnership Grant (APP1161223) and VicHealth.

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.2022.1031628/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 30 November 2022
DOI 10.3389/frhs.2022.1004167

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 27 July 2022
ACCEPTED 09 November 2022
PUBLISHED 30 November 2022

CITATION
Bacon C, Malone S, Prewitt K, Hackett R, Hastings M, Dexter S and Luke DA (2022) Assessing the sustainability capacity of evidence-based programs in community and health settings. *Front. Health Serv.* 2:1004167. doi: 10.3389/frhs.2022.1004167

Assessing the sustainability capacity of evidence-based programs in community and health settings

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Background: Within many public health settings, there remain large challenges to sustaining evidence-based practices. The Program Sustainability Assessment Tool has been developed and validated to measure sustainability capacity of public health, social service, and educational programs. This paper describes how this tool was utilized between January 2014 and January 2019. We describe characteristics of programs that are associated with increased capacity for sustainability and ultimately describe the utility of the PSAT in sustainability research and practice.

Methods: The PSAT is comprised of 8 subscales, measuring sustainability capacity in eight distinct conceptual domains. Each subscale is made up of five items, all assessed on a 7-point Likert scale. Data were obtained from persons who used the PSAT on the online website (https://sustaintool.org/), from 2014 to 2019. In addition to the PSAT scale, participants were asked about four program-level characteristics. The resulting dataset includes 5,706 individual assessments reporting on 2,892 programs.

Results: The mean overall PSAT score was 4.73, with the lowest and highest scoring subscales being funding stability and program adaptation, respectively. Internal consistency for each subscale was excellent (average Cronbach's alpha = 0.90, ranging from 0.85 to 0.94). Confirmatory factor analysis highlighted good to excellent fit of the PSAT measurement model (eight distinct conceptual domains) to the observed data, with a comparative fit index of 0.902, root mean square error of approximation equal to 0.054, and standardized root mean square residual of 0.054. Overall sustainability capacity was significantly related to program size ($F = 25.6$; $p < 0.001$). Specifically, smaller programs (with staff sizes of ten or below) consistently reported lower program sustainability capacity. Capacity was not associated with program age and did not vary significantly by program level.

Discussion: The PSAT maintained its excellent reliability when tested with a large and diverse sample over time. Initial criterion validity was explored through the assessment of program characteristics, including program type

and program size. The data collected reinforces the ability of the PSAT to assess sustainability capacity for a wide variety of public health and social programs.

KEYWORDS

sustainability capacity, implementation science, program sustainability, evidence-based interventions, community, health

Introduction

What enables programs to continue delivering effective services over time? This is an important question funders and public health leaders pose as they look beyond the initial investment and implementation of a program. As Shelton et al. (1) note, funders want to know the investment they make into a program will continue to have an impact long after the investment ends. In addition, communities come to rely on these programs and if they end prematurely it may have lasting consequences. The discontinuation of these programs results in communities developing "low levels of community support and trust in research and public health/medical institutions" therefore creating challenges to future community efforts (1, 2). Program sustainability has been identified as critical for realizing the long-term impacts of a program. However, researchers and practitioners still lack knowledge about how to measure or enhance sustainment of public health or clinical care programs. The growing evidence base in dissemination and implementation science focuses mostly on the translation of research into practice to develop effective programs and policies (1). Many implementation science studies focus on the early stages of implementation and short-term outcomes; thus there is an important research and evaluation opportunity focusing on how effective programs are sustained over time after their initial adoption (1, 3, 4).

Sustainability has been defined as the ongoing use of an intervention with enough fidelity to continue to have desired program impact with subsequent improved outcomes (1). In addition to this foundational definition, recent empirical work has examined various research and measurement aspects of assessing sustainment in public health settings (5–8). Together, this information to improve sustained implementation will help both researchers and practitioners realize the full impact of their programs and practices.

Despite these research successes, it remains challenging for practitioners to maintain evidence-based activities and programs across a wide range of settings. Public health and community programs often depend on time-limited financial resources, after which programs are expected to secure alternative funding (9). Programs may also lose political and community support, become targets of political or commercial opposition, or face organizational challenges such as staff turnover (1). Sustaining programs that work is the main way we can ensure that communities get their intended health benefits; for that reason it is critical to be able to measure and understand the factors influencing program sustainability.

Public health program sustainability can take many forms (10). For example, practitioners can seek to maintain program activities, community-level partnerships, organizational practices, benefits to clients, and the salience of the program's core issue (11). However, little is known about how a program can best position itself to deliver these outcomes over time. Research and theory on the concept of value-based care has also focused on some of these organizational activities and describes a need to focus on overall value of care and team-based care instead of simply focusing on reducing costs of care (12). By focusing on building sustainability capacity, or the structures and processes that allow a program to leverage resources to effectively implement and maintain evidence-based policies and activities, programs can better understand and strengthen the factors within their control to increase the likelihood of maintaining benefits to clients in some form over time (10).

To better understand the factors that affect a program's ability to deliver benefits over time, Schell et al. (10) developed a sustainability conceptual framework using concept mapping, reviews of the implementation science literature, and expert input. This framework identifies a set of organizational factors affecting program sustainability capacity. These factors are organized into external (environmental support, funding stability) and internal (partnerships, organizational capacity, program evaluation, program adaptation, communications, and strategic planning) domains (see Figure 1).

This eight-domain conceptual framework is useful to help programs and organizations looking to understand the factors beyond simple funding that affect a program's capacity for sustainability. For example, programs that collect evaluation data about their processes and outcomes can better demonstrate the necessity of their program to leadership and stakeholders (13). Communicating concise outcome data to policymakers and showing a program's impact on the community better positions the program for continued funding and support (14).

To address the relative lack of tools available to evaluate program sustainability, Luke et al. (15) translated the program sustainability conceptual framework into a measurement instrument: the Program Sustainability Assessment Tool (PSAT). The development of the tool was guided by four basic design principles: (1) short and easy to use; (2) usable by both

FIGURE 1
Conceptual domains for the program sustainability framework.

small and large programs; (3) applicable to a wide variety of program types; and (4) useful as a research, evaluation, and program planning tool.

The PSAT was originally created to reflect the concepts represented in each of the eight domains in the program sustainability framework (10). The assessment instrument was developed and tested on over 250 state and local public health programs across a variety of program types (tobacco control, obesity, nutrition, etc.). Psychometric analyses of the PSAT using these original data demonstrated good reliability (i.e., internal consistency) and confirmatory factor analysis supported the suitability of eight domains measured by five items per domain (15).

The PSAT was designed to allow comparisons between programs as well as within-program comparisons over time. Since 2014, the tool has been used by more than 5,000 people to rate sustainability capacity of more than 2,500 public health, social services, clinical care, and education programs of varying sizes in the US and internationally. Among many others, the PSAT has been used to examine the sustainability capacity of inter-professional collaborative practice model for population health, evidence-based practices in adolescent substance abuse, local health department programs and policies, and chronic disease prevention interventions (16–21).

The variety of settings and amount of use provides the opportunity for further exploration of program sustainability capacity across program type, size, implementation level, and age. An example application of the PSAT in public health programming is how the Centers for Disease Control & Prevention (CDC)'s Office on Smoking and Health requires state tobacco control programs create a sustainability plan and encourages programs to use the Program Sustainability Assessment Tool to drive sustainability planning (22). Additional departments within CDC (Division of Population Health, Division of Nutrition, Physical Activity and Obesity, and the Center for Putting Prevention to Work, among others) have encouraged their state programs to use the PSAT, as have other federal organizations (National Cancer Institute, Canadian Partnership Against Cancer), and many state health departments, health foundations, and professional networks (American Evaluation Association, Association of State Public Health Nutritionists, and CDC-OSH National Partner Network) (23).

In this paper we describe program sustainability capacity for public health, clinical care, social services, and education programs using data passively collected on https://sustaintool.org between January 2014 and January 2019. We also examine how a small set of programmatic factors are related to program sustainability capacity. This paper adds to the sustainability knowledge base in two important ways, first, by identifying characteristics of programs that are associated with organizational capacity for sustainability, and second by providing further evidence supporting the utility of the PSAT as a continuing part of the implementation science sustainability toolkit.

Methods

In this paper we report updated reliability, measurement model characteristics, and validity data for the Program Sustainability Assessment Tool (PSAT), which can be used to assess capacity for sustainability of a wide variety of public health, social service, and educational programs.

Measures

The PSAT (Additional File 1) consists of 40 questions, five items in each of eight domain subscales, with 7-point Likert-scale responses. Individual items can be rated from 1 (program has or does this to *no* extent) to 7 (program has or does this to the *full* extent). Subscale and total scores are the averages of the individual item scores, so scores can range from 1 to 7. Higher scores are interpreted as the program having greater sustainability capacity in that area (e.g., funding stability, program evaluation, etc.).

In addition to the PSAT total scale and subscale scores, participants provided information on four important program-level characteristics. *Program type* classified programs into five groups: public health, social service, clinical care, education, and other. As an example of a clinical setting, the PSAT has been used to examine the sustainability capacity of pediatric asthma care coordination (17). Public health programs both in the United States and abroad used the assessment. The Reducing Violence against Women and their Children grants program used the PSAT for funded prevention initiatives in diverse settings across Victoria, Australia to prevent violence against women (24). In the United states, Well-Ahead Louisiana, the state tobacco cessation and prevention program used the PSAT to assess their comprehensive statewide tobacco prevention efforts (25).

Program level captured how the program was organized and who it served. Programs were either community-level, state-level, or greater than state level. This latter category included national, tribal, and international programs. An example of a community-level program is the "Som la Pera" intervention; a school-based, peer-led, social-marketing intervention that encourages healthy diet and physical activity, in low socioeconomic adolescents (26). *Staff size* was the number of staff and personnel who were directly involved with the program or project being rated, including volunteers. *Program age* was the number of years that the program or project had been in existence.

PSAT data collection

The PSAT analyses presented here are based on PSAT profile and data passively collected on https://sustaintool.org/ between January 2014 and January 2019 through individual and group self-assessments. Per the site privacy statement (with associated Washington University IRB approval), users passively consented to analysis of their de-identified PSAT profile data upon submission.

After downloading the PSAT data from the web server, the raw data were cleaned up by deleting test entries, and entries that had missing data for every item in the PSAT. (These were due to people who visited the website, started the PSAT assessment, but quit before filling anything out.) After cleaning, the dataset included a total of 5,706 respondents reporting on 2,892 programs. Examining missing data patterns, 65% of the respondents filled out every one of the 40 items in the scale, and 96% filled out at least half of the items (≥20).

Users of the online PSAT can fill out an individual assessment (one person rating the sustainability capacity of an individual program), or a group assessment (multiple people rating the sustainability capacity of the same program). Of the 2,892 program assessments included in the dataset, 2,283 were individual assessments (79%). For group assessments, the respondent numbers ranged from 2 to 31, with a median group size of 5. The main purpose of this paper is to understand characteristics of program sustainability capacity, so the raw data were aggregated by program. Specifically, the group PSAT total and subscale scores were calculated by averaging the scores for all individuals taking part in a particular group assessment. So, the scores are meant to represent program and organizational characteristics, not individual characteristics.

Table 1 presents the program-level characteristics of the total PSAT sample. This sample includes a wide variety of types of programs. Almost half of the programs are public health (46%), followed by social service (20%), clinical care (15%), and education (10%). A large majority of the programs are organized at the community level (74%), but over 700

TABLE 1 Program characteristics of PSAT sample ($N = 2,892$ programs, based on 5,706 individual assessments).

Program characteristic	Number	%
Program type		
Public health	1,322	45.7
Social services	585	20.2
Clinical care	425	14.7
Education	293	10.1
Other	267	9.2
Program level		
Community	2,082	73.8
State	452	16.0
Beyond state	285	10.1
Staff size		
1–3	566	21.2
4–10	988	36.9
11–20	453	16.9
>20	668	25.0
Program age		
<1 year	696	25.5
1–3 years	804	29.5
>3 years	1,228	45.0

TABLE 2 PSAT subscale characteristics and reliabilities.

Scale	Mean	SD	Cronbach's α
Environmental support	5.08	1.13	0.85
Funding stability	3.97	1.41	0.88
Partnerships	4.47	1.43	0.92
Organizational capacity	4.98	1.22	0.89
Program evaluation	5.08	1.31	0.91
Program adaptation	5.23	1.23	0.92
Communications	4.64	1.42	0.94
Strategic planning	4.42	1.36	0.89
Total PSAT scale	4.73	1.04	NA

programs are organized at higher levels (e.g., state, national, international). Programs represent both small and larger organizations, ranging from 3 or fewer staff members (21%) to more than 20 members (25%). The programs also varied in age, ranging from <1 year of existence (26%) to over 3 years (45%).

Analyses

Frequencies and means were calculated to obtain descriptive statistics of the sample, as appropriate. One-way analyses of variance were conducted to understand PSAT score differences related to program focus, size, age and level. Two-way analyses of variance were conducted to assess the interaction between program focus and program size, age and level. Psychometric analyses were conducted to assess the reliability (internal consistency) of the eight PSAT subscales. Finally, confirmatory factor analysis was used to test the measurement model of the PSAT, and how well that measurement model fit with the observed PSAT data.

Results

The goal of these analyses is to describe the characteristics of the Program Sustainability Assessment Tool (PSAT) as it has been applied to rate sustainability capacity in a variety of settings and programs. These analyses can help determine if the psychometric properties have remained stable as the PSAT has been rolled out for wider application, and to assess how a small number of program characteristics are related to PSAT overall and subscale scores.

Overall PSAT characteristics

All of the scores for the PSAT were out of a possible total of 7, with 7 being the greatest extent of each domain. Across all programs, the mean PSAT score was 4.73 (Table 2). PSAT subscale scores were lowest for funding stability ($M = 3.97$), followed by strategic planning ($M = 4.42$), partnerships ($M = 4.47$), communications ($M = 4.64$), organizational capacity ($M = 4.98$), program evaluation ($M = 5.08$), environmental support ($M = 5.08$) and program adaptation had the highest average score ($M = 5.23$). Although the subscale and total mean scores are somewhat high relative to the seven-point scale, score variabilities are relatively high (standard deviations ranging from 1.13 to 1.43), indicating only minor issues with restriction of range. Figure 2 presents violin plots of the total and subscale scores, displaying the median values for each, as well as the score variabilities.

PSAT reliabilities and measurement structure

In our original PSAT development study, average internal consistency (Cronbach's alpha) of the 8 subscales was 0.88 and domain subscales ranged from 0.79 to 0.92 (15). In the current study, we had data on more programs, and these programs were more diverse (i.e., educational, clinical, social service, and public health programs). Despite the greater program diversity, psychometric analyses reveal that the PSAT maintains its excellent reliability (Table 2). Specifically, for the new data subscale reliabilities ranged from 0.85 to 0.94, with an average of 0.90.

In addition to the subscale reliabilities, we examined the domain structure of the PSAT using confirmatory factor analysis (CFA) to see how well the observed data matched our overall conceptual framework of eight distinct conceptual domains (see Figure 1). CFA results show an excellent fit of the data to the hypothesized measurement structure. Specifically, the fit indices for the eight factor model include the comparative fit index (CFI = 0.902), root mean square error of approximation (RMSEA = 0.054) and standardized root mean square residual (SRMR = 0.054). All indicate good to excellent fit (27–29). Furthermore, we compared the fit of the eight factor model to a simpler single factor model (that assumes that there is just a general concept of sustainability capacity that does not have a more complicated multi-domain structure). A comparison of the two models using Vuong's distinguishability test showed that the eight factor model was a significantly better fit to the data than the single factor model (LR = 47,277.2, $p < 0.001$) (30). More detailed results from the CFA analyses (including model fits and diagnostics) are available from the authors.

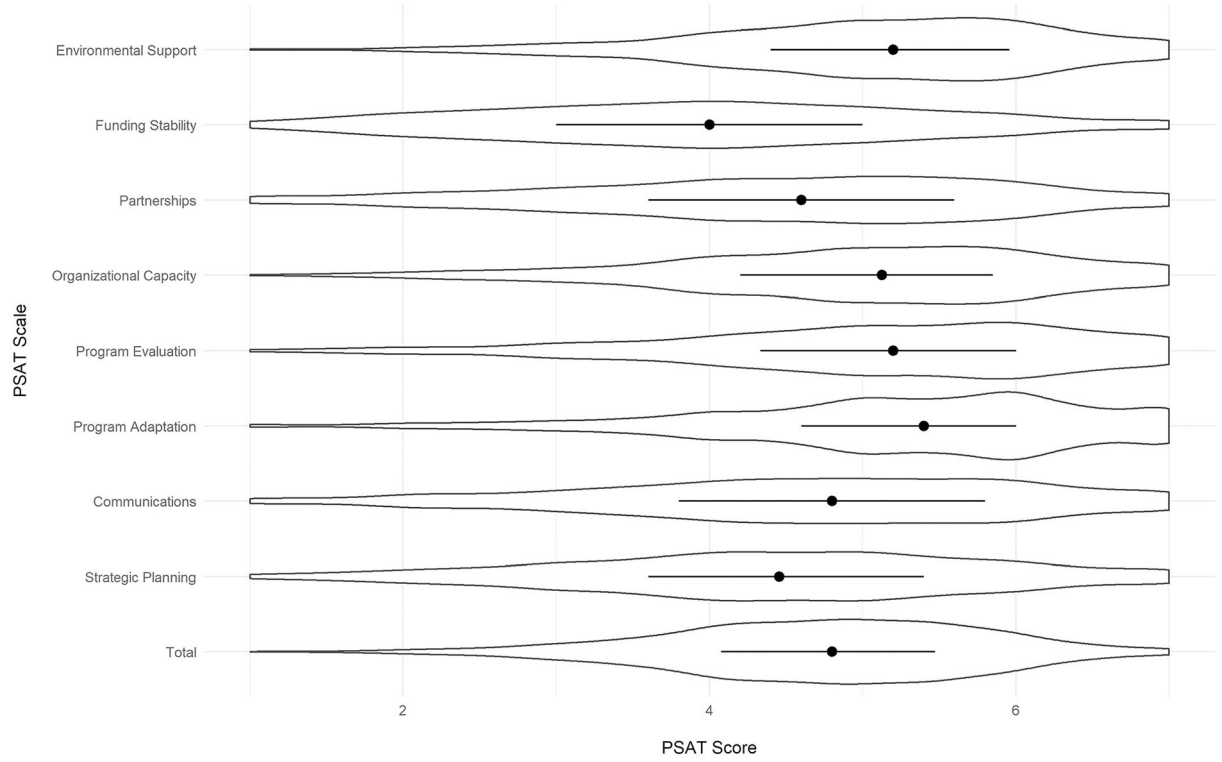


FIGURE 2
Variability of PSAT total and subscale scores (N = 2,892 programs).

TABLE 3 Tests of PSAT subscales score differences by program type, level, staff size, and age.

Scale	Program type		Program level		Staff size		Program age	
	F	*p*	*F*	*p*	*F*	*p*	*F*	*p*
Environmental support	7.92	0.000	0.10	0.903	21.08	0.000	0.26	0.773
Funding stability	10.10	0.000	3.06	0.047	17.25	0.000	7.03	0.001
Partnerships	22.91	0.000	1.03	0.358	27.22	0.000	1.19	0.305
Organizational capacity	2.38	0.068	2.39	0.092	20.06	0.000	0.24	0.791
Program evaluation	11.20	0.000	0.37	0.692	16.34	0.000	8.54	0.000
Program adaptation	21.11	0.000	2.19	0.112	5.54	0.001	7.26	0.001
Communications	6.82	0.000	6.95	0.001	9.11	0.000	2.68	0.069
Strategic planning	7.34	0.000	2.14	0.117	16.23	0.000	3.04	0.048
Total PSAT scale	8.66	0.000	0.61	0.542	25.56	0.000	1.49	0.226

PSAT characteristics by program type

PSAT scores were analyzed by program type for four types of programs: public health, social services, clinical care and education. Overall, PSAT total and subscale scores varied significantly by program type, except for organizational capacity (see Table 3). Clinical programs reported the highest total PSAT scores (M = 4.92), followed by public health (M = 4.78), social services (M = 4.64), and finally education (M = 4.61). Figure 3 shows the pattern of PSAT total and subscale scores by the four types of programs. Clinical programs tended to show higher subscale scores, especially for engaged stakeholders, financial stability, program evaluation, and program adaptation. Public health programs, on the other hand, showed higher scores on partnerships and communications. Social service programs have the lowest score profile of the four program types, with the possible exception of partnerships.

