Advancements and challenges in implementation science

2023

Edited by

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Advancements and challenges in implementation science: 2023

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Using normalization process theory to inform practice: evaluation of a virtual autism training for clinicians

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Background: There is growing demand for developmental and behavioral pediatric services including autism evaluation and care management. Clinician trainings have been found to result in an increase of knowledge and attitudes. This study utilizes Normalization Process theory (NPT) to evaluate a clinician training program and its effects on practice.

Methods: The year-long virtual training program about autism screening and care management included didactic portions and case presentations. Focus groups and interviews were conducted with primary care clinicians (n = 10) from community health centers (n = 6) across an urban area five months post-training. Transcripts were deductively coded using NPT to uncover barriers to implementation of autism screening and care, benefits of the training program, and areas for future training.

Results: Participants were motivated by the benefits of expanding and improving support for autistic patients but noted this effort requires effective collaboration within a complex network of care providers including clinicians, insurance agencies, and therapy providers. Although there were support that participants could provide to families there were still barriers including availability of behavior therapy and insufficient staffing. Overall, participants positively viewed the training and reported implementing new strategies into practice.

Conclusion: Despite the small sample size, application of NPT allowed for assessment of both training delivery and implementation of strategies, and identification of recommendations for future training and practice sustainability. Follow-up focus groups explored participants' practice five months post-program. Variations in participants' baseline experience and context at follow-up to enable application of skills should be considered when using NPT to evaluate clinician trainings.

KEYWORDS

implementation research, normalization process theory, qualitative evaluation, autism, extension for community healthcare outcomes

1. Introduction

For the past decade, autism diagnosis and demand for developmental-behavioral pediatric care has been steadily rising with the most recent autism prevalence reported at 1 in 36 children (1). Increased demand of developmental services combined with disinvestment (2) and disruptions from the COVID-19 pandemic (3) has led to service delays. This is problematic given that benefits of early autism diagnosis and evidence-based care are well established (4, 5). Although screening is recommended to occur between 18 and 24 months of age (6), most children receive diagnosis after their third birthday, which is the cutoff for state-funded early intervention programs (7). Access to autism developmental care is especially strained in low-income and minoritized communities partly due to shortage of pediatric specialists (8).

A proposed strategy to address gaps in services is training more clinicians to conduct developmental screening and evaluations (9) instead of waiting for referral to specialists. The Extension for Community Healthcare Outcomes (ECHO®) has shown promise in equipping primary care clinicians (PCC) with skills and knowledge on a variety of clinical areas (10, 11) including autism. The ECHO model consists of a Hub institution comprised of topic experts responsible for delivering trainings and Spoke institutions comprised of PCCs (10) less expert in the topic. Researchers found that autism-focused ECHO programs resulted in increased participant knowledge and confidence (12-16). For example, Mazurek et al. (2019) found that a 12-month ECHO program increased clinicians' ability and selfefficacy to screen for autistic patients in Missouri, United States (13). There has been little evidence, however, that autism-focused ECHO programs result in practice change (17). Most studies on ECHO programs focusing on autism used a pre/post design but did not qualitatively assess practice change at follow-up (13-15, 18-20). Evaluating both pre/post knowledge/skills changes and application of practice within the service delivery setting are necessary to understand training impact.

The current study uses Normalization Process Theory (NPT) (21) as a framework to guide the Boosting Capacity to Screen and Care for Underserved Autistic Children ECHO Program (BCAEP), a training designed to enhance autism screening and care in primary care settings. The BCAEP training was conducted virtually during the COVID-19 pandemic and supported PCCs during major care disruptions. NPT posits that there are four components of practice change, namely coherence (i.e., what the new practice is), cognitive participation (i.e., one's and others' roles in the new practice), collective action (i.e., steps needed to accomplish the new practice), and reflexive monitoring (i.e., evaluation of the new practice) (21). NPT emphasizes individual and collective behaviors, in addition to attitudes and beliefs, which aids practice-focused queries (22). Past studies have utilized NPT to assess new practices in healthcare settings (22, 23). This study advances previous research by applying NPT to evaluate delivery and effectiveness of PCC trainings in urban safety-net settings as well as the extent to which learned skills and knowledge are applied in practice months after the training.

2. Methods

2.1. Program description

The BCAEP training was conducted virtually between November 2020 and October 2021 over 12 60-min sessions. Participants (n = 47) represented PCCs in seven health centers in the Greater Boston Area caring for safety-net populations. Trainings were facilitated by a senior developmental behavioral pediatrician with over 30 years of experience and an advanced practice clinician with 19 years of experience; both were affiliated with a safety-net academic medical institution. Each session consisted of didactic lectures and deidentified patient case discussions as per the ECHO model (10). Topics of the didactic lectures were determined based on an initial participant survey and were adjusted according to participants' interests. Examples of lecture topics were administration of different autism screening tools, engaging with patients in a culturally sensitive manner, and communicating an initial autism diagnosis to families.

2.2. Study design

This study was part of a larger mixed methods evaluation of the BCAEP training and represents the qualitative component of the evaluation. Focus groups and interviews with BCAEP PCCs (n = 10) were conducted to contextualize quantitative survey responses and provide actionable practice recommendations. Participants were asked to complete a brief pre-focus group assessment that gathered information about their practice (Table 1); nine responded to the survey and ten participated in focus groups. There were 30 pre-test (before first session), 19 mid-point (after sixth session), and 17 post-test (after twelfth session) survey responses, with nine matches from pre-test to post-test. Survey findings indicated an increase in participants' reported knowledge and self-efficacy in administering autism screeners and managing care in post-test compared to pre-test. Each of these quantitative findings warranted further exploration qualitatively and at a time when participants had a chance to implement the training learnings in practice.

Focus groups and interviews were conducted virtually approximately 6-months post-training using Zoom or in-person depending on participants' availability. This study was reviewed and approved as exempt by the Boston University Institutional Review Board (IRB #H-40718).

2.3. Participants

Participants for the qualitative assessments were recruited through convenience sampling of PCCs who attended the training. Participants represented PCCs from six out of seven (85.7%) eligible health centers. Recruitment emails consisting of abbreviated consent forms were sent. Participants were asked to complete a brief pre-focus group assessment that gathered information about their practice (Table 1).

TABLE 1 Focus group and interview participants characteristics $(N = 9)^a$.

Are you attending this focus group in-person or virtually?	
In-person	1 (11.11%)
Virtually	7 (77.78%)
Neither: I am participating in a personal interview	1 (11.11%)
What is your title/role?	·
Physician	4 (44.44%)
Nurse Practitioner	4 (44.44%)
Administrative leadership	1 (11.11%)
Number of years in practice	<u>'</u>
Less than 2 years	0 (0.0%)
3–5 years	3 (33.33%)
6-10 years	1 (11.11%)
11-20 years	3 (33.33%)
21 + years	2 (22.22%)
What is your medical specialty?	
Pediatrics	7 (77.78%)
Psychiatry	1 (11.11%)
Other (integrated behavior health)	1 (11.11%)
How many ECHO sessions did you attend?	
Mean (SD)	10.1 (1.96)
Min, Max	6, 12
Are you currently implementing strategies (e.g., first-level/sopatient education, resources) from ECHO Autism in your p	
Yes, all strategies	4 (44.44%)
Yes, some strategies but not all	4 (44.44%)
No, I'm not implementing any strategies	1 (11.11%)
Is your clinic currently implementing strategies (e.g., first-le screeners, patient education, resources) from ECHO Autisn protocol?	
Yes, all strategies	2 (22.22%)
Yes, some strategies but not all	7 (77.78%)
No, my clinic is not implementing any strategies	0 (0.0%)
I don't know	0 (0.0%)
Were there other providers/staff members in your clinic which this ECHO Autism training program?	no also participated in
Yes	9 (100%)
No	0 (0.0%)

^aOne participant did not complete the pre-interview survey. Therefore, nine participants were included in this table and ten participants participated in the focus groups.

2.4. Data collection

Semi-structured focus groups and interviews were conducted in March 2022 using a guide (Appendix A) to gather information on individual level and clinic-level application of strategies taught in the BCAEP training as well as opinions about the training delivery. Questions were informed by survey findings, NPT constructs (21), and outcomes indicated on the logic model. Focus groups were conducted by two evaluation team members; a lead moderator and note-taker. One member was present at all focus group and interview sessions for consistency. Audio recordings were transcribed and verified by two different members for accuracy.

2.5. Analysis

Deductive coding (24) using NPT constructs (21) and content analysis (25) were conducted on six transcripts. The coding team

consisted of three evaluation team members who were trained to conduct qualitative analysis using NVivo12 (26). Each transcript was coded by two members. All three members then met to discuss discrepancies by consensus with the third member serving as tiebreaker if consensus was not reached.

3. Results

From the nine pre-focus group assessments, participants included physicians (n=4), nurse practitioners (n=4), and administrative leadership (n=1) with most participants having 3–5 years (n=3) and 11–20 (n=3) years of experience. Specialties included pediatrics (n=7), psychiatry (n=1), and integrated behavior health (n=1). On average, participants attended 10 out of 12 training sessions. Themes were organized by NPT constructs and presented with frequencies and illustrative quotes (Table 2) in order to provide a framework for actionable recommendations.

The following sections consisted of quotes coded with the corresponding constructs. NPT consisted of four constructs, each with four sub-constructs (21) that start with an understanding of the new practice (i.e., coherence), operationalizing change (i.e., cognitive participation), implementing the change (i.e., collective action), and ending with its evaluation (i.e., reflexive working) (22). While all constructs contributed to the findings and subsequent recommendations, reflexive working and collective action, given the role of clinicians to implement the concepts and assess the utility in practice, were most often mentioned.

3.1. Coherence

Coherence occurs when an individual attempts to make sense of the new practice (21). This construct manifests through an individual's perception on a practice as well as their motivation and role for the new practice implementation.

3.1.1. Differentiation

In the current study, differentiation occurred when participants discussed how strategies taught in the training differed from their current practice (21). For example, one participant shared that "in the old model, we could put in a referral to [external institution] developmental-behavioral peds" but there are "kids [who] might be better served if we can keep them sort of inhouse." Another participant mentioned how behavioral observations may differ depending on the child's age and that "having more concrete examples... maybe also seeing... the videos... [of] kids of different ages and genders" could be helpful to deepen their understanding of screening procedures. Additionally, one participant described how the training reminded them to score screenings "right away when it's fresh."