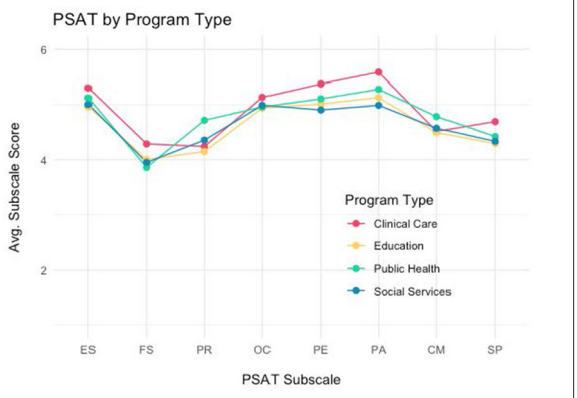


FIGURE 3
PSAT subscale scores by type of program.

Impact of programmatic factors on PSAT trends

Additional analyses were conducted to understand how program size, age and level impact sustainability capacity (Table 3). Overall sustainability capacity was significantly related to program size ($F = 25.6$; $p < 0.001$). In general, larger programs (>20 staff and volunteers, $M = 4.93$) were perceived as more sustainable than smaller programs (<4 staff and volunteers; $M = 4.47$). This pattern was apparent across all of the subscale domains as well-programs with three or fewer staff and volunteers reported significantly less capacity for sustainability compared to programs with 21 or more staff and volunteers for all eight of the subscales. Figure 4 shows the subscale means by size of the program, and there is a discernible dose-response pattern where larger staff sizes are associated with higher PSAT subscale scores.

In comparison, program level and program age were not as strongly or consistently related to sustainability capacity scores. Overall sustainability capacity was not associated with program age ($F = 1.49$; $p = 0.226$). However, older programs (>3 years, $M = 4.04$) reported higher capacity for funding stability ($M = 4.04$; $F = 7.03$; $p = 0.001$), while younger programs (<1 year) showed greater capacity in program evaluation ($M = 5.25$; $F = 8.54$; $p = 0.000$) and program adaptation ($M = 5.36$; $F = 7.26$; $p = 0.001$).

Overall program sustainability capacity did not vary significantly by program level ($F = 0.61$; $p = 0.54$). However, state-level programs reported the lowest level of communications capacity ($M = 4.42$; $F = 6.95$; $p = 0.001$) while higher level (beyond state) programs reported higher financial stability ($M = 4.11$; $F = 3.06$, $p = 0.047$).

Discussion

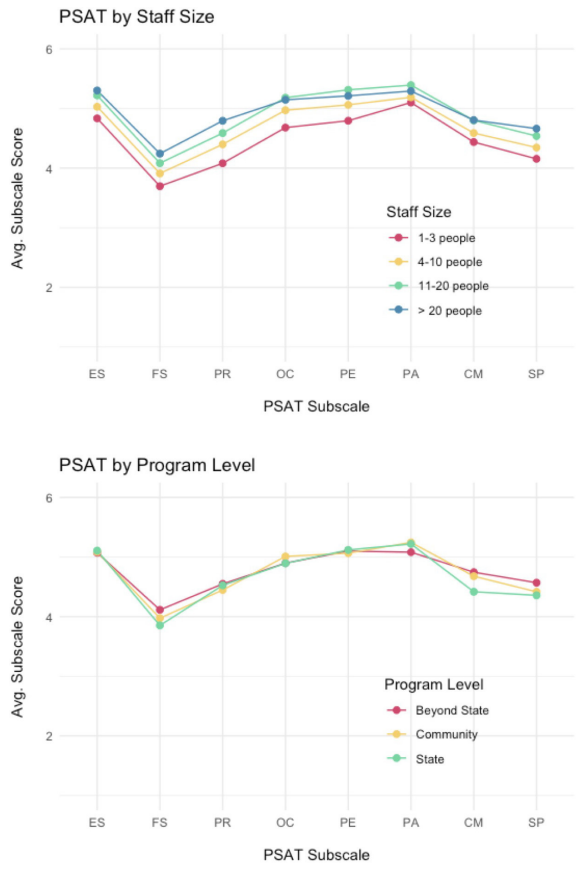
This study evaluated the PSAT continued performance in two major areas: first, through assessment of reliability and measurement structure, and second, in understanding some program characteristics that affect programs' sustainability capacity. The PSAT maintained its excellent reliability when tested with a larger and more diverse sample over time, further solidifying it as a reliable tool for assessing sustainability capacity. Initial criterion validity was explored through the assessment of program characteristics, including program type and program size. The data collected across differing programs and users reinforces the ability of the PSAT to assess sustainability capacity in relevant areas. The PSAT aids in assessment of many areas of public health, including those that address addiction and mental health programming.

The PSAT, therefore, remains a reliable and valid instrument for practitioners to use when assessing their program's sustainability capacity. While some work has adapted the PSAT for specific areas, this work suggests that the PSAT remains valid in its entirety, even when assessed in a larger and more diverse sample (31). While there have been other measures developed for sustainability capacity in certain areas or to assess sustainment, this capacity focused measure is both pragmatic and generalizable to different settings and amongst those in different roles, including both practitioners and research team members (5). This assessment responds to the need for reliable measures within implementation science, specifically in the area of sustainability research (1, 32, 33).

Further, this data provides information about real-world programs to support and enhance program sustainability. This allows for practitioners and researchers to better understand what constructs should be targeted to enhance program sustainability in public health, mental health, and clinical care.

Ultimately, this theoretically driven work helps move from considerations about definition into better understanding of measurement of this construct. Next, studies of sustainability need to focus more about prediction and mechanisms on which sustainability acts. This study helps tie important information about theory and frameworks to data around these contextual factors that can drive sustainability capacity. These PSAT domains could inform future qualitative studies to explore the concepts further and elucidate how they could contribute to interventions to increase future sustainment.

A strength of this study is the large number of participants, even though the sample was comprised of those who sought out the measure for use. The time span covered by the sample further allows for strengthening of outcomes related to reliability and validity. Finally, this sample represents many types of programs as well as locations of assessment, including programs both within the United States and



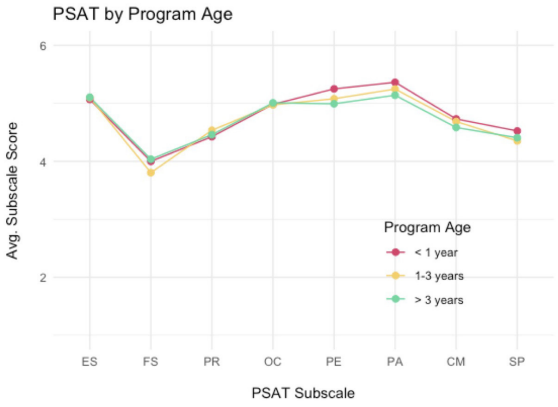


FIGURE 4
PSAT subscale scores by program level, staff size, and program age.

internationally. International participants were from countries including: Australia, Canada, and the United Kingdom. However, we do not collect specific location of sites through our online survey at this time. Additionally, this assessment was conducted prior to a Spanish translation of the measure being available, so is limited to English speaking respondents. Future validation work can expand on the initial variables used in this sample to assess criterion validity as well as explore PSAT responses in multiple languages.

The PSAT provides a reliable tool for assessing a program's sustainability capacity. In addition, the PSAT has been found to be easy to use, requiring no or minimal training (34). As a result, practitioners, evaluators, and researchers can use the PSAT in their sustainability planning efforts with confidence. This study further supports the reliability, validity, and usefulness of this instrument. While other instruments have been developed for specific settings, this tool assists with implementation practice and evaluating a wide variety of programs. This study does not connect sustainability capacity to sustainment outcomes, due to a lack of information about the sustainment metrics of the programs. Future research ought to investigate the link between sustainability capacity and sustainment outcomes.

Additionally, clinical settings often have been identified as having unique processes and structures to those in public health programs (6). For example, clinical settings are often less reliant on finances than public health programs. To assess these settings, an adaptation of the PSAT was developed that focuses on clinical programs and practices. The Clinical Sustainability Assessment Tool has also been translated for use in other languages and has been demonstrated as reliable in both domestic and global settings (35).

In addition to future work focused on broader dissemination of this tool for practice, there are opportunities to explore how different organization contexts influence program sustainability. The contexts within which different programs, such as public health and educational programs, are delivered can vary widely, even within similar geographic regions. Therefore, further work should focus on understanding this varying context, including differences in program level, populations, and settings, and their relationship to overall sustainability capacity. While other work

has adapted this tool for specific clinical contexts, the PSAT should continue to be utilized and tailored for other audiences.

Data availability statement

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

Author contributions

CB led the design of the study and drafting the manuscript. SM assisted with planning the study, reviewing the data, and drafting the manuscript. KP provided supervision of the study and assisted with the design of the study and drafting the manuscript. RH assisted with data collection, data preparation, and editing the manuscript. MH assisted with the design of the study and drafting the manuscript. SD assisted with data collection and study design. DL led the data analysis and assisted with planning the study and drafting of the manuscript. All authors reviewed and approved the final manuscript.

Funding

This work was funded by the Centers for Disease Control and Prevention, Office on Smoking and Health, contract no. 75D301-20-R-68063.

Acknowledgments

The authors thank the Centers for Disease Control and Prevention, Office on Smoking and Health for their support of the tool development and website at www.sustaintool.org.

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.2022.1004167/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 09 January 2023
DOI 10.3389/frhs.2022.1005986

OPEN ACCESS

EDITED BY
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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 28 July 2022
ACCEPTED 15 December 2022
PUBLISHED 09 January 2023

CITATION
Moucheraud C, Epstein A, Sarma H, Kim SS, Nguyen PH, Rahman M, Tariquijaman Md, Glenn J, Payán DD, Menon P and Bossert TJ (2023) Assessing sustainment of health worker outcomes beyond program end: Evaluation results from an infant and young child feeding intervention in Bangladesh.
Front. Health Serv. 2:1005986.
doi: 10.3389/frhs.2022.1005986

Assessing sustainment of health worker outcomes beyond program end: Evaluation results from an infant and young child feeding intervention in Bangladesh

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Introduction: Alive and Thrive (A&T) implemented infant and young child feeding (IYCF) interventions in Bangladesh. We examine the sustained impacts on health workers' IYCF knowledge, service delivery, job satisfaction, and job readiness three years after the program's conclusion.

Methods: We use data from a cluster-randomized controlled trial design, including repeated cross-sectional surveys with health workers in 2010 (baseline, $n = 290$), 2014 (endline, $n = 511$) and 2017 (post-endline, $n = 600$). Health workers in 10 sub-districts were trained and incentivized to deliver intensified IYCF counseling, and participated in social mobilization activities, while health workers in 10 comparison sub-districts delivered standard counseling activities. Accompanying mass media and policy change activities occurred at the national level. The primary outcome is quality of IYCF service delivery (number of IYCF messages reportedly communicated during counseling); intermediate outcomes are IYCF knowledge, job satisfaction, and job readiness. We also assess the role of hypothesized modifiers of program sustainment, i.e. activities of the program: comprehensiveness of refresher trainings and receipt of financial incentives. Multivariable difference-in-difference linear regression models, including worker characteristic covariates and adjusted for clustering at the survey sampling level, are used to compare differences between groups (intervention vs. comparison areas) and over time (baseline, endline, post-endline).

Results: At endline, health workers in intervention areas discussed significantly more IYCF topics than those in comparison areas (4.9 vs. 4.0 topics, $p < 0.001$), but levels decreased and the post-endline gap was no longer significant (4.0 vs. 3.3 topics, $p = 0.067$). Comprehensive refresher trainings were protective against deterioration in service delivery. Between baseline and endline, the intervention increased health workers' knowledge (3.5-point increase in knowledge scores in intervention areas, vs. 1.5-point increase in comparison areas, $p < 0.0001$); and this improvement persisted to post-endline, suggesting a sustained program effect on knowledge. Job satisfaction and readiness both saw improvements among workers in intervention areas during the project period (baseline to endline) but regressed to a similar level as comparison areas by post-endline.

Discussion: Our study showed sustained impact of IYCF interventions on health workers' knowledge, but not job satisfaction or job readiness—and, critically, no sustained program effect on service delivery. Programs of limited duration may seek to assess the status of and invest in protective factors identified in this study (e.g., refresher trainings) to encourage sustained impact of improved service delivery. Studies should also prioritize collecting post-endline data to empirically test and refine concepts of sustainment.

KEYWORDS

implementation science, sustainability, public health, global health, Bangladesh, infant and young child feeding (IYCF)

1. Introduction

Optimal breastfeeding and complementary feeding (defined as timely and adequate introduction of appropriate foods to an infant's diet in addition to breastmilk) strongly influence nutrition, growth and health outcomes in children (1, 2). Poor early-life nutrition contributes to malnutrition-related conditions (e.g., stunting) (3, 4) and delayed child development (5), and may cause up to an estimated 45% of all child deaths worldwide (6). Although some interventions to improve infant and young child feeding (IYCF)—i.e., optimal breastfeeding and complementary feeding—have achieved improvements, they have struggled during scale-up and sustainment (7, 8).

Sustaining components of effective interventions and program activities is essential for maintaining and supporting improvements in IYCF practices. Whether and how interventions are integrated into ongoing practices and institutions, for example through building capacity, can support sustainable implementation (6). However, there are many challenges to sustaining momentum or effective results with unpredictable funding resources that are largely donor driven, like limited multisectoral coordination and inadequate personal capacity (including high employee turnover) (9).

Sustainment can be conceptualized as ongoing activities that continue to result in improved outcomes (10). Sustainability of donor-funded programs is a crucial but understudied issue. As international organizations and donors increasingly wish to transition implementation responsibilities to recipient countries, and in some cases, ultimately phase out funding (11–13), it is imperative to better understand factors that enable (or hinder) lasting impacts from programs (10, 14–22). Data are lacking on the dynamics of outcomes affected by donor-funded programs after funding has ceased, and on factors that contribute to program sustainability (23, 24). Therefore, to advance the field of implementation science, research is needed evaluating longer-term outcomes of sustainability (e.g., sustainment) (25).

Alive & Thrive (A&T) supported nutrition interventions to improve maternal nutrition and infant and young child feeding practices in several countries including Burkina Faso, Ethiopia, India, Nigeria and Vietnam. In Bangladesh, A&T was implemented from 2009 to 2014 as a demonstration project of an at-scale model for achieving IYCF improvements (see ***Program Description***, below). Findings from impact evaluation showed that A&T was associated with improved IYCF knowledge and behaviors: health workers in intervention areas had significantly greater improvements in IYCF knowledge and job motivation during the program period (2010 to 2014) relative to workers in comparison areas (26). A post-endline evaluation (conducted in 2017) of health workers in these same areas similarly found significantly better IYCF knowledge and job satisfaction in intervention vs. comparison areas (14, 27). While there is evidence that certain outcomes persisted beyond the end of the project period, data from baseline, endline, and post-endline have not been linked to estimate the degree of sustainment. Each evaluation effort deliberately aligned study samples and survey

instruments, so it is possible to analyze the degree to which any intervention effects observed from 2009 to 2014 persisted until 2017.

In this paper, we investigate the presence and magnitude of "voltage drop"—i.e., attenuation of benefits over time (28)—after the A&T program in Bangladesh ended in 2014, i.e., the extent to which improvements in health worker outcomes in intervention areas were sustained or returned to the same level as in the comparison areas. This is an important area of study since capacity and resource limitations were identified as potential issues that could curtail scale-up and long-term improvements for A&T (29). Is there evidence of sustained differences in outcomes (quality of IYCF service delivery, IYCF knowledge, job satisfaction and job readiness) among health workers in intervention areas, vs. those in comparison areas, after the A&T initiative ended in Bangladesh? We also examine whether changes in these outcomes post-endline were differentially affected by program activities i.e., refresher training and receipt of financial incentives.

2. Materials and methods

2.1. Program description

Alive & Thrive (A&T) is an initiative supported by the Bill and Melinda Gates Foundation that aimed to demonstrate at-scale improvements in IYCF behaviors in Bangladesh, Ethiopia and Vietnam during Phase 1 from 2009 to 2014 [see detailed descriptions (26, 29, 30)]. Specific intervention details varied in each country but had a common core that included: interpersonal counseling, mass media, community mobilization, and policy advocacy activities– all bolstered by partnerships and strategic use of data (31, 32). In Bangladesh specifically, the A&T initiative included interpersonal communication (IYCF counseling with pregnant women and mothers of young children) and community mobilization (local meetings with stakeholders and village theater performances); these components were delivered by BRAC, a large non-governmental organization with a network of community-based volunteers, in areas assigned to A&T interventions. Mass media (television commercials and radio stories about IYCF) and policy advocacy (dissemination and the creation of a National IYCF Alliance) were also conducted country-wide across intervention and comparison A&T areas.

Here, we focus specifically on the interpersonal communication (IYCF counseling) and community mobilization components of the A&T program in Bangladesh. The unit of analysis are frontline health workers who deliver at-home health services to pregnant women and mothers of young children. We conceptualize the main outcome of interest as the quality of IYCF service delivery, operationalized as the quantity of IYCF topics discussed in counseling sessions. Quality of service delivery is imperative as it is associated with downstream improved IYCF outcomes among clients (33). We hypothesize that this is influenced by intermediate outcomes of IYCF knowledge, job readiness and job satisfaction—and that, in turn, these can be impacted by program activities of training and incentives (**Figure 1**).

2.2. Study design

A&T Phase 1 was implemented using a cluster-randomized control trial design, and impact evaluation data were collected *via* cross-sectional surveys conducted in 2010 and 2014. There was a random selection of 20 rural upazillas (sub-districts) for the trial: 10 received the intervention A&T Phase 1 package of activities (the intervention areas) and 10 continued to implement standard care by BRAC frontline workers (comparison areas). These 20 upazillas were selected from among 357 upazillas in the participating 5 (of 7) divisions of Bangladesh. More information about the selection and randomization process has been previously published (14, 26, 34).

2.3. Data collection

Across the 20 participating upazillas in Bangladesh, 200 villages were randomly selected for data collection (from 3581 villages total); these 200 villages comprised the sampling frame for all three rounds of data collection. All health workers in these villages were surveyed in 2010 (baseline) and 2014 (endline). In 2017 (post-endline), these upazillas were revisited and health workers were randomly sampled using BRAC's rosters (ranging from 2 to 9, depending on the number available). To be eligible for participation in 2017, the health worker must have had a planned household visit within 2 days of initial contact by the study team, and must serve pregnant women and/or women with young children. A sample of 30 health workers per upazilla were invited to participate in the survey using random exclusion of eligible workers in the roster. A national total of 600 surveys (300 in intervention areas, 300 in comparison areas) were completed in 2017.

2.4. Variable definition

A summary of all variables included in the analysis is presented in **Table 1**.

The primary outcome for this analysis was quality of IYCF service delivery, defined as the count of topics covered by the health worker during IYCF counseling (self-reported; range 0–14); this measure is available at endline and post-endline.

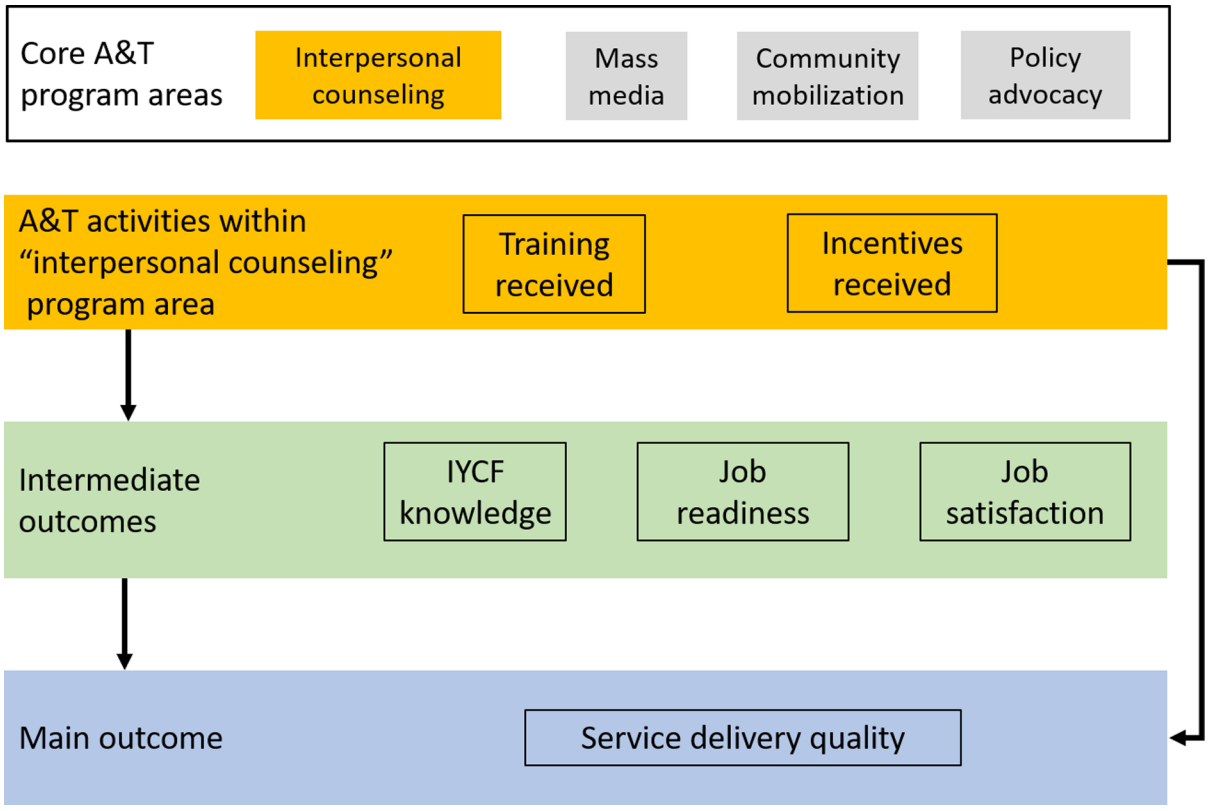

FIGURE 1
Conceptual framework of the hypothesized relationship between Alive & Thrive Phase 1 program areas and activities, and outcomes among health workers (intermediate and main outcomes).

Eligible IYCF topics that health workers could mention are listed in **Supplementary Appendix Table S1**.

We also assessed three intermediate outcomes hypothesized to be on the causal pathway between the A&T intervention and service delivery (**Figure 1**). First, we defined IYCF knowledge (both breastfeeding and complementary feeding) as the count of items answered correctly during the baseline, endline, and post-endline surveys (range 0–14). Items included were common across all three surveys (**Supplementary Appendix Table S1**). Second, we defined job satisfaction as a binary variable (very satisfied vs. not very satisfied). At baseline and endline, this was measured using a 10-point scale and "very satisfied" was operationalized as scores ≥8 on this scale; at post-endline, this was measured using a 5-point scale, and "very satisfied" was defined as reporting ≥4. Third, job readiness was a binary variable representing whether the health worker felt they had adequate training for their job (binary yes/no variable).

We hypothesized that two A&T intervention activities could modify sustainment of effects: (1) comprehensiveness of refresher training, defined as the proportion of self-reported topics a health worker recalled receiving at their last refresher training (measured only at endline and post-endline); and (2) receipt of incentives, measured through two variables: a binary variable representing whether the health worker received incentives in the last year, and a continuous variable representing the amount of incentive received in the last year (with 0 if no incentive was received). Both financial incentive variables were measured only at endline and post-endline.

We adjusted for a number of covariates that could impact IYCF service delivery and its sustainment over time, including heath worker cadre (binary: standard health workers defined as Shasthya Shebika [SS]/Pushti Shebika [PS], vs. higher-level health workers including Shasthya Kormi [SK]/Pushti Kormi [PK]), age in years (continuous), years in job (continuous), and education level (categorical: none, some or completed primary, some or completed secondary, and higher than secondary).

2.5. Statistical analysis

We specified multivariable linear regression models (for continuous outcomes, including quality of service delivery, knowledge score, and incentive amount), and linear probability models (for binary outcomes, including job

TABLE 1 Summary of variables included in analysis.

Variable type	Variable name	Definition	Measurement time points
Primary outcome	IYCF service delivery	Continuous (0–14); count of topics covered by the health worker during IYCF counseling (self-reported; range 0–14) (endline: no recall period specified; post-endline: in the last 30 days)	Endline and post-endline
Intermediate outcomes	IYCF knowledge	Continuous (0–14); count of breastfeeding and complementary feeding knowledge items answered correctly	Baseline, endline, and post-endline
	Job satisfaction	Binary; very satisfied vs. not very satisfied	Baseline, endline, and post-endline
	Job readiness	Binary; health worker felt they had adequate training for their job	Baseline, endline, and post-endline
Effect modifiers (program activities)	Comprehensiveness of refresher training	Continuous (0–1); proportion of self-reported topics a health worker recalled receiving at their last refresher training	Endline and post-endline
	Receipt of incentives	Binary; health worker reported receipt of incentives in past year	Endline and post-endline
	Incentive amount	Continuous; amount of incentive received in past year	Endline and post-endline
Covariates	Cadre	Binary; standard health workers vs. higher-level health workers	Baseline, endline, and post-endline
	Age	Continuous; in years	Baseline, endline, and post-endline
	Time spent in job	Continuous; in years	Baseline, endline, and post-endline
	Education level	Categorical; none, some or completed primary, some or completed secondary, and higher than secondary	Baseline, endline, and post-endline

satisfaction, job readiness, and whether the health worker received an incentive in the previous 12 months). Linear probability models were utilized for binary outcomes to aid in ease of interpretation of findings. Difference-in-difference (DID) estimates were generated by interacting an indicator variable representing intervention areas (vs. comparison areas) and an indicator variable representing time (baseline, endline, and post-endline, with endline as the reference time point). To assess effect modification by refresher training quality and financial incentives, we included three-way interaction terms (intervention vs. comparison, and the hypothesized modifier), with lower order (two-way) interactions and main effects included. To visualize the three-way interaction terms, we dichotomized the refresher training variable using the 10th and 90th percentile of topics covered during training. For each model, we generated marginal predicted probabilities of the outcome at each time point in intervention and comparison areas. These marginal predicted probabilities allowed us to compare between-group differences (intervention vs. control) at each time point. Furthermore, we assessed whether the slope differed between each time point for intervention and control. Within-group changes in the post-endline period should be interpreted as exploratory. All models included robust standard errors allowing for intragroup correlation clustered at the upazilla (intervention) level. Models were adjusted for health worker cadre, age, years in job, and education level. Analyses were carried out in Stata v17.

3. Results

A total of $n = 290$ health workers were surveyed at baseline (147 in intervention areas, 143 in comparison areas), $n = 511$ at endline (347 in intervention areas, 164 in comparison areas), and $n = 600$ at post-endline (300 in each area) (**Table 2**). Most respondents were SS/PS cadre and had an average number of 5–10 years in their current role. The sample was not fully balanced at endline and post-endline: respondents in comparison areas had more years of experience, and educational attainment was different; respondents from the comparison were also slightly older at endline and there was a difference in the percentage of cadre represented at post-endline (**Supplementary Appendix Table S2**).

3.1. Sustainment of program activities and outcomes at each round

3.1.1. Primary outcome

The program effect was not sustained for quality of IYCF service delivery, i.e., number of IYCF topics discussed during

TABLE 2 Sample characteristics among frontline health workers at each survey round.

	Baseline survey, 2010 ($n = 290$)		Endline survey, 2014 ($n = 511$)		Post-endline survey, 2017 ($n = 600$)	
	Intervention areas ($n = 147$)	Comparison areas ($n = 143$)	Intervention areas ($n = 347$)	Comparison areas ($n = 164$)	Intervention areas ($n = 300$)	Comparison areas ($n = 300$)
Cadre, % (n)						
SK/PK	27.2 (40)	33.6 (48)	43.2 (150)	36.0 (59)	39.0 (117)	22.0 (66)
SS/PS	72.8 (107)	66.4 (95)	56.8 (197)	64.0 (105)	61.0 (183)	78.0 (234)
Years spent in role, mean (SD)	6.0 (4.4)	5.3 (4.0)	4.8 (4.6)	7.6 (5.1)	7.6 (5.0)	9.9 (6.0)
Age, mean (SD)	36.6 (10.5)	34.9 (10.4)	35.4 (10.6)	38.9 (12.4)	39.9 (10.8)	40.3 (10.9)
Years of schooling, % (n)						
None	27.2 (40)	18.9 (27)	11.5 (40)	18.3 (30)	10.0 (30)	8.0 (24)
Primary, some or completed	23.8 (35)	27.3 (39)	30.6 (106)	22.6 (37)	30.7 (92)	29.3 (88)
Secondary, some or completed	44.2 (65)	47.6 (68)	42.4 (147)	51.8 (85)	38.0 (114)	53.0 (159)
Beyond secondary	4.8 (7)	6.3 (9)	15.6 (54)	7.3 (12)	21.3 (64)	9.7 (29)

care. As shown in Table 3 (comparing the outcome at each time point for intervention vs. control) and Figure 2 (demonstrating the differences in the changes in the outcome over time), the adjusted marginal predictions of self-reported number of IYCF topics discussed during IYCF counseling visits was significantly higher among health workers in intervention areas than comparison areas at endline (4.93 [SE 0.10] topics covered by health workers in intervention areas and 3.97 [SE 0.18] topics covered by health workers in comparison areas). By post-endline, delivery of IYCF messages declined among both intervention and comparison health workers, with no significant difference in this decline (DID $p = 0.32$). The difference between intervention and comparison areas was marginally significant at post-endline (3.97 [SE 0.18] topics covered by health workers in intervention areas and 3.34 [SE 0.28] topics covered by health workers in comparison areas).

3.1.2. Intermediate outcomes

Findings for intermediate outcomes over time are presented in Table 3 (comparing the outcome at each time point for intervention vs. comparison) and Figure 3 (demonstrating differences in changes in the intermediates outcomes over time). At baseline, there were no substantive differences between all intermediate outcomes—IYCF knowledge, job satisfaction, and job readiness—comparing intervention and comparison areas. At endline, significantly better IYCF knowledge was observed among all health workers in both intervention and comparison areas compared to baseline, but gains were significantly larger among health workers in intervention areas. There was evidence of a sustained program effect for IYCF knowledge as these improvements in intervention areas persisted to post-endline. The gap between intervention and comparison areas remained largely unchanged by post-endline (IYCF knowledge score of 12.65 [SE 0.95] among intervention health workers vs. 11.13 [SE 0.050] among comparison workers), with no detectable difference in the slope for these changes between endline and post-endline.

In comparison areas, job satisfaction declined across all periods. In intervention areas, job satisfaction increased during the project period (baseline to endline); however, there was no detectable difference in the changes over time (DID $p = 0.29$). Subsequently, job satisfaction among workers in intervention areas declined at post-endline and reached a similar level as comparison areas (48% [SE 4.4] satisfied health workers in intervention areas and 38% [SE 3.8] satisfied health workers in comparison areas).

In intervention areas, health workers experienced an increase in reported job readiness by endline, while there was no change among workers in comparison areas (DID $p = 0.014$). However, by post-endline intervention-area workers had returned to their baseline level, while health workers in comparison areas reported no change (DID $p = 0.002$).

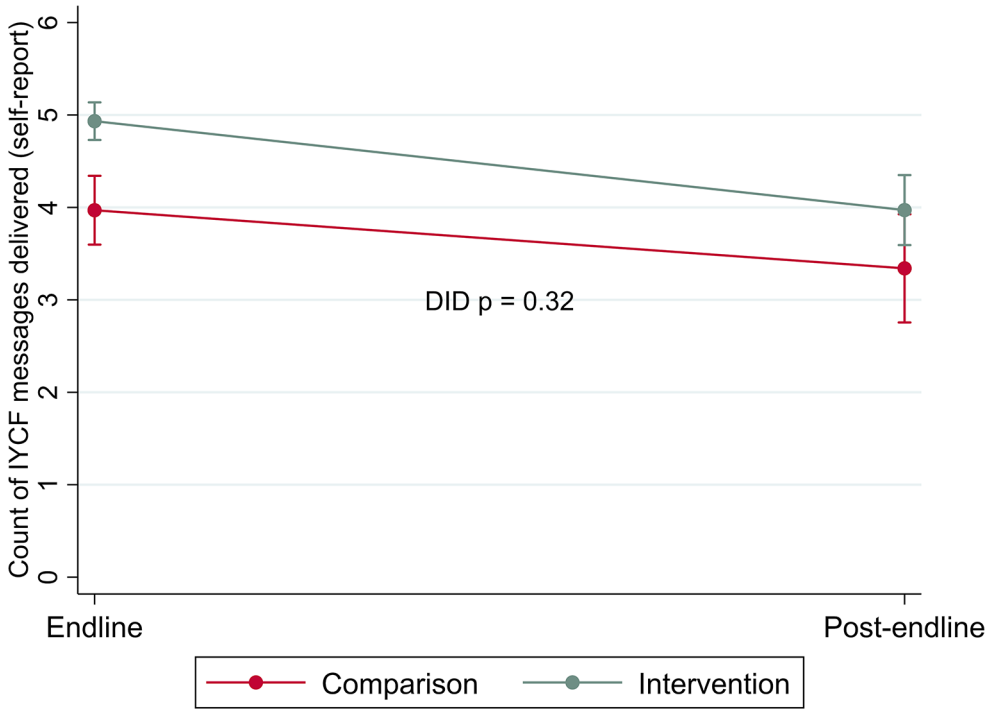

FIGURE 2
Changes in delivery of the quantity of IYCF messages included during counseling by area over time (difference in difference estimates).

3.1.3. Program activities

Sustainment of program activities are presented in **Table 3** (comparing the outcome at each time point for intervention vs. comparison) and **Figure 4** (demonstrating differences in changes in the program activities over time). Despite declining from endline to post-endline (DID $p = 0.002$), IYCF topics covered at last refresher training remained significantly higher in intervention areas at post-endline vs. comparison areas. Incentive payments declined substantially from endline to post-endline among both intervention and comparison health workers, with a steeper decline among those in intervention areas (DID $p < 0.001$). At endline, incentive payments were significantly more common in intervention areas: 90% of workers in intervention areas and 46% of workers in comparison areas said they had received an incentive payment. At post-endline, these values had fallen to 5% and 11%, respectively.

3.2. Factors modifying the sustainment of program effects

We assessed whether program activities modified the sustainment of program effects of the primary outcome (IYCF service delivery, **Figure 5**).

Comprehensive refresher trainings potentially protected against the deterioration of the primary outcome (service delivery): workers who reported more comprehensive refresher trainings (above the 90th percentile of reported topics discussed) delivered significantly more IYCF messages during counseling by post-endline, in both intervention and comparison areas. Workers in intervention areas who had less-comprehensive refresher trainings experienced the largest declines in IYCF counseling by post-endline. However, more comprehensive IYCF refresher training was not associated with any difference in knowledge (intermediate outcome) across treatment groups, between endline and post-endline (**Supplementary Appendix Figure S1**). There was however no apparent interaction between comprehensiveness of refresher training, and job satisfaction or job readiness, in either group over time (**Supplementary Appendix Figures S2, S3**).

There was no apparent effect of incentives, whether presence of any incentive or the amount of incentive, on quality of IYCF service delivery nor on intermediate outcomes (**Figure 5** and **Supplementary Appendix Figures S1–S3**), with the exception of job readiness—health workers in intervention areas with no incentive reported lower job readiness at endline, but converged with their peers at post-endline.

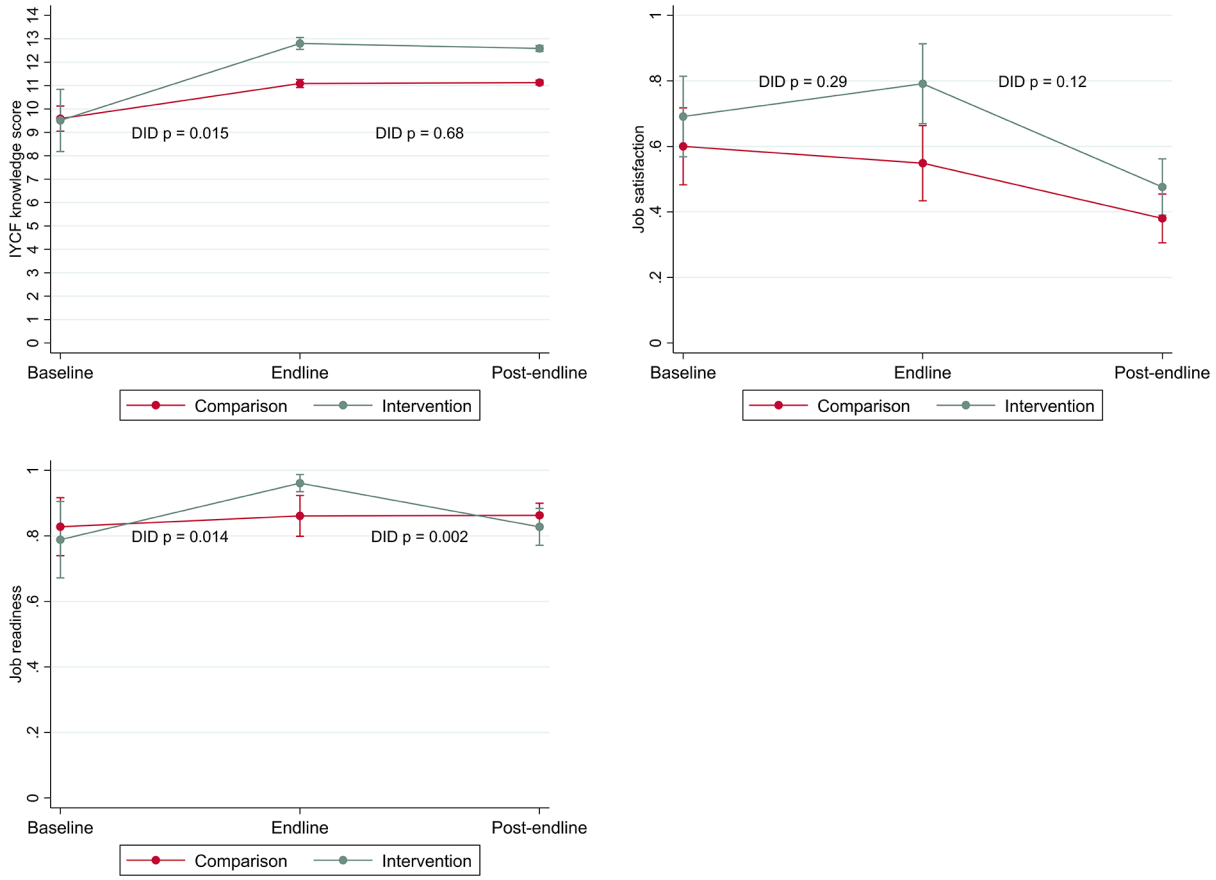

FIGURE 3
Changes in intermediate outcomes (IYCF knowledge, job satisfaction, job readiness) by area over time (difference in difference estimates).