3.1.2. Internalization

Internalization refers to motivations to implement a new practice, once participants have understood what the new

TABLE 2 Qualitative findings from focus groups and interviews with primary care clinicians organized using normalization process theory.

Construct	Definition	Illustrative Quotes Frequenc	Frequency
Coherence is the initial ser learning about these new I	nse-making work that is involved in ultimately implemoractices, as well as identifying their roles as individual	Coherence is the initial sense-making work that is involved in ultimately implementing new tools and methods in practice. This sense-making involves both individual and communal aspects, such as individuals defining internal motivation for learning about these new practices, as well as identifying their roles as individuals and within a community of providers as they begin to think about how these practices will realistically be applied.	motivation for
Differentiation	Participants identified how strategies and protocols discussed during the training sessions differed from their current practice. Examples include referral protocols, addressing behavior in different demographic groups (e.g., children of different ages), and implementing available assessment tools at different times.	109: "Listen, it is glaringly obvious that this is a child who has autism. And in the old model, we could put in a referral to [outside institution] developmental-behavioral peds, and know that eventually they get to a great clinician who's gonna do the assessment, get that diagnosis, and then get them the services that they need. But that bucket of kids might be better served if we can keep them sort of in-house with the [community health center]'s team and use these tools that, you know, [psychiatrist] was using There [are] probably some kids that the PCPs more and more could and should be doing those tests, and that's what [my clinic] is trying to, to do moving forward." 102: "Uh having like more concrete examples, umm maybe also seeing the different kinds of, the videos, for instance kids of different ages and genders and seeing some of those behaviors can like bring it back and see how, you know, I remember seeing a certain example and so when you see it again that's helpful too." 109: "like, don't see the kid and then finish it, and then wait to score your CARS like a week later. Like it is really important, do it right away when it's fresh, and that was something I, I directly tr—um, took, and have been trying to do a much better job about doing."	4
Internalization	Participants shared the internal motivations that they had to engage in the BCAEP. Generally, participants found the BCAEP valuable as it reinforced some of the concepts that they had learned about in previous training. Many participants already had a particular interest in autism and developmental screening prior to completing the training, especially considering that they are seeing more patients with autismrelated concerns, and because of influence from peers who had previously participated in other ECHO programs and had positive experiences.	were wrong I had a little bit more appreciation of the evaluation, although I learned that on top of experience with those evaluations from 20 years ago I learned how things had been refined I guess for me it was updating mostly' cause I had put some effort, some misplaced effort into it before in my career and kind of cycled back to it a little bit more." 110: "And I think part of the reason I feel comfortable doing this training and then starting that primary care is that a lot of my team members have done the ECHO training and felt like it, like, feel even more confident in being the person to diagnose autism and talk about next steps and help support them with management afterwards." 108: "I've been in practice for 25 years. And I never had this many autistic kids, and I'm not talking about the subtle ones, I'm talking the ones that are so obvious. I don't know what's going on but it's really, it's really taken up a great part of my practice, so this was terrific."	42
Individual Specification	Participants noted their individual tasks and responsibilities related to autism healthcare and diagnosis. Participants' roles varied such as medical director, nurse practitioners, and other clinicians. There appeared to be two categories of participants: (1) specialists who can use the information that they learned in BCAEP to strengthen the practices that they already had in place, and (2) primary care clinicians who do not necessarily specialize in autism but can use the information from BCAEP to better screen for and follow up with autistic patients, rather than always having them see a specialist. A strong theme of differences between healthcare and ABA providers was discussed in multiple focus groups, and how it might be helpful for healthcare clinicians to learn more about ABA so that they can implement elements of it in their to the strong that they can implement elements of it in their to the strong that they can implement elements of it in their to the strong that they can implement elements of it in their to the strong that they can implement elements of it in their to the strong that they can implement elements of it in their to the strong that they can implement elements of it in their they can be a strong that they can implement elements of it in their they can be a strong that they can implement elements of it in their they can be a strong that they can implement elements of it in their they can be a strong the strong that they can implement elements of it in their they can be a strong the strong that they can implement elements of it in their they can be a strong the strong	because I would have loved to [learn more about] the ABA portion itself. I find it very difficult to address [ABA] with parents because I don't really know how ABA. I mean I have an idea. But really, because parents ask and say 'Okay, what is ABA and how is it going to get better with ABA?' And that's something I'd love to try to explain better" 105: "So I think that all of it was more learning for me. Because we don't work with autism, so it was a way of getting more than just reading, more than just book knowledge, and thinking about what [we are] looking for. So, for the team that's working with the [young children], or even someone who is a teenager: what are those signs we might want to be noticing that we can then loop back and say, 'Hey, we've been spending this amount of time, and this is what we noticed? And so, for me, this is about how do I take that information from the trainings and put it into some practice? 105: "Our family partners are pretty amazing in the work that they're doing And I would love to learn more about what Early Intervention is doing on Are there these little tidbits that we can do in primary care? We're not gonna be able to do what in-home or true ABA or anything like that [does]. But are there tools and small things that we can support parents on doing to help their child in the interim?"	34
	metical practice.		:

TABLE 2 Continued

Construct	Definition	Illustrative Quotes Frequ	Frequency
Specification Specification	Participants discussed coming to a shared understanding of objectives with their colleagues, patients, and families. Participants discussed how to collaborate with colleagues to improve clinical systems and be on the same page about a patient's diagnosis. Participants found it useful to hear about challenging cases that came up in other healthcare centers and how other clinicians addressed the situation in informing their own understanding of these screening tools. Further, participants expressed a desire to better understand the roles of others acting in the field (e.g., pediatricians, ABA providers) to work toward a common goal.	we're not diagnosing but we're at least being able to support or follow through on the conversation the pediatrician is having. So, we're not diagnosing but we're at least being able to provide bidirectional information. And I think that's what really important." 109: "I think that I've felt more confident through hearing other health centers talk about maybe those challenging cases How do you talk about what ASD [autism spectrum disorder] is When we look at it through a lens of a biomedical sort of Western medicine-informed diagnostic entity but I'm seeing a newly immigrated from Albania family that doesn't speak English In their culture, there's an idea that not talking until the age of five is actually pretty typical, and [the family is] not concerned about that at all We need to somehow meet each other in the middle and do what we think is in the child's best interest while honoring that family's values I think the ECHO was also really useful to hear different clinics talk about those types of dilemmas, and this is how I would talk to the parent about that 105: "Being able to think and understand how pediatricians approach a patient, as well as the concerns and challenges they face in thinking from that behavioral health lens What could we do? What could we hold with them so they're not holding it alone?" 110: " I think we're more able to discuss what ABA therapy looks like. I think we're getting trained on level two screeners in two weeks, and gonna hopefully be using that to do some diagnosis onsite"	88
Cognitive participation in lead to positive change in the	Cognitive participation involves problem identification, collaborations within a clinic to lead to nositive change in their individual and clinic-level practice. This thinking involves	Cognitive participation involves problem identification, collaborations within a clinic to work towards solving the problem, and how clinicians can confidently sustain their practices. Participants identified the pieces that need to come together to lead to no sortive chance in their individual and clinic-level practice. This thinking involves identifying the individuals who will bring about this chance and the context in which they will be doing so. Further, naticipants reflected on whether they are	me together to
confident that they have th	confident that they have the tools and people necessary to exact change		
Initiation	Participants recognize long wait times and gaps between appointments as barriers in their practice. Participants reflected on the gap between their current practice and new strategies introduced in BCAEP. Many BCAEP participants were building from practices that they already had in place following the training. However, others were just getting started with thinking about how to change their practice to better serve autistic patients.	trained in the CARS as a fellow, probably, you know, actually performed it with some small [number of patients], and then I was in the real-world practicing and using it" 107: " Compared to the other health centers that were involved in the ECHO, [we are] so much bigger that we should be better able to make a change like that. Whether we actually are good enough to actually make a change like that, is a whole different issue you know what I mean? But we can make decisions that smaller health centers can't make" 110: "Oh, how I [determine whether new protocols are working for my community health center!? I would foresee that the majority of time when we have a child who has some developmental or other concerns that bring autism—the child would have an answer, or at least a next-step plan within two months. You wouldn't have a child that's eighteen months old and wait for a diagnosis or at least for a next-step screener for more than two months. [Moderator 2: Mhm. Okay.] Or older child, but I'm thinking of eighteen months to three-year range."	L
Enrollment	Participants discussed how they collaborate and learn within their health center, such as having screener trainings and having separate groups to target unique aspects of autism diagnosis/ treatment. BCAEP solidified the desire of many participants to enroll additional individuals who previously did not screen to implement autism screening measures, for example, as well as to participate in the BCAEP itself.	109: "Listen, it is glaringly obvious that this is a child who has autism. And in the old model, we could put in a referral to [outside institution] developmental-behavioral peds, and know that eventually they get to a great clinician who's gonna do the assessment, get that diagnosis, and then get them the services that they need. But that bucket of kids might be better served if we can keep them sort of in-house with the [community health center]'s team and use these tools that, you know, [psychiatrist] was using There [are] probably some kids that the PCPs more and more could and should be doing those tests, and that's what [my clinic] is trying to, to do moving forward." 106: "As I said, we're sort of working on, we had just started trying to become more autism friendly and then the pandemic came. So, I think that sort of a combination of that, plus the ECHO plus [clinician]'s mini fellowship. [Clinician] and I are working on making almost sort of a mini developmental clinic day type thing so that we have much better, we have more wraparound services than we had before." 110. "I wouldn't say that we've implemented any direct change yet. But we're doing a training on April 13th with a developmental pediatrician who was at [academic institution] and is now at [hospital] training our primary care providers in the RITA-T screener. [Moderator 2: Mhm] With the plan that we'll start a practice of, um, using the RITA-T to decide who is—has a high enough score that that could be consistent with a diagnosis for autism and actually writing the letter to diagnose within our primary care practice, and who's in this kind of middle of the road area where maybe a developmental pediatrician."	41
Legitimation	The BCAEP increased participants' confidence in implementing screenings and follow-up procedures. It also served as a reassuring place for healthcare professionals to be able to share feelings and ideas about challenging situations.	106: "I did start doing CARS evaluations after the program started, partially because I just had more confidence in doing it The CARS doesn't have an official training per se. I think that part of the reason I started doing them during the program was cause I just, it gave me a little bit more confidence, and partially because that's just kind of when things fell into place." I 10: "I think our clinicians are increasingly confident in using the autism word and saying autism is something I'm worried about, or autism is something I'm thinking about, or autism is something I think we need to evaluate for, which I think helps, um, I think—"	10