4. Discussion

This paper adds to the empirical literature on sustainability as there are relatively few quantitative studies that estimate the degree to which program outcomes endure over time (19). We find mixed evidence about the sustainment of outcomes from the Alive & Thrive initiative three years after the program's conclusion in Bangladesh. On the main outcome of IYCF service delivery and quality (i.e., number of topics discussed during counseling), we see evidence of "voltage drop" (28): the intervention was associated with a significant improvement in service delivery at endline, but three years later, quality had declined for workers in both intervention and comparison areas and was no longer significantly different between the groups.

Importantly, we find that although there were not enduring improvements in intervention areas for the main outcome of service quality, a critical intermediate outcome—IYCF knowledge—was sustained, as was an associated related program activity of IYCF topics covered at refresher trainings. This indicates that interventions that seek to improve health worker knowledge may have an enduring effect but that this may not continue to impact behaviors. This adds a new dimension to the "know-do gap" literature, which has demonstrated the potential disconnect between what health workers know and their clinical practice (35–39). Prior IYCF research in Ethiopia found mothers with better access to nutrition education had higher knowledge scores, improved child feeding practices, and reduced rates of stunting among their children (40). However, while knowledge may be a necessary ingredient to achieving—and sustaining—behavior change, it may not be sufficient. Future research should assess health workers' knowledge-sharing efficacy and other factors that may also impact IYCF service delivery and quality (41).

Two key intermediate outcomes—job satisfaction and job readiness—increased over the program period but this improvement was not sustained. Our previous research has indicated that this may be directly attributable to the end of A&T: removal of incentives has been shown to negatively impact BRAC health workers' IYCF service delivery quality (42) and desire to perform (43).

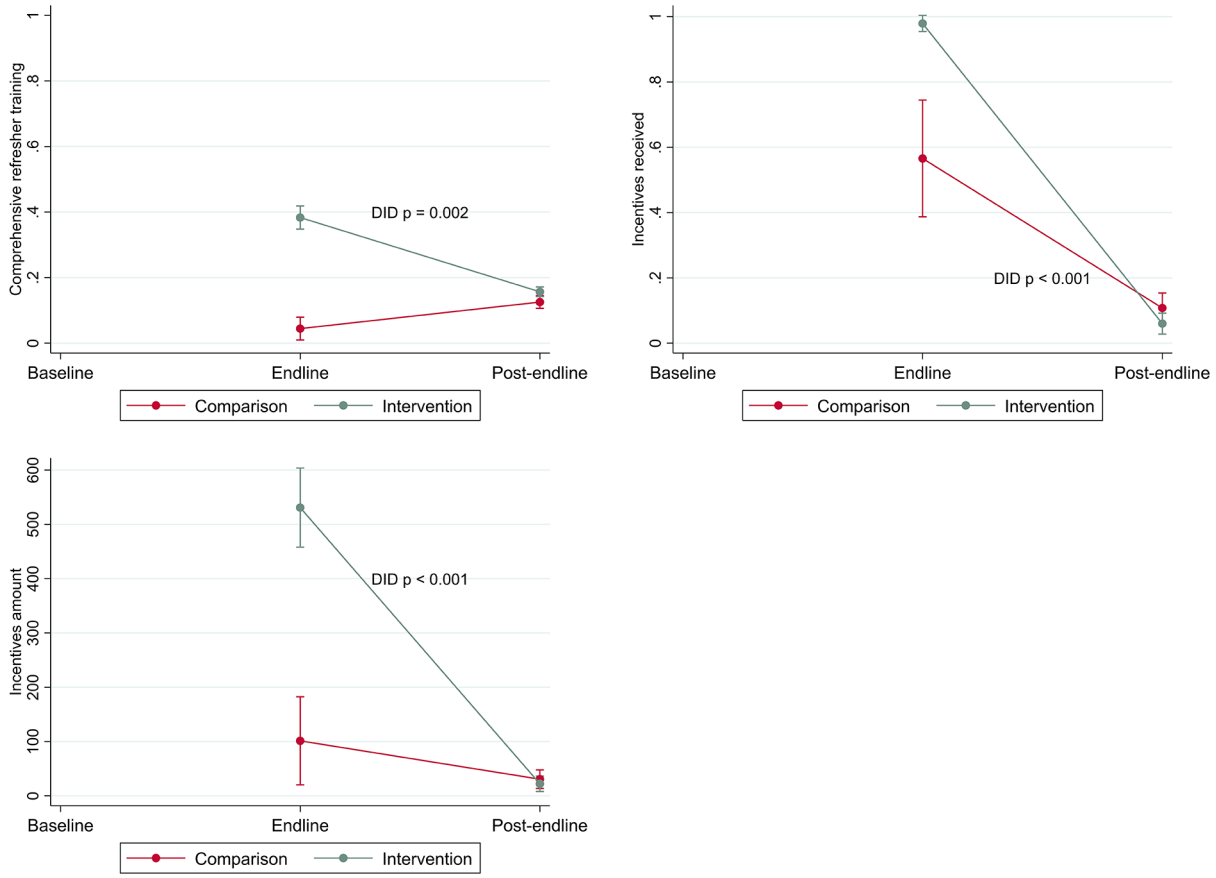

FIGURE 4
Changes in program activities (refresher trainings, incentives received, incentive amount) by area over time (difference in difference estimates).

Alive & Thrive was designed as a "proof of concept" initiative: if it demonstrated success, then governments would have the evidence necessary to implement it. Although some activities have endured in Bangladesh, not all have continued in the format or intensity as in the initial design (14). Externally-funded programs and projects cannot continue forever; these findings add new insights to the growing literature on sustainability by measuring sustainment across a program's theory of change. If, as in this case, an intervention can have lasting effects on health worker knowledge, but cannot continue to make material contributions that may help translate this knowledge into action—for example, incentive payments or job readiness—what are reasonable sustainability expectations? It is important to consider this finding in the context of the study population: BRAC community health workers include both paid and unpaid (volunteers), and different types of health workers may differentially respond to programs, and to their end (44, 45). Further, there may be other factors—including macroeconomic factors or structural changes in the healthcare system—that may impact intermediate outcomes, like job satisfaction for health workers. Previous research has explored how social factors, like religious norms, may affect BRAC workers' job performance (46). It is important to consider contextual factors like these when preparing for and assessing sustainability.

This is also particularly noteworthy when considering our exploratory finding that refresher trainings may protect against the "voltage drop" in service quality. More research that attempts to disentangle sustainment of effects across a program's theory of change may help policymakers prioritize areas for continued investment after programs end, in order to catalyze ongoing impacts.

This analysis is innovative in its design and approach, but is not without limitations. First, the primary outcome—number of IYCF topics discussed during recent counseling visits—is not a perfect measure of service quality. It was self-reported and blinding of the intervention was impossible so health workers in intervention areas so may have over-reported their performance. Additionally, IYCF counseling is not a "one-size-fits-all" activity and the topics discussed will naturally differ across clients, so more topics is not necessarily a

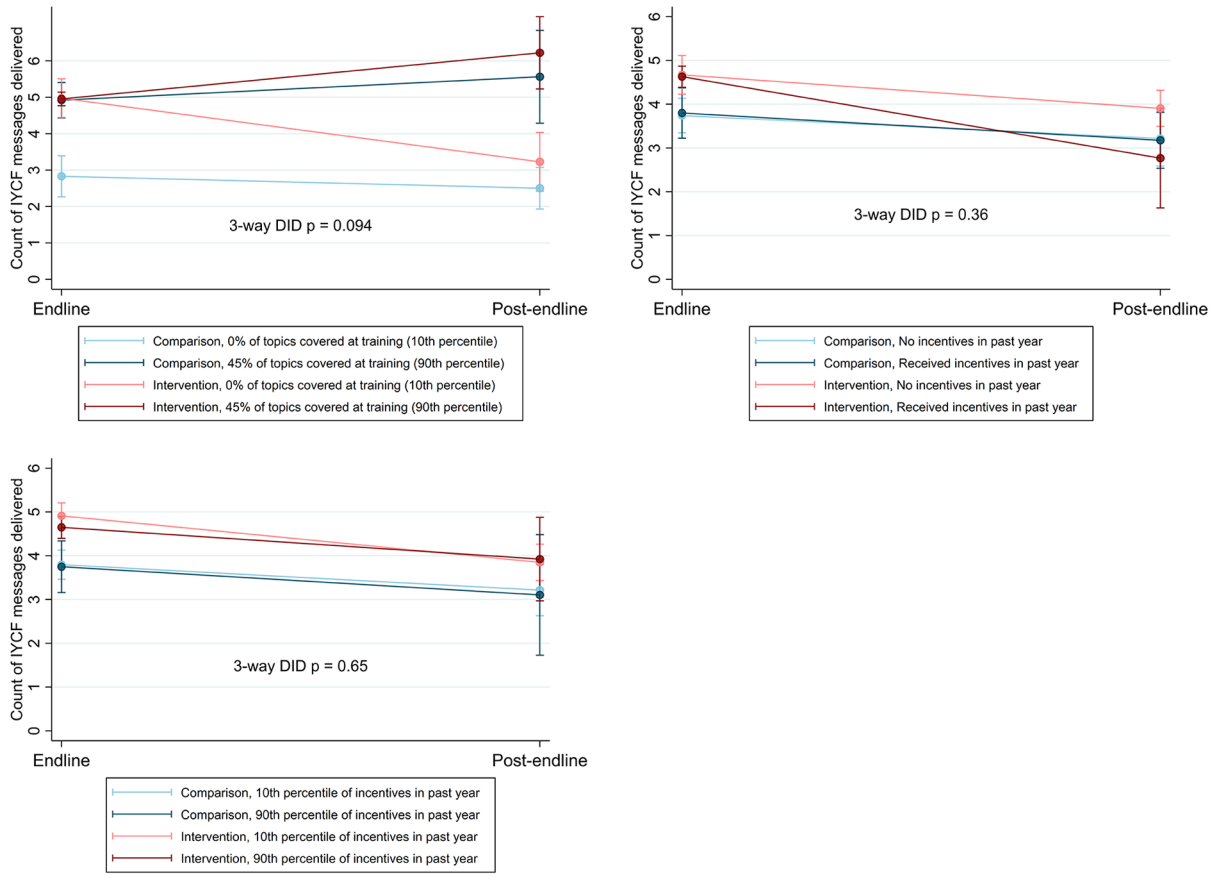

FIGURE 5
Changes in delivery of IYCF messages during counseling by area over time, including interaction terms for program activities.

measure of high-quality counseling. There were also measurement challenges with this variable owing to different recall periods: no recall period was specified at endline, but at post-endline health workers were only asked about counseling in the last 30 days. This may account for at least some of the decline in messages reportedly delivered. Second, some outcomes were measured only at endline and post-endline, so we cannot assess whether the observed declines represent returns to baseline levels. Third, response options varied slightly between survey rounds; for example, the job satisfaction variable used 10-point Likert scale in the baseline and endline surveys, but a 5-point scale in the post-endline survey. This may account for some difference in responses over time. Fourth, this analysis was not powered to detect changes over time, nor to assess effect modification over time. Nevertheless, the findings do indicate evidence of "voltage drop," and suggest some factors that may protect against declines in program sustainment. To assess whether the hypothesized effect modifiers could instead be mediators, we conducted a mediation analysis using Barron and Kenney methods to test whether the difference-in-difference coefficient was statistically different with and without potential mediators in the model—however the results showed no statistical difference. Fifth, this analysis focused solely on outcomes among health workers and did not include key IYCF measures among caregivers of children, such as exclusive breastfeeding; although this is a limitation, our previous research has found that service quality (IYCF messages delivered during counseling) is associated with improved IYCF outcomes in this population (33). Lastly, some outcomes may have been impacted by social desirability bias (such as job satisfaction and job readiness); however, we do not expect this bias to differ between intervention and comparison areas nor over time.

This was a unique analysis: we linked three separate cross-sectional surveys—performed over a 7-year period and spanning intervention baseline, endline and post-endline—to quantitatively examine sustainment of program outcomes and activities. The study teams deliberately aligned survey tools and sampling frames in order to enable this analysis, and both the study design and its limitations offer useful lessons for scholars of sustainability. We find evidence of "voltage drop" in the primary outcome of quality of service delivery,

TABLE 3 Primary and intermediate outcomes and program activities at each survey round: marginal predicted outcomes resulting from difference-in-difference models (SE in parentheses); *p*-values for the null hypothesis of no difference in predicted outcomes in intervention and comparison areas at each round.

	Baseline survey, 2010			Endline survey, 2014			Post-endline survey, 2017		
	Intervention areas	Comparison areas	*p*-value	Intervention areas	Comparison areas	*p*-value	Intervention areas	Comparison areas	*p*-value
Primary outcome									
Count of IYCF messages delivered (range 0–14)	n/a	n/a	n/a	4.93 (0.10)	3.97 (0.18)	<0.001	3.97 (0.18)	3.34 (0.28)	0.067
Intermediate outcomes									
Total IYCF knowledge score (range 0–14)	9.51 (0.64)	9.59 (0.26)	0.91	12.80 (0.12)	11.09 (0.082)	<0.001	12.65 (0.95)	11.13 (0.050)	<0.001
Satisfied with job (binary 0–1)	0.69 (0.063)	0.60 (0.060)	0.28	0.79 (0.062)	0.55 (0.058)	0.0079	0.48 (0.044)	0.38 (0.038)	0.10
Job readiness (binary 0–1)	0.79 (0.060)	0.83 (0.045)	0.58	0.96 (0.013)	0.86 (0.032)	0.0021	0.83 (0.029)	0.86 (0.019)	0.28
Program activities									
Proportion of topics covered at last refresher training (range 0–1)	n/a	n/a	n/a	0.38 (0.017)	0.044 (0.017)	<0.001	0.15 (0.0070)	0.13 (0.0092)	0.018
Received incentive in last 12 months (binary 0–1)	n/a	n/a	n/a	0.90 (0.03)	0.47 (0.077)	<0.001	0.054 (0.017)	0.11 (0.021)	0.046
Amount of incentive received in last 12 months (continuous)	n/a	n/a	n/a	530.90 (34.92)	101.25 (38.86)	<0.001	22.14 (6.84)	30.64 (8.15)	0.38

Adjusted for cadre, years spent in role, age, and education. Standard errors are clustered at the upazilla level.

10.3389/frhs.2022.1005986

although refresher trainings may protect against this deterioration. There are sustained improvements in knowledge among health workers in intervention areas compared to their counterparts in comparison areas, but this was not sufficient to achieve sustained outcomes. We hope this analysis stimulates more research to empirically measure and quantify sustainment, particularly across interventions' theories of change and into post-endline periods.

Data availability statement

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found below: https://dataverse.harvard.edu/dataverse/AliveandThrive.

Ethics statement

The studies involving human participants were reviewed and approved by the Bangladesh Medical Research Council and the Institutional Review Board at the International Food Policy Research Institute (baseline and endline); and the institutional Review Boards at the Harvard T.H. Chan School of Public Health, the University of California Los Angeles, and the icddr, b in Bangladesh (post-endline). Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

The post-endline study was led by CM and TJB, with data collection led by HS, MR and MT, and data analysis and research assistance from AE, JG and DDP. The baseline and endline studies were led by SSK, PHN and PM. This combined analysis was led by CM and AE with design inputs from SSK, PHN, JG, DDP, PM and TJB. All authors reviewed the results and contributed to the interpretation. CM and AE wrote the first draft of the manuscript, which all authors reviewed and gave feedback. All authors contributed to the article and approved the submitted version.

Conflict of interest

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

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.1005986/full#supplementary-material.

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 17 February 2023
DOI 10.3389/frhs.2023.1040992

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Implementation Science, a section of the journal Frontiers in Health Services

RECEIVED 09 September 2022
ACCEPTED 25 January 2023
PUBLISHED 17 February 2023

CITATION
Arbour M, Fico P, Floyd B, Morton S, Hampton P, Murphy Sims J, Atwood S and Sege R (2023) Sustaining and scaling a clinic-based approach to address health-related social needs.
Front. Health Serv. 3:1040992.
doi: 10.3389/frhs.2023.1040992

Sustaining and scaling a clinic-based approach to address health-related social needs

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Objective: Scaling evidence-based interventions (EBIs) from pilot phase remains a pressing challenge in efforts to address health-related social needs (HRSN) and improve population health. This study describes an innovative approach to sustaining and further spreading DULCE (Developmental Understanding and Legal Collaboration for Everyone), a universal EBI that supports pediatric clinics to implement the American Academy of Pediatrics' Bright Futures™ guidelines for infants' well-child visits (WCVs) and introduces a new quality measure of families' HRSN resource use.

Methods: Between August 2018 and December 2019, seven teams in four communities in three states implemented DULCE: four teams that had been implementing DULCE since 2016 and three new teams. Teams received monthly data reports and individualized continuous quality improvement (CQI) coaching for six months, followed by lighter-touch support *via* quarterly group calls (peer-to-peer learning and coaching). Run charts were used to study outcome (percent of infants that received all WCVs on time) and process measures (percent of families screened for HRSN and connected to resources).

Results: Integrating three new sites was associated with an initial regression of outcome: 41% of infants received all WCVs on time, followed by improvement to 48%. Process performance was sustained or improved: among 989 participating families, 84% (831) received 1-month WCVs on time; 96% (946) were screened for seven HRSN, 54% (508) had HRSN, and 87% (444) used HRSN resources.

Conclusion: An innovative, lighter-touch CQI approach to a second phase of scale-up resulted in sustainment or improvements in most processes and outcomes. Outcomes-oriented CQI measures (family receipt of resources) are an important addition to more traditional process-oriented indicators.

KEYWORDS

scale - up, quality improvement, pediatric primary care, social determinansts of health, well child care, interdiscipinarity approach, data driven adaptation, evidence based interventions in primary care

1. Introduction

Evidence-based interventions (EBIs) delivered through the pediatric medical home can improve outcomes among families with young children (1). Integrating health-related social needs (HRSN) screening and support into primary care is a priority strategy to improve population health outcomes (2). The American Academy of Pediatrics (AAP) Bright

Futures™ 4th Edition (BF4) recommends that pediatric clinics address HRSN during well-child visits (WCVs) (3).

Evidence for effectiveness of interventions addressing HRSN in pediatric settings comes mostly from pilot-sized studies (4). However, in the real world, many small-scale pilot studies demonstrating effectiveness are never implemented widely (5, 6). The American Academy of Pediatrics noted that most efforts to expand successful pilot interventions at scale result in disappointingly small effect sizes (7). Emerging literature describes frameworks for large-scale dissemination of EBIs, factors that facilitate uptake, and lessons learned from scale-up attempts (5, 8–13), but there is no established single best approach for scaling EBIs to improve population health (10).

The Institute for Healthcare Improvement's Breakthrough Series Collaborative model (BTS) has demonstrated potential to increase uptake of EBIs across diverse contexts (14–18), by combining continuous quality improvement methodologies and networked peer learning. Continuous quality improvement methods (CQI) engage the entire organization and its frontline providers in a series of ongoing observations, adjustments, and interventions to produce measurable improvements in outcomes (19, 20). Central to this approach are Plan-Do-Study-Act (PDSA) cycles, which allow cross-hierarchical teams of service providers to identify ideas they believe might improve outcomes; they **plan** a small test of that idea, **do** that test in real day-to-day practice, **study** how the test was executed and what resulted (using observations and data), and **act** on those results – i.e., abandoning ideas that did not work, adapting ideas that seemed promising but in need of optimization (then re-testing), or adopting into practice ideas that worked optimally in their contexts. By ensuring that change ideas are tested and adapted to the local context by frontline teams making real-time, data-based decisions, PDSA testing facilitates adaptive design that can accommodate different contexts as an intervention is scaled up (21).

The Breakthrough Series Collaborative model (BTS) combines CQI methodologies with networked peer learning (22). It recruits teams of direct service providers and stakeholders to pursue one shared, specific aim during a defined period of time, typically 9 to 18 months, and creates a structure wherein interested organizations can learn from each other and recognized experts. The model has three core elements: 1) learning sessions that bring teams together periodically for training and collaboration, separated by 2) "action periods" during which teams test what they have learned in practice, using 3) Plan-Do-Study-Act cycles – the structured approach for learning from rapid-cycle testing of innovations in practice. Figure 1 depicts this traditional BTS structure.

Continuous quality improvement and BTS methods have been applied widely. The CQI approach emerged in the 1950s to overcome manufacturing deficiencies (23, 24) and has subsequently been applied in healthcare, public health, nonprofit and public management and, recently, education (25–28). Since 1995, the BTS model has increased uptake of EBIs and improved outcomes in public health (20, 27, 29), including improved rates and reduced disparities in immunizations (30), spread of trauma-informed care practices in child welfare (31, 32), and improved breastfeeding, developmental promotion, and caregiver depression outcomes in home visiting programs (33–35). In clinical medicine, BTS has been applied to several dozen topics involving over 2,000 teams from 1,000 healthcare organizations to achieve concrete results: reducing waiting times by 50%, worker absenteeism by 25%, ICU costs by 25%, hospitalizations for patients with congestive heart failure by 50%, and eliminating 100,000 deaths due to medical

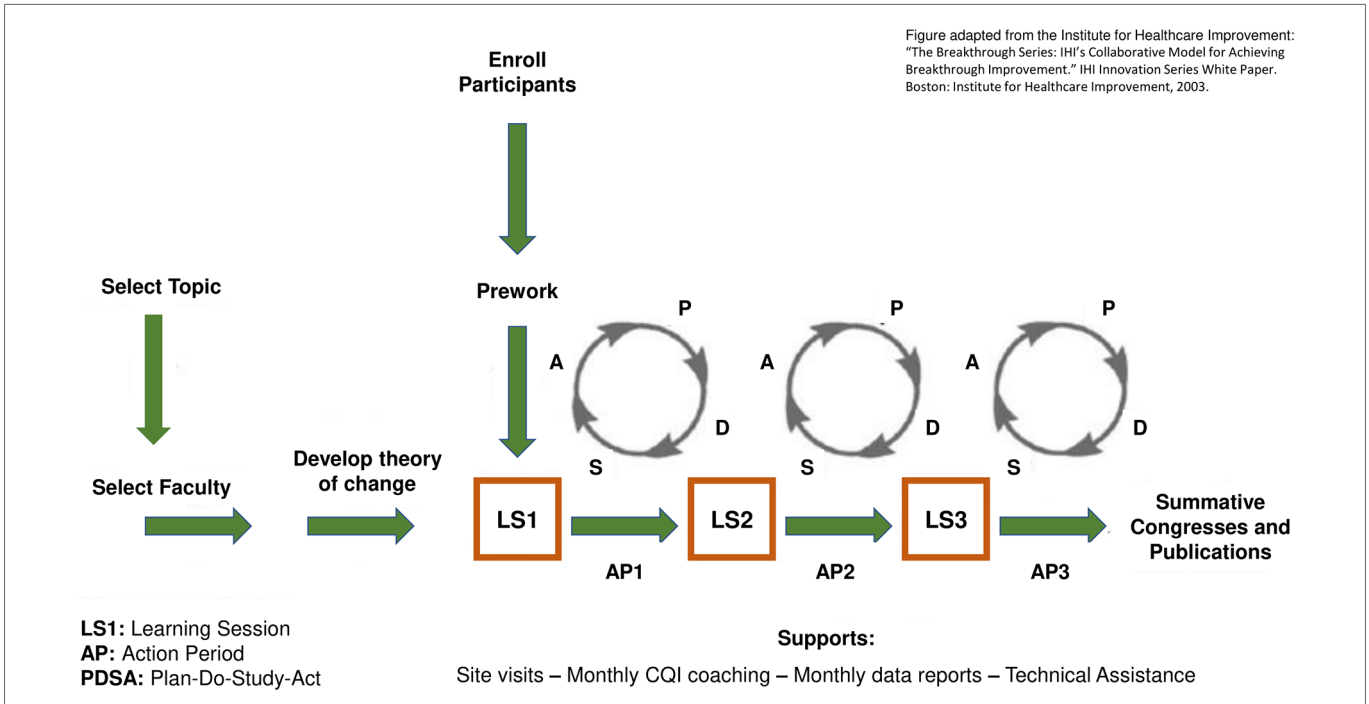


FIGURE 1
The Institute for Healthcare Improvement's Breakthrough Series Learning Collaborative.

errors (15, 36). More recently, the Breakthrough Series has entered the education field as "Networked Improvement Communities." (37–40). For example, two attendance-focused BTS collaboratives increased school attendance: one from 44.9% to 59.2% at seven early childhood education centers in New Zealand (41); another from 83.7% to 87.1% at five public preschools in rural Chile (42).

This study reports an effort to scale DULCE (Developmental Understanding and Legal Collaboration for Everyone) – an evidence-based, cross-sector intervention for addressing HRSN among families with infants that is delivered through pediatric primary care. A first effectiveness trial of DULCE, conducted at a single site with 330 families demonstrated that DULCE increased preventive care adherence and accelerated families' access to HRSN supports (43). A subsequent study of DULCE expansion to five sites serving 692 families used a BTS Collaborative model as its scale framework and replicated these findings - increased on-time WCVs and accelerated access to HRSN resource information (44). That application of the BTS model provided resource-intensive support including four in-person, group training sessions (12 days total), two or three coaching contacts each month (including monthly group implementation webinars and individual site CQI coaching), and two site visits.

Tailoring the type and intensity of support over time as an EBI spreads is crucial, since resources (e.g., time, technical, financial) are often limited (45), and different phases of scale may require different supports (46). Extant literature suggests that later phases of expansion may require less intensive (and less costly) supports because they benefit from people who participated in early phases of expansion championing the EBI and mentoring their peers. In addition, experience gained in the earliest phase of scale – experience testing the theory of change under a broad range of conditions, developing infrastructure and human capacity to support the method being used to scale up, etc.— may facilitate acceleration in the rate of EBI adoption (8). However, sustained implementation of EBIs in real-world settings is a considerable challenge, and many fail to continue once support is decreased or removed.

This study examined whether a lighter-touch application of the same BTS scale framework could be used to sustain DULCE practice improvements in four established sites and spread practice improvements to three new clinic sites. In addition, it added new effectiveness data by measuring families' HRSN resource use. Specifically, it answers two research questions:

1. Can a lighter-touch application of BTS sustain improvements achieved during a prior expansion by four established DULCE teams and spread improvements in on-time WCVs and identification and support for HRSN to three new clinics?
2. What proportion of families use resources after receiving resource information for identified HRSN?

2. Materials and methods

2.1. Intervention

DULCE (Developmental Understanding and Legal Collaboration for Everyone) is a universal, evidence-based pediatric primary care approach for families with infants from birth through 6 months of age. DULCE embeds a community health worker ("Family specialist," FS) within a cross-sector team that includes an early childhood system representative, legal partner, clinic administrator, and pediatric and behavioral health clinicians. The team works together to link families to needed resources.

DULCE's theory of change for improving completion of preventive care is visualized in a driver diagram with four primary drivers – that is, key determinants – that contribute to reaching the goal of on-time well-child visit completion (see **Figure 2**). The first driver focuses on comprehensive care enriched by a Family Specialist (FS, i.e., a community health worker) who attends WCVs, reinforces protective factors, offers developmental guidance and is families' most frequent point of contact. All FS received Brazelton Touchpoints™ training (47). The second driver concentrates on identification of families' strengths and HRSN and family-led problem-solving across seven evidence-based HRSN domains: caregiver depression, intimate partner violence (IPV), housing conditions, housing instability, food insecurity, employment/financial needs, and utilities.

The third driver emphasizes the cross-sector team that includes the FS, an early childhood system representative, legal partner, clinic administrator, and pediatric and behavioral health clinicians. This team conducts weekly case reviews; collaborates to support families' access to benefits, services and legal protections; and identifies opportunities to effect policy and systems improvements (48). The fourth driver prioritizes families as partners *via* diverse strategies, (e.g., *via* exit surveys, periodic celebrations with focus groups, and as DULCE CQI team members).

2.2. Implementation strategy

In previous work (hereafter referred to as "phase one"), a resource-intensive BTS collaborative succeeded in scaling DULCE to five clinical sites that increased on-time WCVs and accelerated access to HRSN resource information. This study ("phase two") aimed to use a lighter-touch application of BTS to sustain improvements in four established DULCE teams (one site from phase one discontinued DULCE due to institutional leadership transitions) and spread improvements to three new clinics.

In both phases, DULCE's implementation was guided by the principles and core components of the BTS model. DULCE sites formed teams of direct service providers and stakeholders that included the Family Specialist, early childhood system representative, legal partner, clinic administrator, and pediatric and behavioral health clinicians. Teams committed to pursue one shared, specific aim (75% of 6-month-old infants and their families receive all five recommended WCVs on-time) during a defined period of time (19 months in phase one, 17 months in phase two).

In both phases, DULCE implementation was supported by the DULCE National team, comprised of staff from the lead organization, the Center for the Study of Social Policy (CSSP), together with DULCE model developers, a CQI expert, practicing pediatrician, and infant mental health specialists. CSSP staff had extensive experience and established relationships with Early Childhood Systems leaders nationally. DULCE model developers

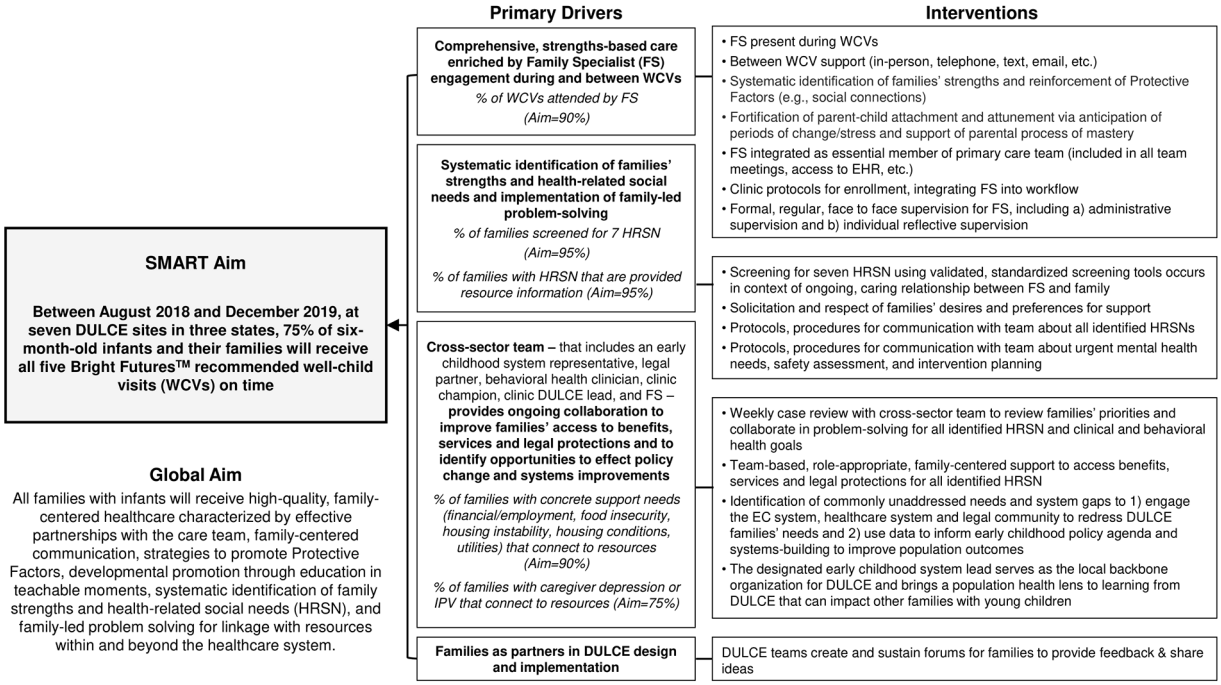


FIGURE 2
DULCE Key Driver Diagram.

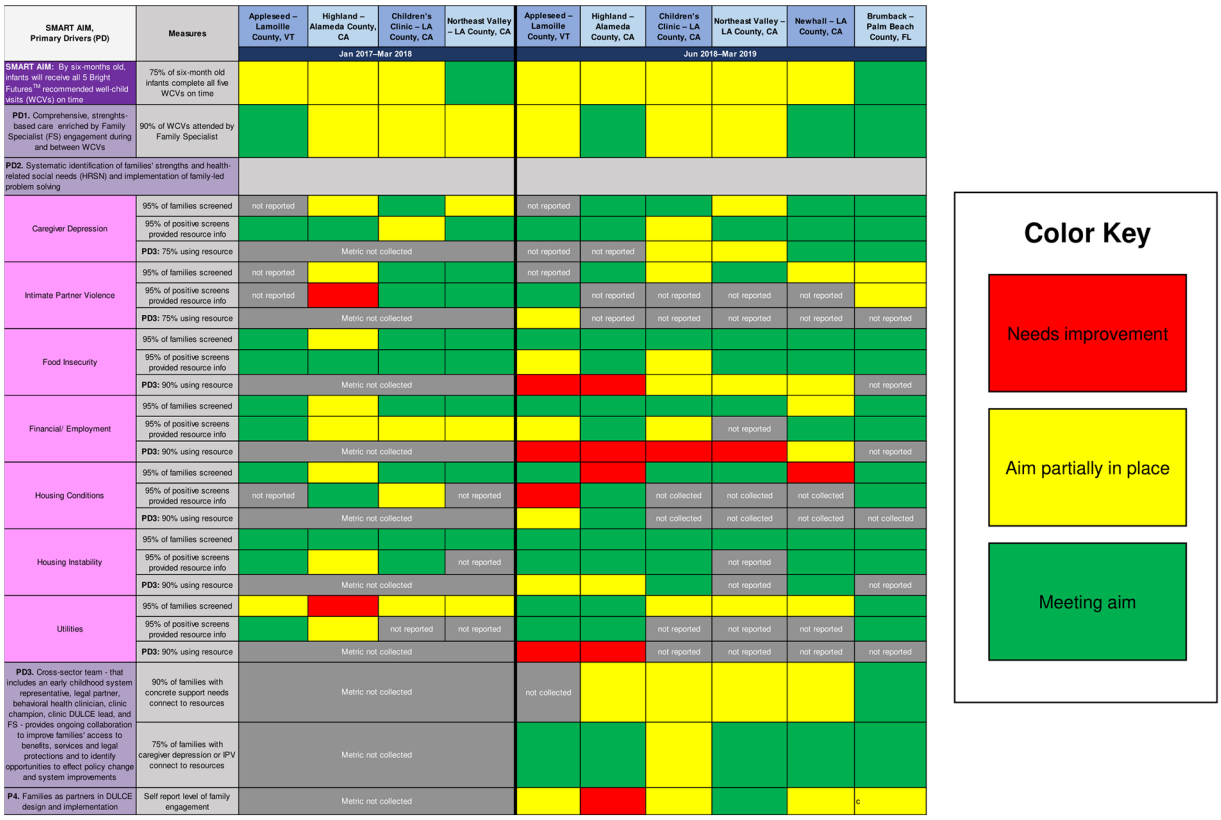
created the DULCE approach and conducted the original randomized controlled trial (RCT), then remained actively involved through phase one and phase two expansion not only as thought partners and strategists, but also as teachers, mentors and coaches to DULCE site teams and their role-specific counterparts (e.g., clinic leaders, providers, and legal partners). Similarly, the practicing pediatrician and infant mental health specialists each led portions of trainings and coached teams, clinicians, and Family Specialists. The CQI expert supported site teams in using data to inform practice and in applying CQI tools (e.g., PDSA cycles, process maps) to adapt DULCE interventions to work well in their local contexts.

In both phases, efforts were made to include DULCE team members who shared lived experience with the DULCE families. This involved hiring Family Specialists from similar racial, ethnic and linguistic backgrounds to the patients served by DULCE. In practice, this meant hiring Family Specialists with bachelor's or paraprofessional educational level, more consistent with a community health worker profile, in contrast with the original RCT that used masters-level Family Specialists. The decision to change the profile of the FS job description reflected two priorities: an effort to accommodate different cultures and languages to better serve local populations, as well as an effort to design for sustainability and scale, since requiring masters-level FS might limit DULCE's potential reach.

Like Family Specialists, DULCE clinics and teams reflect the populations they serve, often coming from the same communities as families. DULCE team members are culturally and linguistically equipped to care for their local populations, which maximizes the impact of their various areas of expertise (e.g., legal, behavioral health). Furthermore, DULCE print and multimedia materials are available in both English and Spanish. When a family cannot communicate in any of the languages spoken by their care team, clinic interpreters are available. DULCE teams also took advantage of trainings that were offered by cross-sector partners for their own employees in order to further develop their teams' capacities to serve their communities. For example, early childhood systems invited DULCE Family Specialists and behavioral health clinicians to participate in trainings on empathic inquiry, cultural humility, and other topics originally designed for public health home visitors. Legal partners invited clinical staff and early childhood partners to attend educational *charlas* they provided for immigrants and other patients on "Know Your Rights.".

The DULCE National team created a structure wherein teams learned from each other and DULCE National using in-person learning sessions, virtual webinars, and individual team coaching. In addition, teams exchanged learning, identified gaps in process and outcome performance, and drafted PDSA cycles to test and adapt DULCE's intervention elements between Learning Network Calls, until they worked effectively in their own context. Throughout, teams shared data, lessons, and best practices to improve collectively.

DULCE teams' readiness and capacity for integrating DULCE practices and adapting them using CQI methods varied, which is expected and desirable within the BTS model. Rather than controlling for differences in organizational capacities, DULCE National facilitated activities at Learning Sessions for local site teams to identify gaps in process and outcome performance, then summarized teams' performance using a Balanced Scorecard (Figure 3). In April 2018 (four months prior to the start of this study period) and again in April 2019, sites compared their



SMART AIM, Primary Drivers (PD)	Measures	Applesead – Lamoille County, VT	Highland – Alameda County, CA	Children's Clinic – LA County, CA	Northeast Valley – LA County, CA	Applesead – Lamoille County, VT	Highland – Alameda County, CA	Children's Clinic – LA County, CA	Northeast Valley – LA County, CA	Newhall – LA County, CA	Brumback – Palm Beach County, FL
		Jan 2017–Mar 2018				Jun 2018–Mar 2019					
SMART AIM: By six-months old, infants will receive all 5 Bright Futures™ recommended well-child visits (WCVs) on time	75% of six-month old infants complete all five WCVs on time										
PD1. Comprehensive, strengths-based care enriched by Family Specialist (FS) engagement during and between WCVs	90% of WCVs attended by Family Specialist										
PD2. Systematic identification of families' strengths and health-related social needs (HRSN) and implementation of family-led problem solving											
Caregiver Depression	95% of families screened	not reported				not reported					
	95% of positive screens provided resource info										
	PD3: 75% using resource	Metric not collected				not reported	not reported				
Intimate Partner Violence	95% of families screened	not reported				not reported					
	95% of positive screens provided resource info	not reported					not reported	not reported	not reported	not reported	
	PD3: 75% using resource	Metric not collected					not reported	not reported	not reported	not reported	not reported
Food Insecurity	95% of families screened										
	95% of positive screens provided resource info										
	PD3: 90% using resource	Metric not collected									not reported
Financial/ Employment	95% of families screened										
	95% of positive screens provided resource info								not reported		
	PD3: 90% using resource	Metric not collected									not reported
Housing Conditions	95% of families screened										
	95% of positive screens provided resource info	not reported			not reported			not collected	not collected	not collected	
	PD3: 90% using resource	Metric not collected						not collected	not collected	not collected	not collected
Housing Instability	95% of families screened										
	95% of positive screens provided resource info				not reported				not reported		
	PD3: 90% using resource	Metric not collected							not reported		not reported
Utilities	95% of families screened										
	95% of positive screens provided resource info			not reported	not reported			not reported	not reported	not reported	
	PD3: 90% using resource	Metric not collected						not reported	not reported	not reported	not reported
PD3. Cross-sector team - that includes an early childhood system representative, legal partner, behavioral health clinician, clinic champion, clinic DULCE lead, and FS - provides ongoing collaboration to improve families' access to benefits, services and legal protections and to identify opportunities to effect policy change and system improvements	90% of families with concrete support needs connect to resources	Metric not collected				not collected					
	75% of families with caregiver depression or IPV connect to resources	Metric not collected									
P4. Families as partners in DULCE design and implementation	Self report level of family engagement	Metric not collected									c

FIGURE 3
DULCE's balanced scorecard, which reflects its Key Driver Diagram measures, assessed sites' implementation strengths and priority areas for improvement during two periods: January 2017–march 2018 (phase one; established sites only) and June 2018–march 2019 (phase two; new and established sites). These were self-assessments, and some sites did not report certain measures.