TABLE 2 Continued

	Definition Skills learned in BCAEP fit into the bigger		
work togeth steps, such a quickly. Loc though BCA available res more straigh diagnoses.	work together more efficiently and get crucial steps, such as an autism diagnoses, done more quickly. Looking ahead, participants feel as though BCAEP would prepare them to seek available resources to offer their patients and be more straightforward with patients about autism diagnoses.	that kid finally gets connected with a, you know, ABA team. And that's the first way to answer your question is that I think we've gotten that kid finally gets connected with a, you know, ABA team. And that's the first way to answer your question is that I think we've gotten more efficient, and the diagnosis is done quicker I have some kids that the diagnosis letter is written, you know, within a week. I saw them, and the diagnosis is clear. We make the diagnosis, and then the referral to those services through the community health worker team is happening faster, so that's one improvement is just the speed of all that." 102: " Better able to talk about like what's available in the moment For instance, Early Intervention for the younger kids or school and getting them set up at schools, and then again like the ABA for afterwards."	
ne action st d resources	Collective action refers to the action steps that participants need to take to implement COVID), allocating time and resources, and building systems of accountability (e.g., d	Collective action steps that participants need to take to implement new practices they learned from the ECHO training program. This involves interacting with the systems already in place (e.g., referral process), barriers (e.g., action to the ECHOIT), allocating time and resources, and building systems of accountability (e.g., defining staff roles and responsibilities) to ensure that these changes are implemented effectively.	. :
Autism many pl interact, ABA pr interacti ease wit BCAEP Particip patients screens medical delays, c collabor capacity	Autism diagnosis and follow-up care involves many players with whom BCAEP participants interact, from schools to insurance agencies to ABA providers and more. The efficiency of these interactions is a major factor in determining the ease with which the practices discussed in BCAEP can be effectively implemented. Participants noted about barriers in getting patients diagnoses after referrals and secondary screens due to long wait times, challenges with medical record systems (e.g., EPIC), billing delays, diagnoses being rejected, little collaboration across departments, and limited capacity of clinicians.	our patients all have the same MassHealth insurance. They all have C3 and so we'll refer someone to ABA through an agency that has a short waiting list. And they'll accept our diagnosis because they think that they'll get paid eventually through MassHealth. Then, they'll get a big waiting list, and we'll go to a different agency, and the different agency won't accept our diagnosis because they think they won't accept our diagnosis because they think they won't get paid through MassHealth. Now that's only because understanding what MassHealth will do and won't do is a bevildering sort of mess. But we have the same person doing the same test with the same letter template They're literally all quite the same and we get different responses and that's because agencies don't know what's going to happen, right? And no agency is going to do six weeks' worth of work and then feel like they're not going to get paid for it Although it would surprise me if any of the agencies could actually trace back any of their individual units of work to real specific dollars that come in for services because we certainly can't at the health center.## So we have no idea whether we're being reimbursed for the service ordes and diagnosis for the visits [and] for the screening that we're doing," 107"Because beyond not being able to match people with ABA therapy the real troubles that we've had over the last couple of years is that our local Early Intervention program has been almost missing in action. I mean [state] school department certainly has been missing in action, right? Moderator 1: yeah] So we have to coordinate with those two agencies and I mean I know why our local Early Intervention program was missing in action. I mean. gratel school department errainly has been missing in action, right? Moderator 1: yeah] So we have to coordinate with those two agencies and I mean I know why our local Early Intervention program was missing in action contributed	
Creat within i BCAE and foll get auti; contrast to enrolln addition	Creating more structure and accountability within individual healthcare centers has allowed BCAEP participants to implement screenings and follow-ups more successfully and to quickly get autistic patients the services that they need. In contrast, lack of structure and accountability led to difficulties in screening and services enrollment. Participants found it helpful when additional colleagues were trained in CARS as it speeds up the diagnosis/treatment process.	diagnosis and write a letter support for ABA and I send a parent out and there's nobody to support them. I know we have the autism team but they are now limited in how., this is maybe internal to our clinic or our institution but I would love someone to walk [families] through this [ABA] process because you see them time and time after that and you're like "Where are you in the process?" (Oh, we haven't really started or we got stuck at paperwork which is the very beginning [step]' But that may require funding for somebody in or, I don't know if there's an online format for someone some website that teaches you how to get that stuff that you need, you know even from EI, if not for the our patient navigators that are in clinic that are wonderful, and I message them cause you refer a patient to EI and then like nothing happens." 105: "And then I would second what you said about the ABA and I'm trying to think about would it be beneficial for some of our staff to be trained to some degree in it so that we can do some little tidbits of support." 106: "We're continuing to have, unfortunately, a lot of trouble getting kids hooked in with ABA, and part of it is that MassHealth now is claiming that I am not qualified to do autism evaluations. [Moderator I: Why is that!] I think that there may have been a misinterpretation at some point about part of their blurb which says "expertise" in developmental, does not say "specialize", so we're working on [Moderator I: Huh.] arguing through that one."	

TABLE 2 Continued

Construct	Definition	Illustrative Quotes Freq	Frequency
Skillset Workability	Overall, BCAEP participants expressed the hope to expand training for autism screening (CARS and RITA-T) beyond specialists and for primary care clinicians as well. When more providers can perform these screening procedures, the process is more time-efficient, and autistic patients can get the help that they need more quickly.	109: " If it was all in the hands of one person to be responsible for all of those pieces, I think it can become a little unwieldy and time intensive. And then you're back to the timeline of we eventually got the kid where they needed to be, but that diagnostic journey took eight months, and that's eight months of their development So that's the main thing is I think that [integrated behavior health program], multidisciplinary approach at [community health center] is gonna help us continue to improve our autism assessment process." 109: "There's talk at the clinic of expanding the training for other providers including the pediatricians themselves to become more skilled with the RITA-T and the CARS [Moderator1: Yeah]. Training them in how to do the diagnostic letter that insurance will accept in order to get ABA, the IEP, all those services going And that sort of to get better as a clinical team [in] involving behavioral health staff, involving primary care provider, to maybe catch those kids that fall under the bucket."	28
Contextual Integration	Contextual Integration Participants discussed barriers in implementing autism screening and follow-up measures in practice, such as short visit times, increasing gaps between screening checkups in pediatric populations, and inefficient recording systems. BCAEP sparked ideas in some participants for addressing these issues. When implementing of 1 th screening and referral protocols, clinicians expressed frustration in scheduling challenges, time-consuming and expensive nature of services (e.g., ABA, developmental evaluations). Difficulties in implementing autism screenings and follow-ups were even further exacerbated by the COVID-19 pandemic when in-person visits were limited.	happens is that kid is too old for Early Intervention, [but] too young for school And the specialists already have a one year waiting list for kids that are 19 months old So now, we want to build something in our practice to catch that but we don't have enough kids in our practice to build that system—to run 1,000 kids through in that age group, you know what I mean? So the math doesn't work for practices I guess." 102: " We're in kind of like a paper world. So, you get the paper screener and then it's put into the computer, or you can yourself put it in or have your medical assistant forl whoever. Sometimes there are lags or drops in [that] process. I think the ultimate goal and what most clinics should be really doing in this day and age is everything should just [be inputted] directly into the computer This is probably off topic, but a lot of practices are like having parents screen things prior or in the waiting forom in avirtual kind of format. So, we weren't there yet so we were kind of talking about that process." 103: "I mean, I do think that certainly a barrier is time, right? I mean we were scheduled with—I mean, for us in, at [community health center], the nurse practitioners get a little bit longer [visit time]. But even still people run late, it takes time to room, then you got your next patient waiting. And so, it's really hard. and to do a full autism evaluation and ADOS or whatever it is they're doing now, it's like an hour, right? And so, it's really hard to get a full picture of a kid's development in a 15-minute timeframe. And so, I do feel like the training has helped in terms of making my time with a family more efficient and trying to figure out. Am I concerned? Am I not concerned? And what is the concern? Is it really just a language delay or is there some additional piece, like the social communication, things like that? 104: "There's only three pediatricians and me and we are teeny tiny. We have two exam rooms each, and w	32
Systemization	Systemization was defined as how participants assessed utility of strategies learned during the training.	102: "We kind of have some difficulties in getting screeners like input into EPIC [electronic medical record system] sometimes so we try to work on that a bit more After the ECHO [training] just realizing importance [of documentation] and trying to make maybe some flow changes or systematic changes to help us to really not mist hese key screeners. 107: "So we do have a provider who has four to six hours a week to just do the screening the screening diagnostic, the secondary screening diagnostic tests, wait, the secondary screening tests Because we wanted to try to move kids faster through the early intervention and school bottleneck And that's working reasonably well which is a big improvement from before As a result of that I believe that we've been able to get kids seen at specialty programs or by neurologists more quickly than if we had not been doing that."	42
Communal appraisal	Communal appraisal occurs when participants evaluate how a strategy learned from the training can be beneficial for their colleagues and families they served. It also occurs when participants reflect on the process of coming to a shared understanding of best practices with other clinicians in the training.	102: "I mean, I think we got to know each other you could tell some personalities throughout the end for sure. And I love the fact that I could see into the thoughts and experiences of others in my very close vicinity that I never would have met, absolutely never would met otherwise especially post-pandemic And to hear maybe some of what other practices are struggling with or doing well with so that whole like community feel I thought was great." 103: "It's always nice to hear about how things run differently in different clinics, because you start to realize well, maybe we could be more efficient in this way. You know, we could adopt some of the processes that are used in other clinics. And so I feel like it's nice, not only for getting to know folks in the community, but also sharing ideas about what's worked, what hasn't worked in their clinics and ways to improve ours."	31