DULCE data (not inclusive of April data) against the Key Driver Diagram's aims, assessing how well they were implementing DULCE processes and meeting DULCE outcomes (needs improvement, partially in place, meeting aim). The Balanced Scorecard identified for DULCE National focused teaching topics and local site teams with strong performance in those areas who could teach alongside DULCE National to demonstrate how they successfully implemented that specific DULCE practice. Simultaneously, the Balanced Scorecard made it easy for each team to talk about their gaps and select priority areas for PDSA testing.

New and established DULCE teams designed PDSA cycles to address implementation challenges and drafted process maps with action plans for testing. Teams initiated PDSA cycles by generating predictions about how certain change ideas would impact implementation; then **plan** how to enact the change idea; **do** what they planned; **study** the data collected; and, finally, **act** on how to move forward with the change to achieve the desired results (adopt, adapt, abandon). Supplement 1 shows the PDSA form teams used to guide this process. In keeping with best practices, DULCE teams held monthly CQI meetings where they reviewed PDSAs and solicited feedback from all DULCE team members and clinic staff involved in testing the change idea, as well as DULCE families (e.g., exit surveys).

Figure 4 provides a comparison of support to sites during phases one and two. In phase one, between January 2017 and July 2018, the resource-intensive BTS support included four (4) two- or three-day, in-person Learning Sessions for all DULCE team members from all sites with the DULCE National team; bi-monthly group implementation webinars (total = 6); cross-site, role-alike calls (e.g., Family Specialists from all sites together (18 calls), legal partners from all sites together (12 calls), Early Childhood Leads all together [(18 calls), providers and clinic administrators all together (3 calls); (total = 51)]; monthly site-level CQI coaching with DULCE National's CQI Lead and data reports provided by DULCE National (13 per site = 52 total); and two site visits per site from the DULCE National team (8 total). Phase two's lighter-touch BTS support included two in-person convenings: an initial two-day in-person training where DULCE National provided training about DULCE and CQI methods and established DULCE teams presented illustrative examples (e.g., a role-play of cross-sector case review), and a second all-site convening halfway through (DULCE National Forum) with expert speakers and team presentations; monthly implementation webinars for new sites (6 total) followed by quarterly all-site webinars (4 total), two Family Specialist role-alike calls, monthly individual-level site-level CQI coaching with data compiled by the sites (6 per site = 42 total), and no site visits.

Thus, the phase two teams received fewer in-person trainings (2 v. 4) and site visits from the DULCE National team (0 v. 2) and fewer virtual supports (2 v. 51 role-alike group calls) for shorter duration (monthly cross-site implementation webinars for 6 months, followed by quarterly v. bimonthly webinars for 12

Site Activities: Modified Breakthrough Series Collaborative	Phase 1 Pilot																		
	2017												2018						
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
In-person group training	E		E					E							E				
Implementation/TA webinar		E		E		E				E		E		E					
Cross-site, role-alike call	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Site-level CQI coaching call							E	E	E	E	E	E	E	E	E	E	E	E	E
DULCE National site visits											E								E

Site Activities: Lighter-touch CQI approach	Phase 2 Scale-Up															
	2018					2019										
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
In-person group training			E,* N														
Implementation/TA webinar				N	N	N	N	N	N								
Cross-site, role-alike call	E	E															
Site-level CQI coaching call	E	E	E	E, N	E, N	E, N	E, N	N	N								
Learning Network Call								E			E, N			E, N			E, N
DULCE National Forum										E, N							

FIGURE 4
Comparison of CQI support during phases 1 & 2 of DULCE scale-up: established sites ("E") and new sites ("N") underwent different levels of CQI intensity when first implementing DULCE.

months; monthly CQI coaching for 6 months v. 13 months). Furthermore, phase two teams managed their own data locally, whereas in phase one, DULCE National managed all data in a centralized registry and provided monthly site-level data reports that included process and outcome measures.

2.3. Intervention study

To recruit participants for DULCE spread, the Center for the Study of Social Policy contacted its Early Childhood Learning and Innovation Network for Communities (EC-LINC), a national network of 14 communities that are early childhood systems innovators. In the first phase of expansion, three communities volunteered and recruited clinics serving predominantly Medicaid-insured patients and local public interest law organizations to form DULCE teams. In this second phase, the Los Angeles community added two additional clinics from healthcare systems that installed DULCE in phase one (Table 1). A third DULCE site, Palm Beach County, joined this CQI cohort during phase two; they began implementing DULCE during phase one but did not collect data nor participate in CQI until phase two and are thus considered part of this new cohort.

2.3.1. Data and measures

Family Specialists entered individual-level data into an online, custom-built registry. Demographic characteristics included infant sex; caregiver role, age, marital status, race, and ethnicity; household composition (number of adults and children) and language(s) spoken in the home. Implementation measures included the proportion of families offered participation that enrolled in DULCE, the proportion of enrolled families that completed DULCE, duration of participation (in weeks), number of encounters, and total contact time between families and the Family Specialist. A measure of case review implementation was added for phase two (percent of families discussed in case review at least once within 2 months of DULCE enrollment) because experience from phase one taught us that weekly cross-sector case review was difficult for teams to implement, initially. It was new and logistically challenging to get all DULCE team members in the same room at the same time, especially during clinic operating hours when patient care is the priority. However, once teams experienced case review, it was highly valued and became self-sustaining. As one team leader shared at the October 2018 onboarding when established teams were asked to provide a piece of advice for new DULCE teams: "Commit yourself to weekly cross-sector case review; it's the heartbeat of DULCE.".

Process measures aligned with the primary drivers: PD1) percent of WCVs attended by the FS, PD2) percent of families that were screened for seven HRSN using validated, standardized screening questions, and, among positive screens, the percent of families provided resource information PD3) percent of families with identified HRSN that used HRSN resources.

The main outcome was the percent of six-month-old infants who received all recommended WCVs on time. It includes infants who completed the intervention and received five WCVs on time and infants who dropped out and received all recommended WCVs on time up to the date of dropout. DULCE National defined "on time" based on precedent (44, 49).

Families' data was aggregated to the clinic site where they received care, except for the Children's Clinic–Los Angeles (LA)

TABLE 1 Cross-sector DULCE team members and participating communities.

	Early Childhood System Lead Agencies	Clinic Partners	Legal Partners
Unique contribution	Accountable for a local system of services for families with young children	Offer universal reach and longitudinal relationships with families	Offer a professional orientation toward problem-solving and advocacy
Expertise	Well-versed in community resources for families and training opportunities for FS	Well-versed in the use of standard protocols to improve quality of care	Well-versed in family rights and system responsibilities
Role on team	Inform team of available community resources, champion evidence-informed practices, influence policy	Provide ongoing monitoring of families' status and coaching of the FS to respond to unique infant and family circumstances	Lend a policy lens and expertise, offer ongoing identification of supports and strategies to address family needs
Communities[a]			
Alameda County, CA	First 5 Alameda County	Highland Pediatric Clinic (Oakland, CA)	East Bay Community Law Center
Lamoille Valley, VT	Lamoille Family Center	Appleseed Pediatrics	Vermont Legal Aid
Palm Beach County, FL	Children's Services Council of Palm Beach County	**C.L. Brumback Health Center**	Legal Aid Society of Palm Beach County, Inc.
Los Angeles County, CA	First 5 Los Angeles	The Children's Clinic (Long Beach, CA)	Legal Aid Foundation of Los Angeles
		The Children's Clinic – The S. Mark Taper Foundation Health Center	
		Northeast Valley Health Corporation, Sun Valley	
		Northeast Valley Health Corporation, Newhall Health Center	

[a]New DULCE clinical sites that participated in the second phase of scale-up have been bolded.

sites [Central Long Beach Family Health Center, S. Mark Taper Foundation Health Center (SMTF)], whose data was reported together. As a result, there are data from one mixed new-established site (Children's Clinic–LA), two new sites (Newhall–LA and Brumback–Palm Beach), and three established sites (Appleseed–Lamoille, Highland–Alameda, Northeast Valley–LA).

2.4. Definition of the sample

Families with newborns up to 8 weeks of age were enrolled at their first office visit, excluding newborns hospitalized for >7 days after birth because they may warrant specialized services. At sites with more newborns than one FS could serve, DULCE was offered to a randomly selected subset. Clinics introduced DULCE as part of routine care, included information about DULCE in welcome packets, and introduced the FS as a care team member at the first WCV. Families could opt out.

Newborn enrollment (up to 8 weeks of age) was ongoing and continued beyond the study period. This report includes babies born June 2018 through December 2019 and followed through their six-month WCV.

Descriptive statistics were calculated for patient demographic characteristics by site and for the complete analytic sample, which includes 989 families with infants born June 2018 through December 2019 (Table 2). To describe the reach of phase two expansion, Table 3 presents a comparison of the early childhood system's catchment population (i.e., the county) to DULCE-enrolled families (the "County" and "DULCE" columns, respectively). To examine how well-aligned DULCE team members' and DULCE families' backgrounds were, the "Team" column of Table 3 presents the composition of each site's DULCE team, which largely reflected the racial, ethnic, and linguistic makeups of their communities and/or DULCE families. Besides the DULCE site in Vermont, which enrolled 127 of 346 newborns (37%) in the county, all other sites enrolled less than 1% of infants in the early childhood system's catchment area. To put in perspective how many families DULCE reached within each site's healthcare system, we also summarized the number of infants enrolled relative to the system-level and clinic-level newborn populations (Table 4). Similarly, the Vermont site reached a higher proportion of its system-level and clinic-level infants (49.0% and 89.4%, respectively), compared to the California sites' system-level and clinic-level reach, which ranged 8.3%–12.5% and 14.3%–50.0%, respectively.

Table 3 also includes the Social Vulnerability Index (50) for each county: Lamoille County has low vulnerability, Alameda County has medium to high vulnerability, while Los Angeles and Palm Beach counties have a high level of vulnerability. In these latter three counties, Hispanic/Latinx and Black families are overrepresented among DULCE families, relative to county-level demographics. This overrepresentation reflects the intention to launch DULCE in clinics with high Medicaid-enrolled populations, which tend to have higher proportions of Hispanic/Latinx and Black patients.

2.5. Analysis

To answer the first research question – can a lighter-touch application of BTS sustain improvements achieved during a prior expansion by four established DULCE teams and spread improvements in on-time WCVs and identification and support for HRSN to three new clinics? – we first calculated descriptive statistics for measures of implementation fidelity for all sites together and for each clinic-based team separately: DULCE enrollment and completion rates, number of weeks enrolled, total number of encounters per family, percent of families discussed in case review at least once, and FS-family contact time. We compared these values to benchmark values from phase one,

TABLE 2 Demographic characteristics of DULCE families by site.

	Total	Appleseed – Lamoille County, VT	Highland – Alameda County, CA	Northeast Valley – LA County, CA	Children's Clinic[a] – LA County, CA	Newhall[b] – LA County, CA	Brumback – Palm Beach County, FL
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
Full sample	989 (100)	127 (100)	194 (100)	146 (100)	249 (100)	155 (100)	118 (100)
Child sex[c]							
Male	523 (52.9)	60 (47.2)	111 (57.2)	70 (47.9)	131 (52.6)	93 (60.0)	58 (49.6)
Female	465 (47.1)	67 (52.8)	83 (42.8)	76 (52.1)	118 (47.4)	62 (40.0)	59 (50.4)
Primary caregiver[d]							
Mother	974 (98.9)	124 (98.4)	192 (99.0)	143 (99.3)	246 (98.8)	151 (98.1)	118 (100)
Father	3 (0.3)	1 (0.8)	1 (0.5)	1 (0.7)	0 (0)	0 (0)	0 (0)
Other[e]	8 (0.8)	1 (0.8)	1 (0.5)	0 (0)	3 (1.2)	3 (1.9)	0 (0)
Primary caregiver marital status[f]							
Single	353 (42.5)	18 (14.3)	77 (39.9)	11 (7.7)	168 (69.7)	1 (10.0)	78 (66.7)
Married	327 (39.4)	58 (46.0)	68 (35.2)	85 (59.4)	68 (28.2)	9 (90.0)	39 (33.3)
Domestic partner	150 (18.1)	50 (39.7)	48 (24.9)	47 (32.9)	5 (2.1)	0 (0)	0 (0)
Primary caregiver age, median (range)	28 (14–66)	29 (16-43)	28 (14–43)	28 (16–47)	28 (14–66)	29 (17–47)	27 (16–42)
Primary caregiver race/ethnicity[g]							
Hispanic/Latinx	407 (52.9)	0 (0)	104 (62.7)	12 (80.0)	120 (58.0)	102 (71.8)	69 (59.5)
White	160 (20.8)	116 (94.3)	5 (3.0)	1 (6.7)	8 (3.9)	30 (21.1)	0 (0)
Black	157 (20.4)	4 (3.3)	45 (27.1)	1 (6.7)	56 (27.1)	4 (2.8)	47 (40.5)
Asian	35 (4.6)	3 (2.4)	6 (3.6)	1 (6.7)	20 (9.7)	5 (3.5)	0 (0)
Pacific Islander	6 (0.8)	0 (0)	4 (2.4)	0 (0)	1 (0.5)	1 (0.7)	0 (0)
Native American	4 (0.5)	0 (0)	2 (1.2)	0 (0)	2 (1.0)	0 (0)	0 (0)
Secondary caregiver[h]							
Father	585 (96.7)	111 (97.4)	145 (99.3)	11 (100)	193 (93.2)	30 (96.8)	95 (99.0)
Grandparent	7 (1.2)	1 (0.9)	0 (0)	0 (0)	6 (2.9)	0 (0)	0 (0)
Mother	7 (1.2)	2 (1.8)	1 (0.7)	0 (0)	3 (1.4)	1 (3.2)	0 (0)
Other caregiver	5 (0.8)	0 (0)	0 (0)	0 (0)	4 (1.9)	0 (0)	1 (1.0)
Legal guardian	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.5)	0 (0)	0 (0)
Secondary caregiver age, median (range)	30 (17–59)	32 (19–59)	30 (17–51)	35 (19–55)	30 (17–53)	24.5 (17–36)	31 (19–50)
Number of adults in home[i]							
1	70 (7.4)	7 (5.5)	16 (8.7)	9 (6.5)	16 (6.9)	13 (8.4)	9 (7.8)
2	651 (68.5)	106 (83.5)	101 (55.2)	111 (80.4)	145 (62.5)	108 (70.1)	80 (69.0)
3	130 (13.7)	11 (86.6)	31 (16.9)	9 (6.5)	47 (20.3)	18 (11.7)	14 (12.1)
4 or more	99 (10.4)	3 (2.4)	35 (19.1)	9 (6.5)	24 (10.3)	15 (9.7)	13 (11.2)

(*continued*)

TABLE 2 Continued

	Total	Appleseed – Lamoille County, VT	Highland – Alameda County, CA	Northeast Valley – LA County, CA	Children's Clinic[a] – LA County, CA	Newhall[b] – LA County, CA	Brumback – Palm Beach County, FL
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
Number of children in home[j]							
1	349 (39.3)	48 (37.8)	77 (41.6)	59 (45.7)	69 (30.3)	58 (37.9)	38 (58.5)
2	274 (30.9)	49 (38.6)	56 (30.3)	34 (26.4)	76 (33.3)	43 (28.1)	16 (24.6)
3	164 (16.6)	19 (15.0)	28 (15.1)	23 (17.8)	5 (25.9)	31 (20.3)	4 (6.2)
4 or more	100 (10.1)	11 (8.7)	24 (13.0)	13 (10.1)	24 (10.5)	21 (13.7)	7 (10.8)
Primary language spoken at home[k]							
English	620 (63.4)	124 (97.6)	83 (43.0)	97 (67.8)	196 (80.3)	101 (65.2)	19 (16.4)
Spanish	239 (24.4)	0 (0)	67 (34.7)	46 (32.2)	33 (13.5)	39 (25.2)	54 (46.6)
English & Spanish	34 (3.5)	0 (0)	9 (4.7)	0 (0)	5 (2.0)	13 (8.4)	7 (6.0)
Other[l]	85 (8.7)	3 (2.4)	34 (17.6)	0 (0)	10 (4.1)	2 (1.3)	36 (31.0)

[a]This site did not reliably collect data on primary caregiver race/ethnicity or the secondary caregiver's relationship to child.
[b]This site did not reliably collect data on primary marital status or the secondary caregiver's relationship to child.
[c]There was 1 family with a child of unknown sex.
[d]There were 4 families with unknown primary caregiver relationship to child.
[e]4 Foster parents, 2 Legal guardians, 1 Grandparent, 1 Other caregiver.
[f]Percentages calculated among 830 families with known primary caregiver marital status.
[g]Percentages calculated among 769 families with known primary caregiver race.
[h]Percentages calculated among 605 families with known secondary caregiver relationship to child.
[i]Percentages calculated among 950 families with known number of adults at home.
[j]Percentages calculated among 887 families with known number of children at home.
[k]There were 11 families with unknown primary language spoken at home.
[l]Amharic, Arabic, ASL, Bengali, Creole, Dari, French, Igbo, Khmer, Mam, Nepali, Pashto, Popti, Portuguese, Punjabi, Russian, Samoan, Sinhala, Swahili, Tagalog, Tamil, Thai, Tigrigna, Turkish, Vietnamese, Yoruba, English & Other, Spanish & Other.

except for the case review measure which was collected for the first time during phase two.

To determine if improvements were sustained and spread, we calculated the process measures associated with DULCE's primary drivers and the outcome measure associated with its main aim for all sites together and for each clinic-based team separately. We then analyzed process and outcomes in time series as run charts, well-established methods that can identify changes that are unlikely due to chance alone and allow inferences to be drawn from the temporal relationships of interventions and results (51). Subjects were counted in the denominator of each measure once (i.e., denominators are independent of each other) and placed in the month they enrolled (all WCVs on time; all HRSN measures), in the month the data point occurred (FS WCV attendance), or, for the 1-month WCV timeliness measure, in the month containing the last day of the 1-month visit window.

Means were used because these were non-continuous data, and some measures' medians were extreme values due to high baseline performance (e.g., baseline median screening rates of 100%) and small site-level denominators (e.g., months with few or no identified IPV cases). Criteria for applying probability-based rules for identifying improvements were met: denominators were roughly equal over time, and at the aggregate level, data was appropriately dispersed (52).

Two probability-based rules were used to identify changes in the data that have less than 5% probability of occurring by chance: a "shift" of six or more points in a row above or below the mean, and a "trend" of five consecutive increasing or decreasing points (53). When a shift occurred, the average of the six shifted points became the new mean, from which subsequent shifts were identified.

To answer the second research question – what proportion of families use resources after receiving resource information for identified HRSN? – for families that screened positive for HRSN, we calculated the proportion of families that were provided resource information and the proportion that used HRSN resources for caregiver depression and/or IPV, for concrete supports, and for each HRSN separately.

Analyses were conducted using Stata 14.2.

2.6. Ethical considerations

The University of Chicago School of Social Administration's Institutional Review Board (IRB17-0414) approved this study.

3. Results

Table 2 describes the analytic sample. Families of 989 infants born June 1, 2018 through December 31, 2019 participated; 98.9% of primary caregivers were mothers whose median age was 28 years. Forty-three percent were single; 20.8% identified as White, 20.4% as Black, and 52.9% as Hispanic/Latinx. Sixty-one percent of families reported a

TABLE 3 Demographics of the early childhood system's county catchment area, DULCE families, and DULCE teams. .

Demographics	Appleseed –Lamoille County, VT			Highland –Alameda County, CA			Los Angeles County, CA						Brumback – Palm Beach County, FL		
							Northeast Valley		Newhall		Children's Clinic[a]				
Social Vulnerability Index[b]	0.131			0.555			0.869		0.869		0.869		0.796		
	County	DULCE	Team	County	DULCE	Team	County[c]	DULCE	DULCE	Team[d]	DULCE	Team	County	DULCE	Team
Total (N)[e]	346	127	7	25,809	194	6	76,648	146	155	11	249	9	21,014	118	11
Race/Ethnicity[f] (%)															
Hispanic/Latinx	2.0%	0%	0%	22.4%	62.7%	50%	49.1%	80.0%	71.8%	63.7%	58.0%	44.4%	23.9%	59.5%	27.3%
White	94.2%	94.3%	85.7%	29.2%	3.0%	33.3%	25.3%	6.7%	21.1%	18.2%	3.9%	44.4%	52.6%	0%	36.4%
Black	1.2%	3.3%	0%	10.7%	27.1%	16.7%	9.0%	6.7%	2.8%	9.1%	27.1%	0%	20.1%	40.5%	36.4%
Asian	0.7%	2.4%	0%	33.8%	3.6%	0%	15.6%	6.7%	3.5%	9.1%	9.7%	11.1%	3.0%	0%	0%
Pacific Islander	0.1%	0%	0%	1.0%	2.4%	0%	0.4%	0%	0.7%	0%	0.5%	0%	0.1%	0%	0%
Native American	0.4%	0%	0%	1.1%	1.2%	0%	1.5%	0%	0%	0%	1.0%	0%	0.6%	0%	0%
Multiracial	1.8%	0%	0%	5.6%	N/A	N/A	3.3%	N/A	N/A	N/A	N/A	0%	1.9%	N/A	N/A
Not reported	N/A	N/A	14.3%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Language other than English spoken[f] (%)	3.5%	2.4%	14.3%	46.0%	57.0%	66.7%	55.8%	32.2%	34.8%	72.7%	19.7%	66.7%	33.1%	83.6%	36.4%
Average N household members[f]	2.33	4.04	N/A	2.82	4.53	N/A	2.94	4.08	4.36	N/A	4.53	N/A	2.51	3.96	N/A

N/A; data not available or not collected.

[a]The Children's Clinic includes data for 2 DULCE clinics: Central Long Beach (established site) and S. Mark Taper Foundation (new site).

[b]The Social Vulnerability Index uses U.S. Census data to determine the relative level of social vulnerability of each county: https://www.atsdr.cdc.gov/placeandhealth/svi/interactive_map.html, 0.131 = low, 0.555 = medium to high, 0.796 and 0.869 = high.

[c]The county-level data for Los Angeles County applies to all three sites: Northeast Valley, Newhall, Children's Clinic.

[d]Northeast Valley and Newhall shared the same DULCE team.

[e]County totals represent the newborn population in each county over the study period.

[f]County-level data from 2020 U.S. census. These demographic data are not restricted to families with infants: https://www.census.gov/quickfacts/fact/table/US/PST045221.

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TABLE 4 DULCE's reach within each site's pediatric clinic(s) and affiliated healthcare system.

Healthcare System	Appleseed – Lamoille County, VT	Highland – Alameda County, CA	Los Angeles County, CA			Brumback[a] – Palm Beach County, FL
			Northeast Valley	Newhall	Children's Clinic	
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Pediatric clinics in system	3 (100)	5 (100)	9 (100)		9 (100)	2 (100)
Pediatric clinics that implemented DULCE	1 (33.3)	1 (20.0)	2 (22.2)		2 (22.2)	1 (50.0)
Infants that received care at all clinics in the system	259 (100)	1,558 (100)	3,632 (100)		2,182 (100)	26,316 visits
Infants that enrolled in DULCE among all infants receiving care in system	127 (49.0)	194 (12.5)	301 (8.3)		249 (11.4)	118 (n/a)
Infants that received care at DULCE-implementing clinic(s)	142 (54.8)	388 (24.9)	580 (16.0)		1,741 (79.8)	10,574 visits
Infants that enrolled in DULCE among all infants at DULCE-implementing clinics	127 (89.4)	194 (50.0)	146 (25.2)	155 (26.7)	249 (14.3)	118 (n/a)

[a]The C.L. Brumback Primary Care site provided the number of pediatric visits over the study period, not the number of infants served.

second caregiver: 96.7% were fathers, whose median age was 30 years. Families mainly spoke English (63.4%) or Spanish (24.4%). Families represented the demographics of the clinics' populations and were similar to families in DULCE's phase one expansion (44). The level to which families reflected county-level demographics (i.e., the early childhood system's catchment area) varied by site (Table 3). For example, the demographic characteristics of DULCE families at Appleseed Pediatrics were similar to those of Lamoille County, but Highland Hospital in Oakland, CA (a safety-net hospital) served a much higher proportion of Hispanic/Latinx and Black families than are represented in Alameda County's demographic data.

To answer the first research question – can a lighter-touch application of BTS sustain improvements achieved during a prior expansion by four established DULCE teams and spread improvements in on-time WCVs and identification and support for HRSN to three new clinics? – we first consider the main outcome (i.e., on-time WCVs) then implementation and process measures. We compare them to the phase one outcome, implementation, and process measures.

Figure 5 shows the main outcome: at baseline, 41.4% of six-month-old infants completed all five recommended WCVs on time. A shift to 48.1% occurred at six months (February 2019).

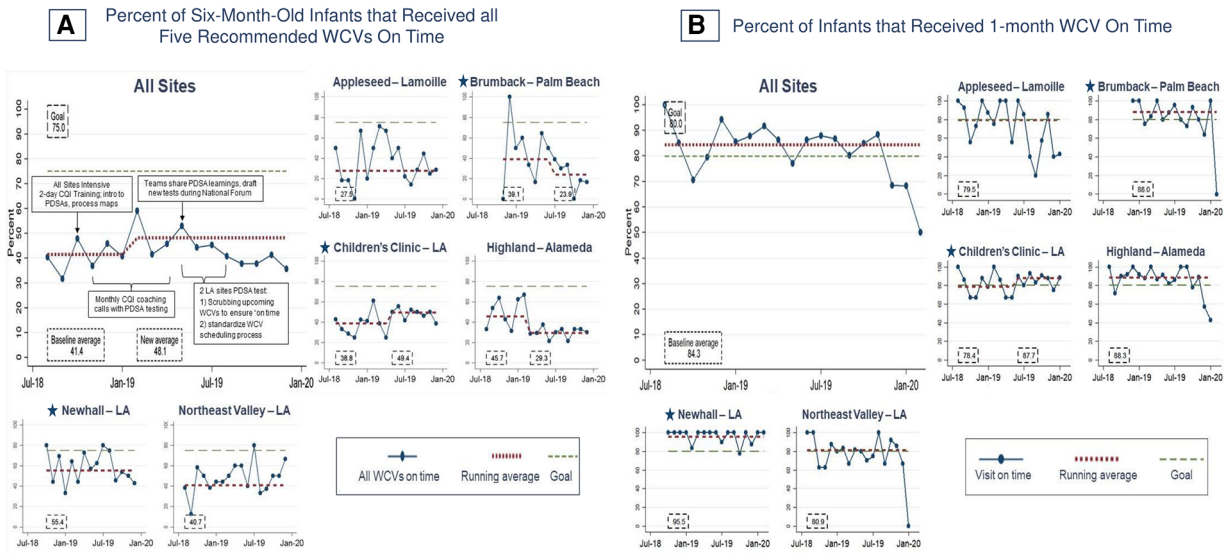

FIGURE 5
Percent of infants that received recommended well-child visits on time. Star symbols denote new DUCLE sites: Brumback (Palm Beach County), The Children's Clinic [Los Angeles (LA) County], which aggregated data for its established and new DULCE clinics, and Newhall, part of the Northeast Valley Health Corporation (LA county), a previously established DULCE site.

One clinic (Children's Clinic–LA) demonstrated an increase from 38.8% to 49.4% that correlated with improved 1-month WCVs timeliness (78.4% to 87.7%) when they tested standardized scheduling at their two clinics (one established and one new). Overall, this is comparable with phase one, during which sites demonstrated a shift from a baseline average of 45.8% to 65.4% that also was associated with improvements in on-time 1-month WCVs at three sites (Appleseed–Lamoille, Highland–Alameda, and Northeast Valley–LA). The more modest improvement might be explained, at least in part, by the decrease in preventive care by infants and their families during the COVID-19, which affected this measure for all infants born after August 2019. In addition, during phase two, one established site and one new site experienced downward shifts concurrent with the transition from individual site-level monthly coaching with data provided by DULCE National to quarterly Learning Network Calls and local data management: from 45.7% to 29.3% at Highland–Alameda (March 2019), and 39.1% to 23.9% at Brumback–Palm Beach (July 2019).

Overall, implementation measures were similar between phases one and two. All families offered DULCE enrolled, and 73.8% completed the six-month intervention, mirroring enrollment and completion rates observed in phase one (100% and 79%, respectively). Nearly two-thirds of families that left early moved away or changed clinics (Table 5), like in phase one. In phase two, enrolled families had a median intervention dose of 26 weeks [Interquartile Range (IQR), 20–28], nine encounters (IQR, 6–14), and 180 min of FS contact time (IQR, 120–295), compared to 24 weeks [confidence interval (CI), 23.1–24.2], 11 encounters (CI, 10.3–11.1), and 280 min (CI, 265–294) in phase one. During phase two, teams discussed 67% of families in case review within two months of DULCE enrollment; this measure was not collected in phase one.

Figure 6 shows that the process measure for FS present in WCVs (PD1) was high at baseline and remained stably high throughout phase two: in aggregate, FS attended 89.8% of WCVs (Figure 6). This exceeded phase one performance, which improved from 0% to 66% to 70%. Two phase two new sites immediately achieved and sustained high FS presence: Newhall–LA (92.3%) and Brumback–Palm Beach (92.0%). At the Children's Clinic–LA site, which reported data for its established site and new site together, FS presence in WCVs dipped to 88.2% when the new SMTF site joined, then shifted to 93.3% in October 2018, coincident with the two-day, in-person onboarding. All sites demonstrate a sharp decline in the first quarter of 2020 that corresponds to clinic safety protocol changes in response to the COVID-19 pandemic (Figure 6).

Figure 7 shows process measures for HRSN screening (PD2). The phase two aggregate measure of families screened for all seven HRSN improved from a baseline of 75.7% to 89.9%, with three sites demonstrating shifts: one mixed new-established site [55.1%

TABLE 5 DULCE enrollment, completion and reasons for leaving early.

	Total	Appleseed – Lamoille County, VT	Highland – Alameda County, CA	Northeast Valley – LA County, CA	Children's Clinic – LA County, CA	Newhall – LA County, CA	Brumback – Palm Beach County, FL
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
Families offered DULCE	989	127	194	146	249	155	118
Families enrolled in DULCE	989 (100)	127 (100)	194 (100)	146 (100)	249 (100)	155 (100)	118 (100)
Families that completed DULCE	730 (73.8)	113 (89.0)	141 (72.7)	87 (59.6)	186 (74.7)	117 (75.5)	86 (72.9)
Families that left DULCE early[a]	259 (26.2)	14 (11.0)	53 (27.3)	59 (40.4)	63 (25.3)	38 (24.5)	32 (27.1)
Reasons for leaving early[a]							
Moved home	101 (39.0)	10 (71.4)	12 (22.6)	25 (42.4)	35 (55.6)	15 (39.5)	4 (12.5)
Change clinic or provider	58 (22.4)	2 (14.3)	15 (28.3)	0 (0)	15 (23.8)	11 (28.9)	15 (46.9)
Lost to follow-up	41 (15.8)	2 (14.3)	19 (35.8)	0 (0)	3 (4.8)	7 (18.4)	10 (31.3)
Family requested	17 (6.6)	0 (0)	4 (7.5)	2 (3.4)	4 (6.3)	5 (13.2)	2 (6.3)
Baby died or removed from home	2 (0.8)	0 (0)	1 (1.9)	0 (0)	1 (1.1)	0 (0)	0 (0)
Other	5 (1.9)	0 (0)	2 (3.8)	0 (0)	2 (3.2)	0 (0)	1 (3.1)
Missing	35 (13.5)	0 (0)	0 (0)	32 (54.2)	3 (4.8)	0 (0)	0 (0)

[a]Families that left DULCE prior to completing their six-month well-child visit.

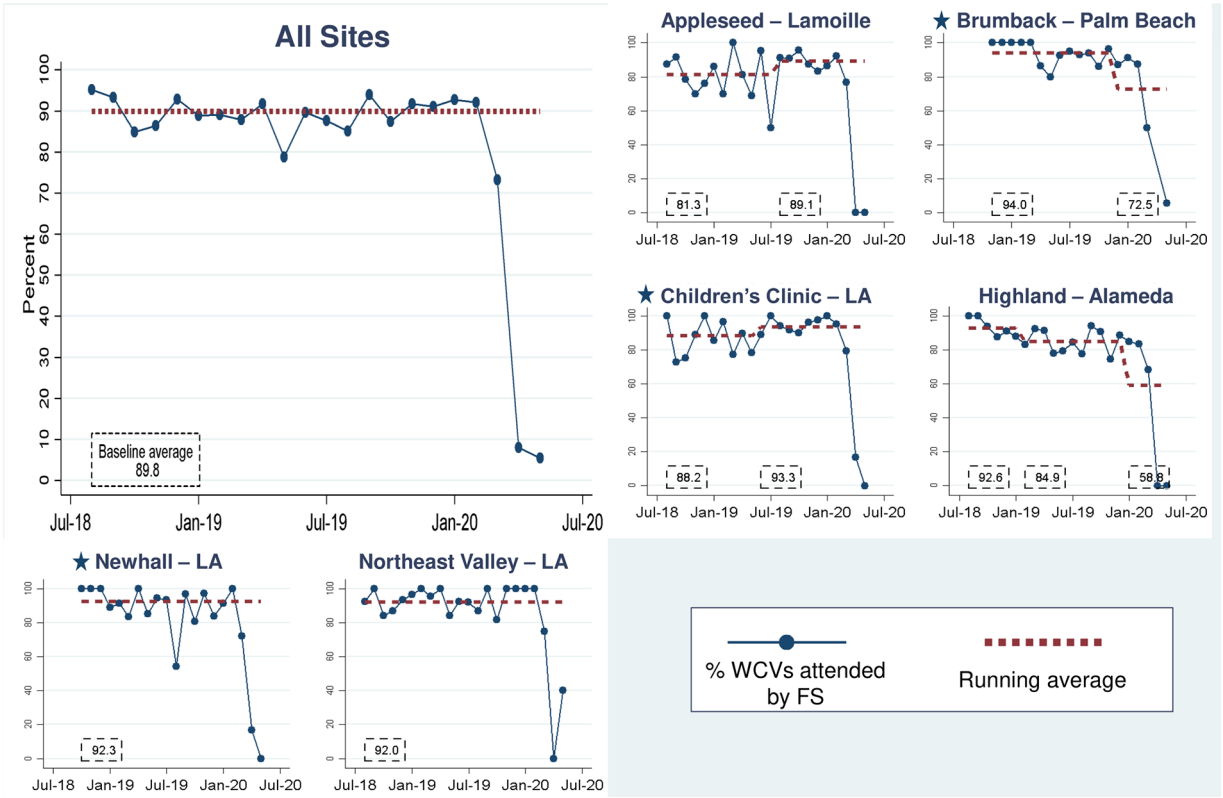

FIGURE 6
Percent of well-child visits (WCVs) attended by the family specialist. Star symbols denote new DUCLE sites: Brumback (Palm Beach County), The Children's Clinic [Los Angeles (LA) County], which aggregated data for its established and new DULCE clinics, and Newhall, part of the Northeast Valley Health Corporation (LA county), a previously established DULCE site.

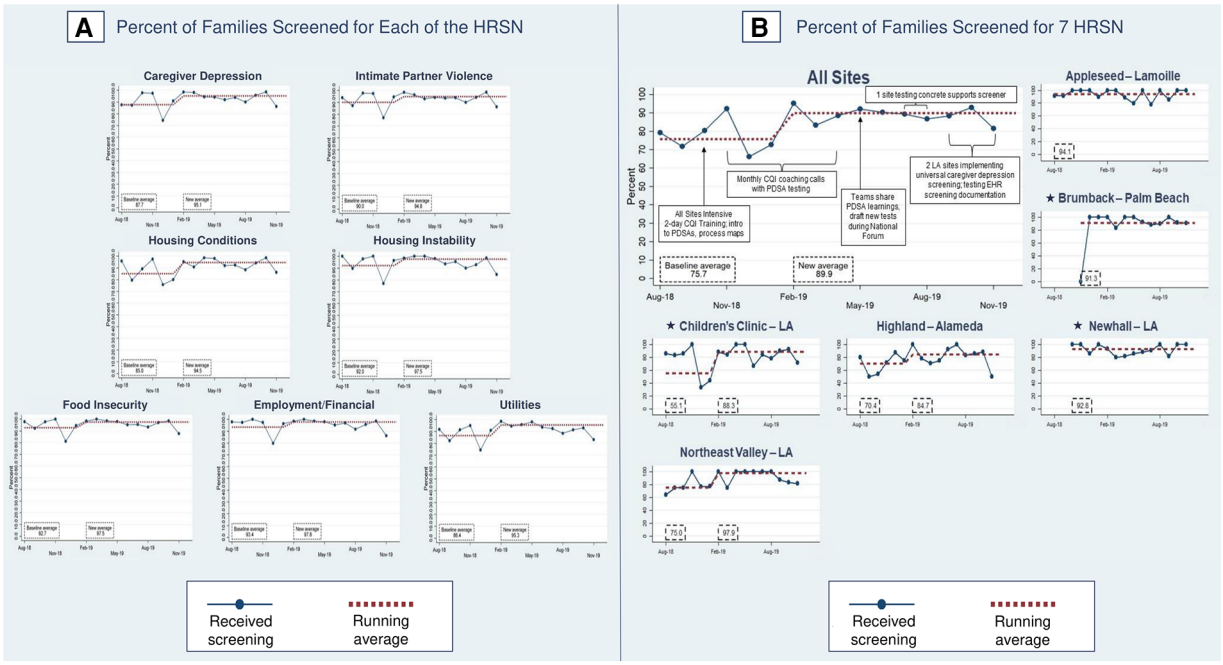

FIGURE 7
Percent of families screened for health-related social needs (HRSN). Star symbols denote new DUCLE sites: Brumback (Palm Beach County), The Children's Clinic [Los Angeles (LA) County], which aggregated data for its established and new DULCE clinics, and Newhall, part of the Northeast Valley Health Corporation (LA county), a previously established DULCE site.

to 88.3% (Children's Clinic–LA)] and two established sites [70.4% to 84.7% (Highland–Alameda), 75.0% to 97.9% (Northeast Valley–LA)]. In phase one, sites screened 92% of families for all seven HRSN.