<u>-requency</u> obviously can't practice on Zoom or in these ECHOs but maybe a couple videos of observing different secondary screeners would be 108: "Just to agree with 101. After the... training, [I] made a point of using the word [autism]. And... I don't know if I was shy about it appreciated hearing that." 110: "...So I guess the only thing I'll say is that it made us even less tolerant of the wait times and moving 109: "I valued... the case presentations. This is gonna be such a psychiatrist answer... we think about things like the process vs. the in, I thought they were just such a great teaching tool like content. And the content was obviously very informative and useful and filed away in some way. But it's more... that one level up. The before or not, but what I learned was that most parents were thinking it anyway, and if you didn't say it, then they continued to worry when [trainer] would show examples for instance of children that had autism or had of different ages. That was great because we because... almost none of them rebelled against it. You know, they almost all, like, just the video may be just a great tool." 102: "...I would love like somewhat, so um maybe times be a barrier for our patients... screeners available either in a virtual format or paper format kind of stocked in every room.' wait with a family with language and cultural and whatever barriers. Like that experience... earth to not let the more work to kind of move heaven and most valuable." 102: "... I loved the videos, whenever probably the way that the ECHO impacted things nside that they might be crazy or something, great, or screeners in general. I think more things and like doing process of [going] Reconfiguration occurs when participants reflect ndividual appraisal occurs when participants ecommendations to improve BCAEP training on current or future/planned changes to their eflect on how the BCAEP benefit them as ndividual clinicians. Participants discussed practice because of the BCAEP. Individual appraisal Reconfiguration Construct

ABLE 2 Continued

practice entails (21). Motivations to engage in the training included an increase in patients with developmental support needs and reinforcement of previously learned concepts. Autism diagnosis and care management appeared to be important and timely skills to refine as one participant shared that they had "been in practice for 25 years and I never had this many autistic kids" and thus developmental care had "really taken up a great part of my practice." Moreover, autism as a diagnosis had evolved considerably in the past few decades and this training allowed one clinician to "completely [learn] some things that I had half learned... and I unlearned a couple of things that were... wrong... on top of experience with those evaluations 20 years ago... I learned how things had been refined."

3.1.3. Individual specification

Participants' roles and backgrounds in developmental care varied but they seemed to fall into two groups, namely specialists who could use tools and strategies introduced in the training to strengthen current practices and non-specialists who were looking for ways to improve care for autistic patients as they wait for a specialist appointment.

One participant mentioned that they "don't work with autism, so... [the training] was a way of getting... more than just book knowledge..." They described a desire to be better able to recognize "signs we might want to be noticing... And... how do I take that information from the trainings and put it into some practice?" Several participants discussed patient education with one participant describing they were looking for "tools and small things that we can support parents on doing to help their child in the interim [while waiting for Applied Behavior Analysis or ABA]?"

3.1.4. Communal specification

Participants discussed shared goals with colleagues, patients, and families. For example, one participant wanted to be better able to support parents who are "expressing concern or follow [ing] through on the conversation the pediatrician is having. So, we are not diagnosing but we're at least being able to provide bidirectional information." Participants described ways to improve their understanding of other staff roles. One participant expressed a desire to be "able to think and understand how pediatricians approach a patient,... What could we do? What could we hold with them so they're not holding it alone?"

3.2. Cognitive participation

Participants engaged in problem identification, collaborations required to solve such problem, and discussed sustainability of the new practice. Participants identified the gap between the current and new practice, reorganized their work accordingly, and reflected on their ability to implement the new practice.

3.2.1. Initiation

Participants reflected on the gap between their current practice and new strategies introduced in the training. When asked about potential care improvements, one participant "foresee[s] that the majority of the time, when we have a child who has some developmental or other concerns that bring autism..., the child would have an answer or at least a next-step plan within two months." Another participant reflected on expanding their clinic's autism screening capacity by "dedicat[ing] some sort of FTE [full time equivalent] resource." This was plausible because their clinic was larger "compared to the other health centers..." and thus could "make decisions that smaller health centers can't make."

3.2.2. Enrollment

Participants discussed how they collaborated and learned, such as having autism screening trainings and separate groups to target unique aspects of autism diagnosis and care. One participant shared that their clinic was "doing a training... [for] our primary care providers in the RITA-T [Rapid Interactive Screening Test for Autism in Toddlers] screener." Similarly, another participant shared their clinic's desire to have PCCs "... doing [developmental] tests" in-house before making a specialist referral, which may involve long wait times.

3.2.3. Legitimation

Participants discussed experiencing increased confidence in administering and advocating for autism screenings as they reflected on the value of strategies taught in the training. One participant "did start doing CARS [Childhood Autism Rating Scale] evaluations after the [training] started, partially because I just had more confidence in doing it." Another participant described how PCCs in their workplace "are increasingly confident in using the autism word…"

3.2.4. Activation

Participants described their decision in enacting strategies introduced in the training. Specifically, how these strategies fit into clinic workflow by allowing PCCs to collaborate more efficiently and getting crucial steps in autism care done promptly. One participant shared that their clinic "ha[s] gotten more efficient, and the diagnosis is done quicker..." and "the referral... through the community health worker team is happening faster." The knowledge of different services needed for different age groups was also conducive to efficient care as described by a participant who was "better able to talk about what [services are] available in the moment..."

3.3. Collective action

Participants shared about implementing strategies introduced in the training within the context of current systems (e.g., referral process), barriers (e.g., the pandemic), time and resource allocations, and systems of accountability (e.g., staff roles and responsibilities).

3.3.1. Interactional workability

Autism diagnosis and care involve multiple collaborators (e.g., school, insurance agency). The efficiency of interactions with such collaborators affected the implementation of strategies introduced in the training. Barriers included long wait times, complexity of electronic medical record (EMR) systems, billing delays, and limited bandwidth.

One participant described "bewildering random delay as to whether... billing agencies will accept [autism] diagnosis." Even when patients "have the same [government] insurance" and presented with "the same [clinician] doing the same test with the same letter template," they may receive varying responses based on the agencies' understanding of whether they would receive reimbursement. Additionally, EMR systems were described as "not talking to one another... So, if you refer to developmental peds [with a different EMR system], I'm not sure how quickly you're actually being able to see [the referral]." Consequently, timely referrals did not always result in timely services.

3.3.2. Relational integration

Participants discussed structure and accountability within clinics needed for successful referrals to long-term services such as behavior therapy. One participant "would love someone to walk [families] through this [ABA] process because... you see [families] time and time after that and you're like 'Where are you in the process?' 'Oh,... we haven't really started or... we got stuck at paperwork which is... the very beginning [step]." This issue did not only occur with ABA, as the participant continued that they "refer[red] a patient to EI [Early Intervention] and then like nothing happens."

3.3.3. Skillset workability

Participants described the distribution of responsibilities in implementing a new practice. Expanding training for autism screening beyond specialists could be key to timely referrals and care. One participant said, "If [screening and referral] was all in the hands of one person to..., it can become unwieldy and time intensive," causing the "diagnostic journey [to take] eight months... of [the child's] development." Multiple participants mentioned that it was helpful to have other PCCs who were able to conduct screenings. One participant felt "very fortunate to have [two colleagues conduct screenings]" as it "helped... take some of the stress of the long wait of getting an evaluation in our developmental clinic."

3.3.4. Contextual integration

Participants discussed barriers to autism screening and care such as gaps between appointments in pediatric patients. One participant described that "[pediatric visits] schedule goes from every two months to... every year... very quickly...." Due to age restrictions for some services, "that kid [becomes] too old for EI, [but] too... young for school." Combined with "specialists already hav[ing] a one year waiting list," the participant expressed a desire to "build something in our practice to catch [kids waiting for services]."

Another barrier discussed was "time, right?... It's obviously really hard to... get a full picture of a kid's development in... 15 min[s]." It is particularly challenging when "a full autism evaluation" takes "an hour." Lastly, limited staffing and resources was cited as a barrier by a participant whose clinic consisted of "only three pediatricians and me... and we are teeny tiny."

3.4. Reflexive monitoring

Individuals described how they evaluated and perceived the utility of strategies introduced in the training. Additionally, participants shared their evaluation of the training delivery and logistics.

3.4.1. Systemization

Participants described how strategies introduced in the training impacted efficiencies of their practice. These changes were reported through informal observations. After the training, one participant "just realizing... importance [of documentation] and trying to make maybe some flow changes or systematic changes to help us to really not miss these key... screeners."

3.4.2. Communal appraisal

Participants shared how they evaluated a new practice as a group. Participants discussed how the training provided an opportunity to come to a shared understanding of best practices with other clinicians. One participant shared that "it's always nice to hear about how things run differently in different clinics...." Learning more about other clinics also created a "community feel I thought was great."

3.4.3. Individual appraisal

Participants reflected on how the training benefitted their individual practice. One participant "valued... the case presentations" because it was "that one level up" from didactic lectures. Another participant "loved the videos... I thought they were just such a great teaching tool" in a virtual environment. Participants also shared recommendations to improve future trainings, such as having more training in addressing "that lag time and the desperation of parents" and "... little interventions or pearls that we can share with parents..."

3.4.4. Reconfiguration

Participants reflected on current or planned changes to their care for autistic patients after the training. One participant recalled "ma[king] a point of using the word [autism]...." Another participant shared that the training had "brought to our primary care practice like a renewed focus on autism." The enhanced understanding of best practices "made us even less tolerant of the wait times and... doing more work to... move heaven and earth to not let the wait times be a barrier for our patients."

4. Discussion

In this study, NPT was instrumental to organize qualitative data into actionable recommendations for a virtual PCC training program on autism screening and care. Qualitative data analysis revealed participants' motivations, attitudes, and perceived barriers regarding autism screening and care management strategies taught in the training. NPT was useful in highlighting both the process (training delivery) and outcome (practice change) aspects of evaluation.

Participants discussed the **coherence** construct understanding of strategies introduced in the training. The training gave participants ideas to improve care by scoring autism screenings sooner, adapting behavioral observations based on patients' age, and providing more in-house care while waiting for external services. Benefits of early autism diagnosis and support are well established (27, 28) yet wait times for developmental-behavioral services in recent years grew due to increased demand (29) and disruptions from the COVID-19 pandemic. Enhancement of in-house care could help bridge this gap (29). Practice recommendations include expansion of topics relevant to primary care (e.g., feeding, sleeping, medication dosages) and having a centralized location for resources about local services that PCCs can share with each other and patients/ families.

Participants were also motivated by an observed increase in patients needing developmental care. Child mental health care was declared as being in a state of crisis partly due to the decline of services available and workforce capacity (2). Additionally, senior clinicians reported wanting to refine their knowledge about autism given recent major changes to autism as a diagnosis (30). Although comprehensive and systemic changes are needed, equipping clinicians with up-to-date knowledge could be a step in bridging gaps in services (31). Strategies that could help expand screening capacity included hands-on opportunities for clinicians to practice autism screening and modelling use of autism screening tools on real patients.

Participants also discussed components needed to implement strategies introduced in the training, which were coded using the **cognitive participation** construct. First, increasing the number of PCCs able to administer and advocate for autism screening could increase access, which aligns with past research (31). Participants described increased confidence in administering autism screening and educating families about autism, which in turn led to increased efficiency. Expansion of autism screening and care could address barriers to timely autism evaluation especially in low resource populations such as those served by this study's participants (32).

Second, a shared understanding of goals and accountability was needed as autism service referrals often involved multiple collaborators (e.g., behavior therapy providers, insurance agencies). Therefore, participants also expressed a desire for stronger understanding of how different services work, particularly EI and ABA as the latter is regarded as the golden standard for autism treatment (33). Including external experts on autism-related care could enhance clinicians' knowledge and

establish connection with key collaborators. Past studies indicated that improvements were needed in follow up care of children who screened positive for autism (34, 35). Although additional research is needed to examine factors affecting low referral rates to follow up services (35), increased understanding of services may enhance PCCs' ability to navigate and advocate for timely service receipt.

Additionally, participants reflected on action steps they took to implement strategies introduced in the training, which were coded using the **collective action** construct. Barriers to autism screening and care were also discussed such as gaps between pediatric visits, EMR complexities, and inconsistent insurance requirements, all of which could contribute to service delays and aligned with prior research (9). Some barriers were outside clinicians' control, yet participants were committed to improving care whenever possible. Considerable investment is needed to expand the developmental-behavioral pediatric workforce and services (36), but enhancing aspects of care within a clinician's control may be one step closer to short-term care improvement.

For example, easy access of screening materials (e.g., printouts in exam rooms, centralized location of digital copies), clear follow-up protocols with defined responsibilities such that screenings have actionable outcomes, and enhanced patient education. Enhanced longitudinal family-clinician rapport that could result from these care improvements may further facilitate family's engagement with clinician recommendations, as found within the context of Latinx families (37).

Lastly, the training was well-received as evident from transcript text coded using the **reflexive working** construct. Participants cited the feeling of community with other attendees. Connection with other clinicians were found to be facilitators of clinician well-being (38, 39), which is crucial to maintain for an increasingly strained workforce (40, 41). The live, synchronous format of the training where trainers could engage attendees in real time appeared to be key in fostering such connection. Moreover, participants reported renewed focus on autism and decreased tolerance of wait times as they now had the tools and strategies to help remedy the situation in the short-term.

There were several limitations to this study. First, there was limited transferability of findings due to small sample size (n=10) and self-selected participants from an urban area in northeastern United States. Participants, however, represented most of the eligible health centers (85.7%) with varying patient populations. Moreover, there was a large range in years of experience despite similar levels of prior interest in autism. Second, clinicians who participated in focus groups may be subject to social desirability bias as many knew and worked with each other. Findings however were gathered from a mix of focus groups and personal interview data.

4.1. Utility of NPT

NPT provided a helpful framework to organize qualitative data into actionable recommendations. Qualitative data analysis revealed participants' motivations, attitudes, and perceived barriers regarding autism screening and care management strategies taught in the training. Findings could guide efforts to enhance and sustain implementation of autism screening and care management in diverse urban settings. NPT could also be used to guide evaluations of other clinician training programs in addition to implementation of specific protocols in healthcare settings (23).

Similar to findings of a review of studies using NPT, we found overlaps between NPT constructs that made it difficult to assign a single construct to our data (22). For example, activation under cognitive participation and individual appraisal under reflexive working. Activation occurred when participants decided to enact a new practice whereas individual appraisal occurred when participants evaluated the value of a new practice after they had enacted it (21). However, participants tended to discuss these topics simultaneously; their decision to enact a new practice was implied by their reasoning involving the value of such practice. overlap did Although the not impact actionable recommendations out of the analyses, it is important to consider when using NPT.

Moreover, because participants varied in their baseline knowledge and experience with autism care, the novelty of their practice change and whether it was influenced by the training was unclear. As such, it was difficult to assign data to the construct differentiation under coherence, which referred to the contrast between existing vs. new practice. Another construct that was challenging to apply was systemization under reflexive working, which referred to participants' way of evaluating a new practice (21). The definition could apply to both formal (i.e., quality improvement studies) and informal (i.e., conversations) evaluation methods, but participants tended to share their thoughts about the training without sharing specifically how they gathered data to come to their conclusions. It was largely implied that they evaluated the training through personal observations and informal conversations with colleagues. Lastly, the current study focused on two innovations, namely the tools and strategies introduced in the training as well as the training delivery itself (i.e., virtual, year-long, inter-professional training). Careful attention was paid to specify which innovation codes applied.

5. Conclusion

PCC training on autism screening and care management could potentially address service access issues. There were distal barriers outside of a clinician's control, but equipping clinicians with knowledge and self-efficacy about autism care may help address proximal barriers within their control. NPT allowed for detailed assessment of process and outcome evaluations for a PCC training program, identification of gaps, and practice recommendations. Moreover, NPT was useful in highlighting both the process (training delivery) and outcome (practice change) aspects of evaluation and providing a framework for delivering recommendations to program implementers. Lastly, NPT could be used as a guiding framework for other clinician

training programs, however, defining the new practice of interest may need to be further clarified when working with a participant group with varying baseline knowledge.

Data availability statement

The authors cannot provide raw data per IRB regulations. Further inquiries can be directed to the corresponding author/s.

Ethics statement

The studies involving humans were approved by Boston University Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin because Verbal consent was obtained by clinicians to participate in this evaluation.

Author contributions

BO led data collection and qualitative analysis and drafted the manuscript. MA, JW, and IH conceptualized the study, delivered the program, and reviewed manuscript drafts. RA delivered the program and reviewed manuscript drafts. CB assisted in data analysis and reviewed manuscript drafts. AU, SF, and AC conducted data analysis and reviewed manuscript drafts. JG conceptualized the study, oversaw data collection and analysis, drafted manuscript, and reviewed manuscript drafts. All authors contributed to the article and approved the submitted version.

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Conflict of interest

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

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Appendix A. Focus group guide with sample questions/probes

Part I: individual-level application of ECHO Autism strategies (Suggested time: 15 minutes)

- What skills are you applying, meaning what are you able to do differently because of what you learned from the ECHO Autism Program? Are any skills missing from what you received in the ECHO Autism Program? (Probe for screening, referral, treatment)
- 2. What knowledge did you gain, meaning what did you learn that you can apply to your practice and relay information to your patients? Are any pieces of knowledge missing? (Screening tools, referral protocols, resources)
- 3. How did the program change your perspective on the education and care of your patients? (*Probe for comfort of using terminology, confidence in referring, managing care*)

Part II: clinic-level application of ECHO Autism strategies (Suggested time: 15 minutes)

1. How has your clinic's practice changed because of your participation in the ECHO Autism Program? Who have

- been implementing these changes? (Probe for administrative support, connection/community within the practice)
- 2. What are some of the benefits to implementing the strategies from the ECHO Autism Program training given your current clinic context? Who are the recipients of these benefits? (Probe for EMR supports, protocols for referral and screening, sense of community)
- 3. How do you determine if strategies from the ECHO Autism Program training are working for your clinic? (Probe for patient satisfaction, staff satisfaction, burnout factors (e.g., feeling worthwhile at work, work is satisfying/meaningful, they are contributing professionally in ways they value)

Part III: opinions about the ECHO Autism training (Suggested time: 10 minutes)

- 1. What parts of the ECHO Autism Program training do you value the most? (*Probe for parts that can be transferrable to other clinics and avenues.*)
- 2. What could have been done differently during the training to better meet the learning objectives? Reflect on your experiences with case presentation and discussion. (*Probe for support from clinic administration, further resources, etc.*)



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Insights into implementation planning for point-of-care testing to guide treatment of chronic obstructive pulmonary disease exacerbation: a mixed methods feasibility study

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The purpose of this mixed methods feasibility study was to gain insights into unmet clinical needs, stakeholder preferences and potential barriers and enablers to adoption for planning the implementation of point-of-care testing for earlier detection and guided treatment of chronic obstructive pulmonary disease (COPD) acute exacerbation in the NHS in England. Exacerbations of COPD cause considerable mortality and morbidity. Earlier identification of exacerbations and guided treatment would lead to reduced exacerbation duration, reduced hospitalizations and mortality, improve health-related quality of life, reduce unnecessary treatments (including inappropriate antibiotic prescribing) which could save the NHS over £400 per patient. During the early stages of product design, we took a multi-disciplinary approach to evidence generation, gaining insights from key stakeholders to test the product concept and inform evidence-based implementation planning. Primary data was collected from 11 health care and service professionals involved in the management of acute COPD exacerbations. Overall, participants agreed that by earlier differentiation of acute exacerbation from stable COPD, patients could be started on appropriate treatment. To implement point-of-care testing into clinical practice, evidence is required to demonstrate the accuracy of differentiating between exacerbation etiologies and to provide information on the beneficial impact to the system in terms of optimized management, reduced long-term side effects, admission avoidance, and cost-effectiveness. This research provides an evidence base for future implementation planning of point-of-care testing for earlier detection and guided treatment of COPD acute exacerbation. Moreover, the technology developers can decide whether to refine the product design and value proposition thereby de-risking product development.

KEYWORDS

insights, COPD exacerbation, implementation science, point-of-care testing (POCT), feasibility study, mixed methods, user-centered design, value-based pricing (VBP)

1. Introduction

Chronic obstructive pulmonary disease (COPD) is characterized by progressive airflow limitation. In 2019, over 200 million cases of COPD were reported leading to >3 million deaths globally (1). In the UK, 1.2 million people suffer from COPD costing health care and service providers >£800 million a year in treatment costs, and COPD is responsible for nearly 30,000 deaths annually (2). Exacerbation is the term used for acute and sustained worsening of COPD symptoms. COPD is irreversible but exacerbations are preventable by treatment and management with drugs such as steroids, beta₂-agonists, antibiotics and vasodilators (3).