For each HRSN, screening rates in phase two were 85.0%–93.4% at baseline and improved, with shifts at 6 months in caregiver depression (87.7% to 95.1%), IPV (90.0% to 94.8%), housing conditions (85.0% to 94.5%), housing instability (92.0% to 97.5%), food insecurity (92.7% to 97.5%), employment/financial needs (93.4% to 97.8%), and utilities (86.4% to 95.3%). Improved rates were similar with phase one screening performance: caregiver depression (95.9%), IPV (96.3%), housing conditions (shift from 94.5% to 95.8%), housing instability (97.2%), food insecurity (97.2%), employment/financial needs (98.6%), and utilities (96.8%).

In phase two, 54% of families had at least one positive HRSN screen: 20% had two and 11% had three or more. This differed from phase one, where 70% of families had at least one positive screen: 25% had two and 16% had three or more. Prevalence of individual HRSN varied as well between phase two and phase one: for food insecurity, 39.0% of phase two families vs. 46.1% of families in phase one; for employment/financial needs, 30.2% vs. 51.0%; for caregiver depression, 20% vs. 14.3%; for housing instability, 5.1% vs. 13.2%; for IPV, 4.3% vs. 5.1%; for unhealthy housing conditions, 2.1% vs. 3.5%, and for utility needs, 1.0% vs. 2.2% (Figure 8).

In phase two, 80% of families experiencing caregiver depression and/or IPV and 90% of families with concrete supports needs received resource information (PD2) (Figure 9), an increase from 70.7% of families with caregiver depression and/or IPV and 86.4% with concrete support needs at the end of phase one. In phase two, FS provided resource information to 92.1% of families with food insecurity, 55.3% with employment/financial needs, to 79.0% of depressed caregivers, 70.2% with housing instability, 61.5% of families with IPV, 94.7% with unhealthy housing conditions, and 55.6% with utility needs (Figure 8).

The last process measure – the percent of families with HRSN that used resources (PD3) – responds to this study's second research question with new data that was not collected in phase one. Among families with at least one identified HRSN, 87.4% successfully used at least one related resource (Figure 8). The percent of families that used concrete supports resources increased from 87.1% to 92.9% of families (Figure 10). Resource use varied by HRSN (Figure 8): food insecurity (97.0%), employment/financial needs (58.2%), caregiver depression (54.7%), housing instability (12.8%), IPV (51.3%), housing conditions (78.9%), and utilities (44.4%).

4. Discussion

This study examined the results of scaling a pediatric clinic-based EBI using a lighter-touch CQI approach. Scaling within existing healthcare and early childhood systems capitalized on existing relationships, infrastructure, and experience, allowing for lighter-touch CQI support that reduced implementation and maintenance costs. The main outcome (percent of infants who received all recommended WCVs on time) initially dropped to a similar baseline average (41.4%) seen in the first phase expansion, then demonstrated modest improvement to 48.1%, despite the lower use of preventive care during the initial phase of the COVID-19 pandemic (54).

Other process measures concerning families' WCVs (1-month WCV timeliness, FS presence) and HRSN (rates of screening, resource discussion, and – newly – resource use) were maintained or improved. These results shed insight into the varying levels of

FIGURE 8
Identification and support for DULCE families' health-related social needs (HRSN), by HRSN domain.

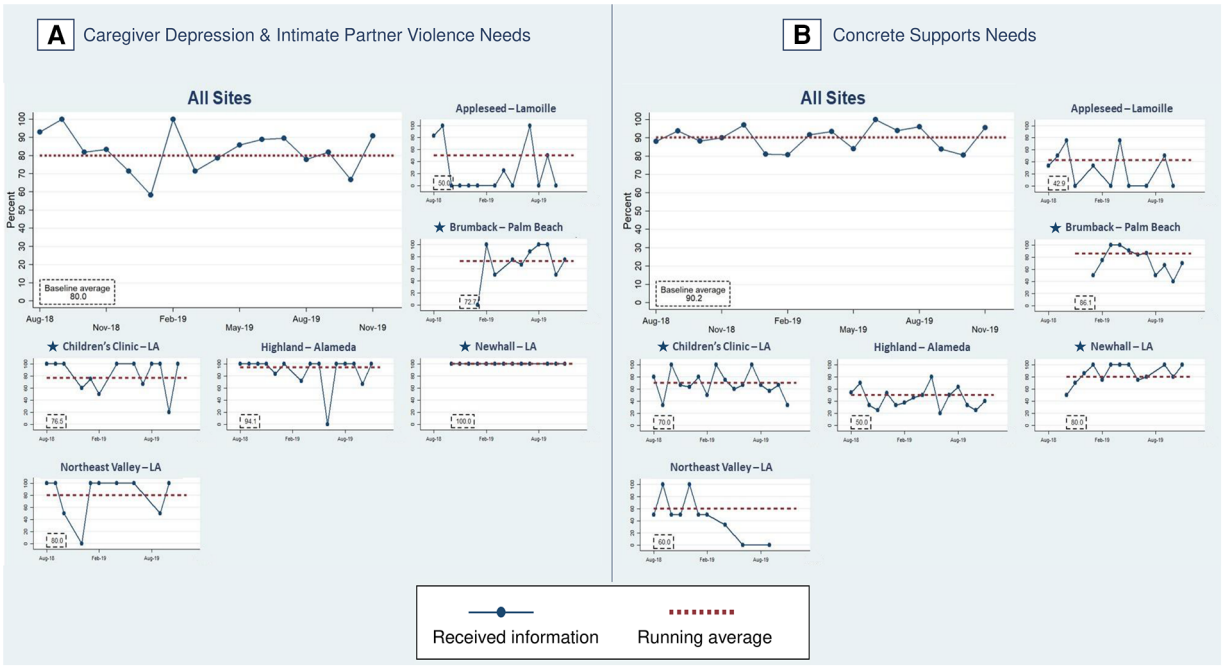

FIGURE 9
Percent of families with identified health-related social needs that received information about available resources. Star symbols denote new DUCLE sites: Brumback (Palm Beach County), The Children's Clinic [Los Angeles (LA) County], which aggregated data for its established and new DULCE clinics, and Newhall, part of the Northeast Valley Health Corporation (LA county), a previously established DULCE site.

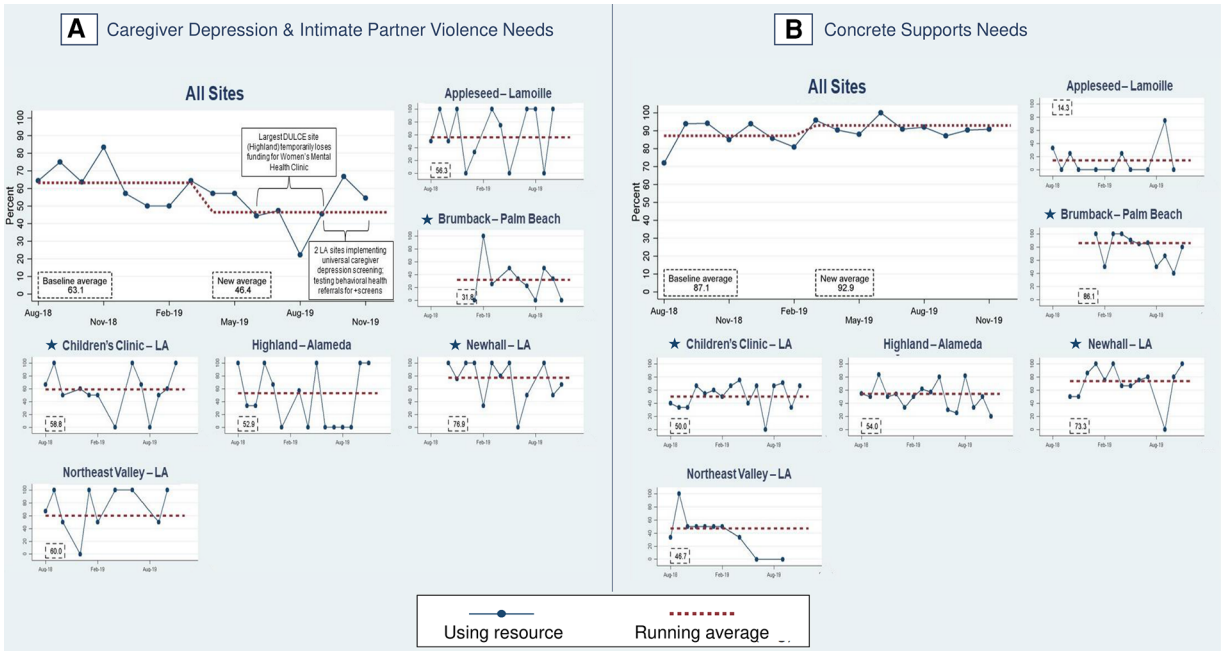

FIGURE 10
Percent of families with identified health-related social needs using resources. Star symbols denote new DUCLE sites: Brumback (Palm Beach County), The Children's Clinic [Los Angeles (LA) County], which aggregated data for its established and new DULCE clinics, and Newhall, part of the Northeast Valley Health Corporation (LA county), a previously established DULCE site.

CQI support needed to introduce or sustain different intervention components.

Many improvements from DULCE's phase one expansion spread quickly to new sites and further improved at established sites. DULCE practice change, namely FS presence in WCVs, increased from 0 to 66% over 10 months of intensive support during phase one, then reached 89.8% in the first six months of this second phase (until COVID-19 necessitated limits to in-person contact).

The second phase benefitted from innovations in phase one, including providers acceptance of FS presence and CQI-driven changes in scheduling practices and clinic workflows (44). This measure's continued improvement suggests that once FSs are integrated into clinical teams, they become an essential, sustainable part of clinic function.

Similarly, HRSN screening and resource discussion processes were sustained by established sites and spread to new sites with lighter-touch CQI support. As is commonly observed in efforts to disseminate EBIs (8, 46, 52), integration of new sites at the beginning of phase two produced a dip in performance that recovered quickly – i.e., phase two's aggregate baseline screening rates were slightly lower than late phase-one levels, but reached very high rates within six months. For example, one site (The Children's Clinic–LA) took one year to improve screening for seven HRSN from 92% to 100% of families in phase one, then dropped to 50% when a second, much larger site (SMTF) was added, and recovered to 88% within six months.

Accelerated adoption by new sites and ongoing improvement of established sites reflects intentional design that included all actors in phase one, then drew on them to harvest tested implementation strategies and leverage the power of peer champions to introduce innovations (as described in the literature) (8, 14, 55, 56). In this case, two of the three new clinic sites were within the same healthcare delivery system as established sites, and clinical leadership benefitted from integrating into their "new" DULCE site teams the same legal partners and early childhood system leaders as the established sites. Such design allows for tapering the intensity of support while maintaining early adopters' outcomes and spreading improvements to additional sites (57).

However, not all phase-one improvements were sustained. The main outcome regressed to pre-phase one levels (~41% of six-month-old infants received all WCVs on time at baseline in both phases) then improved to 48.1% but did not approach the 66% achieved during phase one. Those infants born after September 2019 may have missed visits due to pandemic-related disruptions; follow-on studies would determine whether performance improved as disruptions eased. In addition, none of the DULCE sites were able to monitor this measure during phase two, preventing data-driven CQI activities.

Most of phase one's improvement was associated with improvements in the 1-month WCV, fueled by learning that Medicaid covered this newly recommended visit (44, 58). In phase one, on-time 1-month WCVs improved from 62.5% to 79.5%. The healthcare systems spread the learning across all their sites – including the new DULCE sites – so that by the beginning of phase two, 84.3% of 1-month WCVs were on time. Like FS presence and HRSN process measures above, DULCE teams sustained and spread phase-one improvements in 1-month WCVs.

HRSN screening intends to identify and address family needs. In this second-phase study, we collected data on families' HRSN resource use – addressing a limitation of the many studies that measure referrals but not whether families successfully use the resources (59–62). Connection rates varied by domain (13%–97%), and likely reflect clinics' relationships with different service providers and systemic barriers. Connection rates were highest for food (97%), housing conditions (79%), and employment/financial needs (58%). Over half of families with caregiver depression (55%), and IPV (51%) used resources, compared to four of nine families with utility needs (44%). Use of housing instability resources was lowest (13%), reflective of the affordable housing crisis.

These are promising results. Clinic-based HRSN interventions often struggle to link patients to resources: a CQI collaborative in 19 pediatric clinics increased HRSN screening from 19% to 73%, but did not increase HRSN referrals (63). A recent systematic review suggested that direct referrals or additional assistance with indirect referrals improved patient outcomes compared with indirect referrals only (64). Other pediatric clinic-based interventions that collected data on resource use demonstrated a wide range of connection rates (0.8%–75%), and most EBIs only address a single HRSN domain (61, 65–73).

Families with multiple HRSN often must navigate multiple programs that address single domains of need (74). Breaking down silos between healthcare, public health, legal, and early childhood systems serves families more equitably and efficiently. DULCE's FS and cross-sector team is designed to support families to navigate resources in a streamlined, cohesive manner, often utilizing warm handoffs to facilitate connections. This level of care coordination and family-led problem solving is not feasible for clinicians alone to execute; team-based, cross-sector care distributes this responsibility and strengthens relationships with families. The weekly cross-sector team meetings supported maintenance of this collaborative teamwork at each site.

Continuous quality improvement methods, including BTS, are designed to improve the original intervention and simultaneously promote sustainability in scale-up. Successful CQI efforts develop strong improvement teams that involve stakeholders, institutional leaders, frontline service providers, as well as patients; intentionally develop infrastructure and organizational capacity to support practice changes and a culture of CQI; and rely upon iterative use of data and feedback loops to inform practice changes. It flattens the hierarchy of decision-making within teams and balances power, elevating the voices of those who typically do not contribute to leadership decisions but whose perspectives are invaluable (e.g., frontline workers, families).

Continuous quality improvement also builds teams' capacities to solve their own problems and use data to identify areas of improvement. It transforms the way data is typically used (i.e., from a judgement to a learning opportunity). Furthermore, PDSAs require teams to start testing small (e.g., 1 patient interaction), empowering them to initiate rapid-cycle testing and learn from failure. While many implementation frameworks stress fidelity of implementation, CQI focuses on local adaptation informed by real-time data to retain fidelity to process and outcome measures. These cross-hierarchical, inquiry-driven tools strengthen not just the implementation of one EBI – in this case, DULCE – but these experiences build teams' capacity for learning through iterative trial-and-error, which benefits the entire clinical ecosystem, including parallel social determinants of health (SDOH) efforts and patients not enrolled in any interventions.

While offering many benefits to clinical teams and healthcare systems, CQI collaboratives such as BTS are resource intensive. Many scale-up frameworks intentionally design an early phase of expansion with intensive support to a core set of participants that

represent all actors and relationships in a system. For example, McCannon et al. (46) and Barker et al. (8) both describe large-scale spread of EBIs that intentionally selected a small "wedge" or "scalable unit" — a microcosm of the entire system — to begin. By providing intensive support at a smaller scale, these efforts learn not only what needs to be adapted as the EBI spreads, but how to support teams in their adaptation (i.e., what infrastructure is needed). After this initial intensive learning phase, subsequent scale phase(s) is driven by activating induction-phase participants as peer mentors to help spread the EBI to additional "wedges." (14, 56) In these subsequent phases, improvement is often accelerated – as it was in this DULCE expansion.

With respect to clinics' CQI-driven learnings, several themes emerged. First, identifying HRSN is not risk-free for families (75), particularly those with immigration issues during this study period when the Trump administration's public charge rule was in effect (76). FS built rapport and trust with families over their six-month enrollment, allowing families time to disclose sensitive or stigmatized needs (which typically occurred around the 4-month WCV), and were supported with accurate legal information from the legal partner at each site.

Family-centered care includes respecting families' desires around their HRSN. For example, some parents with infants tolerated overcrowded housing conditions rather than lose their proximity to extended family supports. Better understanding family agency amd priorities is a future area of research within DULCE. In such complex cases, the cross-sector team's diverse expertise generates creative problem solving that adapts solutions to families' circumstances and preferences. Cultivating a consistent, trusting relationship between the DULCE family and their entire care team makes family-led problem solving possible.

Continuous quality improvement also allows sites to develop culturally-aware approaches to some challenges. In some communities, stigma discourages parents from seeking support for postpartum depression. At two sites, the DULCE team collaborated to sidestep this stigma through careful messaging and the use of more acceptable resources. One clinic referred to a Fussy Baby clinic that included parent-child psychotherapy, and another one developed an infant massage class led by a mental health provider. Differences in local culture, resources, and team resourcefulness may have contributed to this cross-site variability.

This study contributes to the literature on CQI strategies for scaling and sustaining healthcare-based EBIs to improve population health. It also reports the results of families' rates of HRSN resource use, an outcomes-oriented indicator that is often omitted in SDOH interventions.

4.1. Limitations

The selection of volunteer sites for implementing DULCE limits generalizability. Our analyses identify improvements that are unlikely due to chance alone but lack causal inference. External events, notably the COVID-19 pandemic, may have affected some measures of reach and effectiveness. This study relied on data reported by Family Specialists for CQI purposes which did not include balancing measures; ongoing work will incorporate data about contextual factors and stakeholders' perspectives, E.H.R and claims data for participants and a comparison group (77).

5. Conclusion

An innovative, lighter-touch CQI approach to a second phase of scale-up resulted in maintenance or improvements in most processes and outcomes at four established clinics and three new clinics. Outcomes-oriented CQI measures (family HRSN resource use) are an important addition to more traditional process-oriented indicators.

Data availability statement

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

Ethics statement

The studies involving human participants were reviewed and approved by The University of Chicago School of Social Administration's Institutional Review Board (IRB17-0414). Written informed consent from the participants' legal guardian/next of kin was not required to participate in this study in accordance with the national legislation and the institutional requirements.

Author contributions

MCA and PF conceptualized and designed the study, designed the data collection instruments, coordinated and supervised data collection, carried out the initial analyses, drafted the initial manuscript, and reviewed and revised the manuscript. BF and SM conceptualized and designed the study, designed the data collection instruments, and reviewed and revised the manuscript. SA carried out the initial analyses and reviewed and revised the manuscript. PH and JMS supported acquisition and interpretation of data and reviewed and revised the manuscript. RS conceptualized and designed the study and critically reviewed the manuscript for important intellectual content. All authors contributed to the article and approved the submitted version.

Funding

DULCE expansion was funded by The JPB Foundation through the Center for the Study of Social Policy.

Acknowledgments

We express our deep gratitude and appreciation for the DULCE families and teams.

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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Supplementary material

The Supplementary Material for this article can be found online at https://www.frontiersin.org/articles/10.3389/frhs.2023.1040992/full#supplementary-material.

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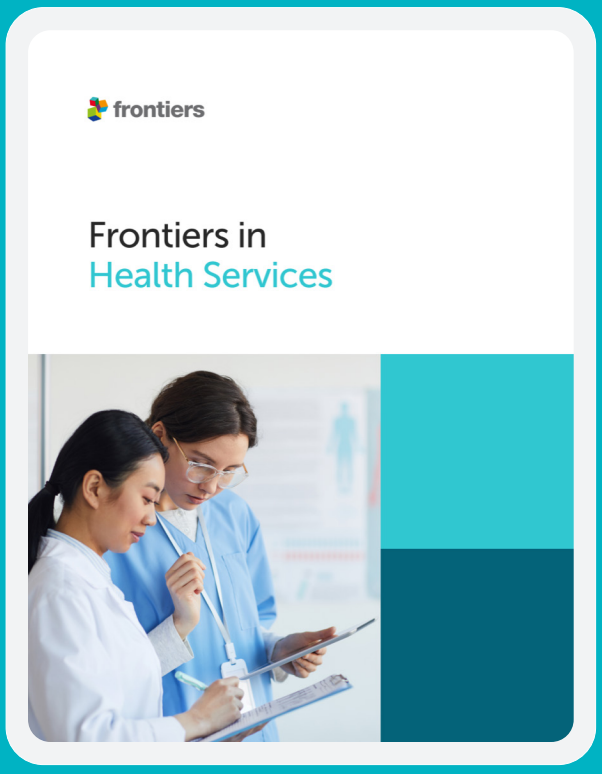

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