Acute exacerbations of COPD reduce the quality of life for patients, increase hospitalizations and are difficult to predict and detect early enough to intervene. Current strategies include the use of patient reported outcome measures (PROMs) and measurement of blood biomarkers or causative agents (4). PROMs have been combined into a smartphone-based algorithm with high diagnostic agreement (5). In the USA, remote respiratory rate monitoring has been proposed as an alternate strategy (6). Techniques to directly measure inflammation in the airways, such as bronchoscopy, bronchoalveolar lavage and biopsy, are too invasive for routine use (7). Systematic reviews recommend further investigation into measuring inflammatory biomarkers in blood, including fibrinogen (8), C-Reactive Protein (8, 9), IL-6 (8, 9) and TNF-alpha (9) to detect acute COPD exacerbation.

The need for more accurate, non-invasive analysis of lung inflammation has led to increasing interest in exhaled breath analysis and urinalysis as methods for identifying surrogates for airway inflammation (10). Use of fractional exhaled nitric oxide (FENO) in breath has been used to differentiate between asthma and COPD exacerbation alongside blood eosinophil counts (11). FENO can be used to guide appropriate therapy in a sub-set of COPD patients (12). However, one study shows that there may not be a link between FENO levels and COPD exacerbation suggesting that breath analysis, such as FENO, may not have clinical utility in identifying COPD patients experiencing acute exacerbation (13).

Use of urinalysis is well-evidenced and implemented in clinical practice for kidney disease and urinary tract infection (14). Measuring a panel of 10 inflammatory biomarkers in urine has been shown to differentiate between stable COPD and acute exacerbation (15). The aim of randomized control trial NCT04296318 was to establish if a point-of-care test measuring 10 inflammatory biomarkers in urine, alongside symptom monitoring, has utility in earlier identification of COPD acute exacerbation and differentiation from stable disease, with sufficient reliability. An early cost-utility analysis showed that measuring inflammatory biomarkers in urine to guide treatment of COPD patients experiencing an exacerbation may be highly cost-effective (16). Evidence exists of user acceptance of the approach (17). This feasibility study was embedded into NCT04296318 alongside a patient usability study led by Leicester, to gain insights from key stakeholders about the product concept and generate evidence to support future implementation planning.

Early economic evaluation of medical technologies helps to ensure that new interventions being implemented in care pathways are more likely to be accurate and cost-effective facilitating more rapid implementation (18). Allotty et al. describe the importance of "developing the critical evidence base that informs effective, sustained and embedded adoption of interventions by health systems and communities" (19). Key criteria for implementation of new technologies have been summarized into a checklist (20). Implementation is defined as "the processes or methods, techniques, activities, and resources that support the adoption, integration, and sustainment of evidence-based interventions into usual settings—sample indicators and outcomes include acceptability, adoption, appropriateness, cost, feasibility, penetration and sustainability" (21). Significant progress has been made developing frameworks to build and disseminate evidence that underpins implementation (21, 22) User-centered design can contribute greatly to evidence-based practice and driving successful implementation (23). The authors observe that test developers do not engage early enough with stakeholders who play a key role in influencing the implementation process. The purpose of this study was to gain insights, during the early stages of product design, into unmet clinical needs, stakeholder preferences and potential barriers and enablers to adoption to inform future development of an evidence-based implementation strategy for point-of-care testing for earlier detection and guided treatment of COPD acute exacerbation in the NHS in England.

2. Methods

In this feasibility study we took a multi-disciplinary approach to evidence generation, bringing together user-centered design, human factors, impact assessment and value-based pricing methods. Similar multi-disciplinary approaches have been developed, tested (24, 25) and supported early economic evaluation (26, 27). The purpose of this study was to gain insights from health care professionals (participants), working in hospitals and primary care, into the proposed implementation of point-of-care testing for earlier detection and guided treatment of acute exacerbation of COPD.

The study was conducted in accordance with the principles of the Declaration of Helsinki (2008) and the International Council for Harmonization and Good Clinical Practice guidelines and as part of NCT04296318 (COPE-WEL) approved by the Research Ethics Committee of University Hospitals of Leicester NHS Trust.

To identify stakeholders, a high-level care pathway for management of COPD acute exacerbation was mapped through discussions with service providers and by consulting the National Institute of Health and Care Excellence (NICE) guideline NG115 (28). Using a convenience sampling approach (29), participants were recruited from contacts already known to the researchers and from the participants' networks because it was essential that all participants were knowledgeable in the management of COPD patients and prescribing of appropriate therapies.

Recruitment was from March 2019 to June 2019. All participants provided informed consent for both the interview and recording of the interview. Participants completed a demographic questionnaire. A discussion guide was provided to participants describing the current care pathway and details of the proposed implementation of point-of-care testing.

- (i) We used qualitative questions to capture participant's perspectives on the current care pathway:
 - a. Definition of acute exacerbation
 - b. Current methods for diagnosis and management
 - c. Burden of inappropriate use of medicines
 - d. Unmet need for an objective diagnostic test
 - e. Long terms benefits from guided treatment
- (ii) Participants were asked to rate their level of agreement on a 7-point Likert-type scale (30) against a series of questions to assess the utility of point-of-care testing in the care pathway where 1 = strongly disagree and 7 = strongly agree.
- (iii) We used a standardized questionnaire to assess stakeholder preferences of perceived usefulness (31) where we asked participants to rate their level of agreement on a 7-point Likert-type scale.
- (iv) Participants were asked about their intention to promote the use of point-of-care using a Net Promoter Score (32).
- (v) To assess an acceptable price point, participants were presented with value-based scenarios and prompted to indicate the maximum price they would be willing to pay for point-of-care testing under the conditions in the scenario.
- (vi) Participants were invited to consider factors that may influence their decision to adopt point-of-care testing for detection and guided treatment of acute exacerbation of COPD. They were provided with 5 key factors (cost and change to care pathway, patient outcomes, hospital admissions, prescribing) and asked to rate the level of impact these factors would have in the decision-making process (High/Medium/Low) and whether the impact would be positive or negative.
- (vii) Participants were asked about the minimum level of sensitivity and specificity that would be acceptable.

Interviews lasted 30–45 min and were recorded using an audio recorder following verbal consent. No financial reimbursement was offered to participants. Each interview was manually transcribed and checked by another team member. The transcripts were analyzed and organized into themes. The saturation point was achieved where no new themes or opinions were observed. For the Likert-type items composite score and percentage level of agreement were calculated. The study output provides evidence for future implementation planning for point-of-care testing for earlier detection and guided treatment of COPD acute exacerbation.

3. Results

All participants had sufficient experience and were actively involved in the treatment of COPD patients. 36.4% of the

participants interviewed were male with a mean of 19.8 years of experience and a mean age of 45.3. 63.6% of the participants interviewed were female with a mean of 13.9 years of experience and a mean age of 46.1 years.

3.1. Insights into the current care pathway and unmet clinical needs

We used qualitative questions to capture participant's perspectives on the current care pathway for COPD acute exacerbation and to assess the level of unmet need for an objective diagnostic test.

- Q1. Participants defined an acute exacerbation of COPD as a sustained worsening of symptoms (increased breathlessness, increased sputum volume or production, sputum purulence, worsening cough and wheezing) beyond the patients' normal variation that required changes to their treatment. All participants concurred that the diagnosis of an acute exacerbation of COPD is currently based on symptoms and clinical assessment.
- Q2. For the management of an acute exacerbation of COPD, treatment options cited were steroids, antibiotics, physiotherapy, beta₂-agonists, bronchodilators, nebulized therapy, controlled oxygen, non-invasive ventilation and intubation. All participants acknowledged the vital role of the community care teams that are contacted by patients to conduct an initial assessment. Only 60% of the interviewees stated that patient self-management plans were well used in their region.
- Q3. All participants agreed that there was a high level of inappropriate prescribing in the management of an acute exacerbation of COPD and all participants stated that this was not limited to antibiotics and steroids but existed across a range of treatment options.
- Q4. All participants agreed that it may be useful to have an objective diagnostic test to direct towards appropriate treatments by differentiating exacerbation etiology, however the test would need to be used as an adjunct to symptom monitoring and clinical assessment.
- Q5. All participants held the opinion that a reduction in steroid use would have long term benefits for patients and reduced antibiotic use would lead to wider population benefits.

We asked participants to rate their level of agreement to assess the utility of point-of-care testing in the COPD care pathway (Table 1).

3.2. Insights into stakeholder preferences

We used a standardized questionnaire to summarize stakeholder preferences as to perceived usefulness (Figure 1A). All participants appreciated the clinical utility of determining treatment options in the event of acute exacerbation. However,

TABLE 1 Participants' level of agreement of the utility and need for implementing point-of-care testing for detection and guided treatment of acute exacerbation of COPD.

Questions	Level of agreement	Comments
Do you agree that there is an unmet need to change the care pathway for managing patients who are experiencing an acute exacerbation?	84%	Participants strongly felt that patients and non-specialist colleagues required more education on the management of an acute exacerbation of COPD.
Do you agree that that quicker patient recovery to the pre-exacerbation (baseline) state could be achieved by more appropriate and targeted treatment?	78%	Specialists in the field commented that there were increased risks of treatment failure if patients were given the incorrect treatment.
Do you agree that by targeting an infectious exacerbation with antibiotics only, this could eliminate unnecessary side effects from steroid use?	83%	By removing the use of oral steroids in these types of exacerbations, it was felt that the overall steroid burden on the patient would also be reduced, and this could result in downstream saving to the system from reduced side effects of long-term steroid use. However, participants emphasized that if an infection also brought on an inflammatory response, then steroids would be necessary.
Do you agree that targeted treatment with steroids for inflammatory exacerbations could eliminate unnecessary side effects?	84%	Treatment with steroids only would be beneficial to the patient but increasing antimicrobial resistance could negatively impact some cohorts of COPD patients.
Do you agree that appropriate and targeted treatment could potentially result in better patient compliance and adherence to medication?	71%	Participants stated that several other factors may also influence better patient compliance and adherence to medication, such as, improved health state and patient engagement in education and improved understanding of their condition.
Do you agree that the proposed test would be suitable for use by a healthcare professional either in clinic or when visiting the patient at home?	94%	If appropriate training was given and the test was easy to use. Two participants also proposed that there was scope to include other healthcare professionals.
Do you agree that this type of point-of-care test could be used by a patient as a self-test prior to using a rescue pack?	71%	Most participants remarked that this approach would only be suitable for a select cohort of patients that understood their condition, that patients followed the correct test procedure and that patients did not attempt to interpret the results themselves.
Do you agree that 10 min is an acceptable length of time to obtain the results from the test when conducted in a GP practice?	81%	Several participants were of the view that the pathway would need to be optimized and that by investing more time with the patient initially in conducting the test could avoid referrals and subsequent visits.
Do agree that connectivity to the electronic patient record would facilitate the adoption of this point-of-care test?	88%	Participants believed with robust record keeping of the test results, the test output could be used as a further education tool for patients and incorporated into their management plans and could be a more efficient way of monitoring patients' disease and exacerbation events over time.
Do you agree that there are potential barriers in adoption for this point-of-care test?	75%	There would be significant barriers to adopting this test to differentiate COPD exacerbation etiology.
Do you agree that changes in the care pathway would be accepted for implementation of this point-of-care test?	79%	If the evidence supported guided therapeutic treatment prescribing based on differentiating COPD exacerbation etiology directed by a point-of-care test and was cost-effective.
Do you agree that this point-of-care test could help in improving the patient management by prescribing tailored and appropriate treatment?	91%	Participants acknowledged that it would need to be proven, however, they could foresee the potential benefits for individualized patient management.
Overall Average of agreement	82%	Reduction in unnecessary prescribing which was reflected in the overall level agreement.

evidence would be required to determine the utility of the inflammatory biomarkers in the differentiation of COPD exacerbation etiology and that point-of-care testing for detection and guided treatment of acute exacerbation of COPD was cost-effective.

Participants were asked about their intention to promote the use of point-of-care using a Net Promoter Score. 73% of participants identified themselves as a potential promoter for using point-of-care testing citing the test results had the potential to translate into actionable treatments. The remaining 27% participants were neutral due to lack of studies to show technical performance, clinical validity and system and patient benefits. There were no detractors.

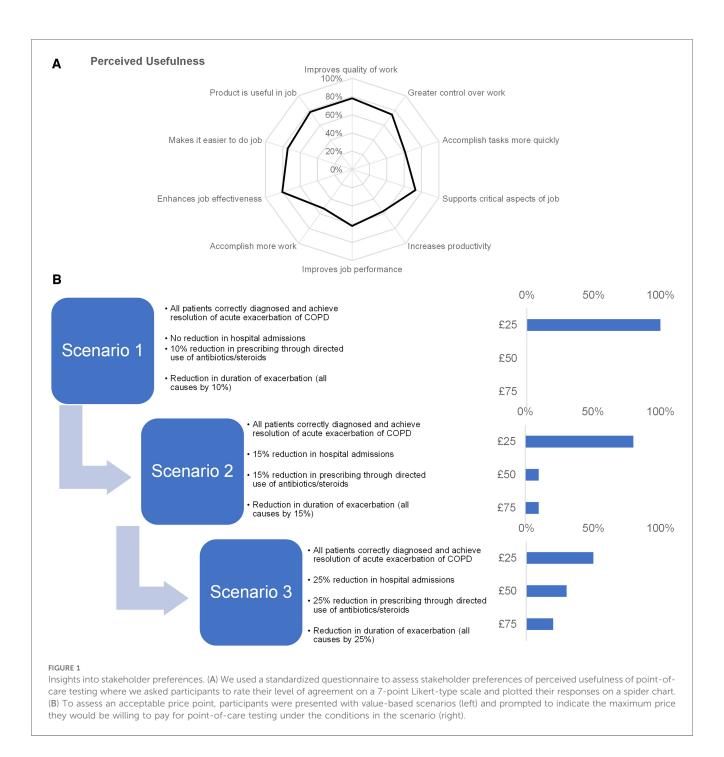
We asked participants to assess an acceptable price point when presented with value-based scenarios (Figure 1B). For scenario 1, all participants agreed that price point of £25 was acceptable. 80% of participants also selected the £25 price point for scenario 2, with the remainder of participants split

between the £50 and £75 price point. For scenario 3, 50% of the participants would accept a higher price point with 30% of participants accepting £50% and 20% participants accepting £75. The remaining 50% of participants cited the maximum acceptable price as £25.

3.3. Insights into key decision factors

For each key decision factor an impact assessment was made based on participant ratings.

Factor 1: Cost was identified as a major potential barrier with evidence required to show benefits in terms of optimized medical management, reduced long-term side effects and cost-effectiveness. All participants rated the cost of introducing point-of-care testing as having high and negative impact.



Factor 2: 45% of participants said that changing the care pathway would have high impact, 55% said it would have medium impact. 91% of participants felt that changes would have positive impact. Further information would need to be provided regarding the specific patient cohorts suitable for point-of-care testing.

Factor 3: All participants felt that the changes to patient outcomes would have high and positive impact and further evidence from clinical validation was needed to demonstrate improvement in patient outcomes.

Factor 4: 82% of participants believed that the potential reductions in hospital admissions would have high impact, with all stakeholders indicating that this would have positive impact as it should translate into cost-savings and service efficiencies.

Factor 5: 91% of participants commented that changes to prescribing would have high impact, with 100% of participants concurring that this would have positive impact. A proven reduction in overprescribing would impact acceptance of point-of-care testing especially if there was potential to prevent the patient from deteriorating by using point-of-care testing.

Factor 6: An average of 84% for sensitivity and 85% for specificity was calculated as acceptable performance levels but robust evidence was required to demonstrate that point-of-care testing accurately differentiated between exacerbation types.

Specific participant quotes regarding key decision factors included:

- Respiratory clinician: "Cost. It needs to be in the system where it is financially viable to have it implemented"
- Pharmacist: "Patients with COPD have other comorbidities, there would need to be information and evidence regarding confounding factors"
- Respiratory clinician: "Evidence for accuracy from a clinical validation is required to overcome concerns around false positives and false negatives"
- Specialist respiratory nurse: "Need evidence for benefits to the system and reduced/appropriate use of medications"

Specific participant quotes regarding the acceptance in changing the care pathway to incorporate point-of-care testing included:

- Pharmacist: "We already phenotype patients, so it would be accepted here"
- Specialist respiratory nurse: "Treatment has been stagnated for a long time... we are not doing it correctly and there are different trajectories depending on the biological mechanism"
- GP: "If it's proven to be cost-effective and makes a difference, we will use it"

4. Discussion

From our interviews we gained an understanding of the key decision factors regarding adoption and implementation of point-of-care testing for earlier detection and guided treatment of COPD acute exacerbation. The evidence we have generated can be be used in developing an implementation strategy. There was agreement that this point-of-care test for earlier detection and guided treatment of acute exacerbation of COPD could be used constructively. Overall, participants agreed that by earlier differentiation of acute exacerbation from stable COPD, patients could be started on the correct treatment (particularly by non-specialists) and use of targeted therapies could lead to a reduction in the use of steroids and inappropriate use of antibiotics.

Next steps for implementation of this point-of-care test includes defining the optimal point for use in the care pathway driven by the key decision-making factors noting that participants raised concerns regarding patients interpreting tests themselves without professional input. Key decision factors are cost and performance (test sensitivity and specificity above 85%). We have identified that to implement the test in clinical practice, more evidence would be required to demonstrate the accuracy of differentiating between exacerbation etiologies and provide evidence on the beneficial impact in terms of optimized management, improvements in patient outcomes, reduced long-term steroid-burden side effects, lower rates of hospitalizations, steroid and antibiotic use, overall cost reduction and cost-effectiveness. A key opportunity was identified in that there was support for funding a point-of-care test which offered accurate

diagnosis at £25 per test, and up to £75 per test for incremental reductions in exacerbation rates and hospitalizations.

The output from mixed methods feasibility studies (24) and multi-dimensional processes (25) can be incorporated into Target Product Profiles to support the design of "fit for purpose" medical technologies (33). To our knowledge, this is the first study to embed a mixed methods feasibility study measuring participant's acceptance of point-of-care testing, into a randomized control trial to generate evidence to guide implementation planning in the COPD care pathway.

In this feasibility study, both qualitative and quantitative methods are used. Interview protocols for qualitative research can deliver a robust evidence base (34) and can be incorporated within a mixed methods approach (35). For analysis of Likert scale data, Norman supports the use of parametric tests (36) but conclusions are similar using parametric or non-parametric tests (37). Care needs to be taken not to misuse Likert scales (38) and the composite score can be calculated without using a statistical test (39). Such approaches are useful where the researcher is investigating the prevalence of behaviors and preferences of participants and wants to connect the data in a single unified result.

The authors recognize the wide range of tools and methodologies available for the early assessment of innovative medical devices including diagnostics. Horizon-scanning helps policy makers to understand the innovation landscape to guide policy development (40), and Multi Criteria Decision Analysis can support regulatory agencies in health technology assessment and priority setting (41). Early technology assessment and early economic evaluation helps innovators to align their products with the specific needs of the market and supports commercialization (42). There is a growing interest across health care and early health technology assessment is gaining in momentum (43). A systematic review identified –1,200 references for value assessment in health care innovation between 2007 and 2017 with 38 methodologies and frameworks identified (44).

Responsible Research and Innovation (RRI) emphasizes the importance of ensuring that publicly funded research and innovation is aligned with unmet needs, stakeholder views and iterative design towards commercialization. RRI recommends use of a development framework across value domains in the product development lifecycle (45). We propose that a mixed methods feasibility study adds value in an iterative product design process and supports the development of implementation strategies, alongside patient and public involvement. Frameworks including non-adoption, abandonment, scale-up, spread and sustainability (NASSS) considers challenges beyond the initial implementation phase (46) as demonstrated within the field of cardiovascular medicine (47). This mixed methods feasibility study tested an early-stage diagnostic product. We have successfully used this approach to generate evidence to guide implementation planning for a market ready test (48, 49). Future research should further explore this approach across different technology areas and expanded geographical coverage. Moreover, NASSS could provide a comprehensive framework for guiding future feasibility studies to support early evidence generation to drive adoption, implementation, scale and spread.

Data availability statement

The datasets presented in this article are not readily available because of restrictions in legal agreements related to data sharing. Requests to access the datasets should be directed to julie.hart@reading.ac.uk.

Ethics statement

The studies involving humans were approved by the Research Ethics Committee of University Hospitals of Leicester NHS Trust. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent to participate in this study was not required from the participants in accordance with the national legislation and the institutional requirements. All participants provided informed verbal consent to participate in this study.

Author contributions

JH: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. AE: Visualization, Writing – review & editing. AS: Conceptualization, Formal analysis, Validation, Writing – review & editing.

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Conflict of interest

Author AS is the Director of Research Health Limited.

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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Using CFIR framework for understanding barriers and facilitators to implementation of community tuberculosis program in Burkina Faso

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Introduction: In 2020, there were nearly 9.9 million new Tuberculosis cases and 1.3 million deaths, with about 95% occurring in developing nations. Burkina Faso implemented a community Tuberculosis program, involving Civil Society Organizations, to increase screening and improve treatment outcomes. Therefore, this study aims to identify the factors influencing the implementation of community interventions involving these organizations in the fight against TB in Burkina Faso.

Method: This qualitative study conducted semi-structured key informant interviews with a purposive sample of health providers from the ministry of health and community health workers. We used framework (the consolidated framework for implementation research was used method to identify barriers and facilitators to implementation of community tuberculosis program in Burkina Faso.

Results: A total of 23 interviews were conducted. The results of this research shed light on several key factors that either contributed to or hindered the program's success. Among the facilitating factors, we identified close collaboration between national and international stakeholders, as well as remarkable program flexibility to adapt to local conditions. Furthermore, continuous training and support for community health workers proved crucial for the program's implementation. However, significant challenges were also unveiled. These challenges encompassed insufficient financial resources, difficulties related to the recruitment and management of civil society associations, and issues regarding program ownership at the peripheral level. Additionally, irregular payments to community health workers had a detrimental impact on their motivation and commitment.

Conclusions: Our study conducted a comprehensive examination of the obstacles and facilitators encountered in the implementation of a community-based tuberculosis control program in Burkina Faso. The results of this research shed light on several key factors that either contributed to or hindered the success implementation of program. Measures should be taken to mobilize national resources, strengthen the capacities of associations, and promote local ownership of the program. Special attention should also be given to improving financial management and resolving issues related to the recruitment and compensation of community health workers. For such community-based tuberculosis programs to succeed in Burkina Faso and in similar context it is essential to address these obstacles and facilitators.

KEYWORDS

barriers, facilitators, implementation, community program, tuberculosis

1 Introduction

Tuberculosis (TB) continues to be a global health challenge, with the World Health Organization (WHO) estimating that a quarter of the world's population is infected with Mycobacterium tuberculosis. In 2020 alone, there were approximately 9.9 million new cases of active TB and 1.3 million deaths attributed to the disease. A significant majority of these cases, about 95%, were reported in developing countries (1). TB is often linked to poverty, exposing affected individuals to economic distress, vulnerability, marginalization, stigma, and discrimination.

Low-income health systems, particularly in sub-Saharan Africa, bear a substantial burden of tuberculosis (1). Burkina Faso, for instance, despite making efforts to control the spread of this infectious, disease continues to face high tuberculosis prevalence rates, particularly in rural and disadvantaged communities. In 2019, Burkina Faso reported an estimated tuberculosis incidence rate of 46 cases per 100,000 inhabitants, with a mortality rate of 9.7 cases per 100,000 inhabitants among HIV-negative TB patients. Moreover, there was a 24% proportion of missing TB cases, and the treatment success rate for new and relapsed patients stood at 81.5% (2).

To address this challenge, community involvement in health promotion has emerged as an effective strategy to enhance health system performance (3). The World Health Organization (WHO)'s Stop TB strategy has recognized the importance of empowering communities to fight tuberculosis as a vital condition for achieving its objectives (4). Engaging community volunteers in the detection process is expected to lead to earlier diagnoses and improved prospects for a full recovery, while also reducing the costs of care.

Data from thirty-eight countries indicate that, on average, 27% of TB patients were notified through Community Health Workers (CHWs) referrals, resulting in an 87% treatment success rate for patients followed by CHWs (3). Building on this success, Burkina Faso implemented an innovative community-based TB program, funded by the Global Fund, to increase screening and enhance treatment success. This program enlisted the involvement of Civil Society Organizations (CSOs) and Non-Governmental Organizations (NGOs) to carry out awareness activities, screening of presumptive TB cases, and community-based Directly Observed Treatment, Short Course (DOTS). The ultimate goal was to alleviate the burden of tuberculosis and save lives (5–7).

However, limited research to date has examined the conditions that facilitate or jeopardize the successful implementation of these kind of program of Community Based Organizations (CSOs and NGOs) in West Africa and their role in the fight against tuberculosis. Therefore, the objective of this study was to identify the factors influencing the implementation of community interventions involving NGOs and CSOs in the fight against tuberculosis in Burkina Faso. Understanding these factors becomes critical when implementing programs under less controlled conditions, such as real-world contexts.

Furthermore, it is essential to synthesize evidence of what has worked and what has not worked in the provision of TB services by

CHWs to benchmark and adapt or adopt similar strategies in comparable country settings. Recently, we evaluated the fidelity of the community-based tuberculosis control program as implemented by Civil Society Organizations (CSOs) in Burkina Faso. The results showed a relatively good fidelity of the program. Community-based programs interface with both health and community systems, requiring optimal integration at different levels. Given the dynamic context and the potential challenges that may arise during implementation at various levels, exploring and comprehending the facilitators and barriers affecting the implementation of this community-based program in Burkina Faso is highly relevant.

2 Study methods

2.1 Description of the community TB intervention in Burkina Faso

The community-based TB program in Burkina Faso was implemented by Community-Based Organizations (CBOs), which are civil society organizations (8, 9). A total of 22 associations operating in 5 districts were involved in the program. Two members from each association were trained to carry out the program's activities. The program included the following components:

2.1.1 Prevention activities

These activities focused on raising awareness, providing information, education, and communication (IEC), and promoting behavior change communication (BCC) within the community. The aim was to increase community knowledge about tuberculosis and encourage behavior changes that could prevent its spread.

2.1.2 Diagnosis activities

The program involved screening and contact tracing to identify individuals who might be symptomatic of tuberculosis. Through active case finding, the program systematically searched for potential TB cases in the community. Presumptive TB cases were then referred to diagnosis and treatment centers (DTCs) located in health centers.

2.1.3 Treatment adherence support and home care

Community volunteers were responsible for providing support to individuals who tested positive for TB. They visited these individuals to supervise the use of anti-TB drugs and ensure treatment adherence. This component aimed to ensure that TB patients received appropriate care and support within their communities.

The individuals trained to carry out these community activities were referred to as community health workers, community volunteers, or animators. The implementation of the program was supervised by two sub-recipients (SRs): SR1—BURCASO

and SR2—URCB. The Principal Recipient (PR) for the Global Fund (GF) funding was the Support Program for the Associative and Community (PAMAC), which served as the financial management unit and provided supervision to the SRs.

2.2 Conceptual framework

To gain a comprehensive understanding of the implementation process, we employed the Consolidated Framework for Implementation Research (CFIR) developed by Damschroder et al. (8). This framework is used to retrospectively identify the factors influencing the implementation of an intervention. Thus, we applied the CFIR to assess both barriers and facilitators to the implementation of the TB community program. The CFIR was specifically designed to guide the systematic assessment of multilevel implementation contexts, aiming to determine factors that might influence the implementation and effectiveness of interventions.

The CFIR is a "meta-theoretical" framework that integrates theories, models, and implementation frameworks from the health field. It is relevant to our case as it allows us to delve into the intricacies of our community intervention. This comprehensive framework takes into account various contextual factors across multiple levels that can impact the implementation and ultimate success of the intervention. It encompasses 37 constructs distributed within 5 domains: (1) intervention characteristics; (2) outer setting; (3) inner setting; (4) characteristics of individuals; and (5) process (8). However, researchers like Damschroder et al. and Kirk et al. have recommended its adaptation to specific contexts (8, 9).

Since the CFIR has primarily been tested with interventions implemented in health facilities such as clinics and primary healthcare centers, we deemed it necessary to add dimensions to tailor it to more or less well-structured community settings. As a result, we made adjustments by removing sub-constructs from some domains. For instance, we excluded the "trialability" sub-construct from the domain of program characteristics as this program was already being scaled, making pilot testing unnecessary. Additionally, we introduced two new sub-domains:

- Characteristics of associations involved: This pertains to the extent to which the type of association (e.g., traditional healers, religious and traditional leaders, etc.) influences the success of implementation in TB control. We hypothesized that the organizational capacity is related to the characteristics of the association. We have therefore replaced the fourth domain (characteristics of individuals) by characteristics of associations involved.
- 2) Support system: This includes the recruitment process, training, and technical assistance that were put in place (10).

Table 1 presents the adapted constructs from the CFIR. The systematic review conducted by Kirk (2016) revealed that the CFIR can be applied at all stages of the implementation process, with particular utility in the post-implementation phase. This further justifies its use in our study (11).

TABLE 1 Domains and constructs adapted of CFIR.

Domains	Constructs
DOMAIN 1: the program's characteristics	Origin Qualité and strength of evidence Relative advantage Adaptability, complexity Quality of design and presentation
DOMAIN 2: The outer context	 Cosmopolitanism or the level of networking of the implementing Organization with other organizations, peer pressure and external policies and incentives.
DOMAIN 3: The inner setting	Culture, compatibility and relative priority of the intervention goal setting and feedback structures, leadership commitment and implementation climate.
DOMAIN 4: The characteristics of the implementing actors (PR, SR, associations, health workers, NTP actors)	Beliefs, knowledge, self-efficacy and personal attributes of individuals
DOMAIN 5: The Implementation	Stages of implementation
process	- Planning, execution, reflection and evaluation, and the presence of key actors(leaders, stakeholder engagement and project champions).
DOMAIN 6: The characteristics of Civil Society Organization	Type of association, the vision, the objectives of the association
DOMAIN 7: The support system	- Training received, supervision and technical support provided.

2.3 Study design and setting

Our study employs a single case study design using the framework method, which provides a valuable approach to understanding the complexities of real-life situations. The case under investigation concerns the implementation of the Community TB program in the central region of Burkina Faso. This qualitative study was conducted in the capital of Burkina Faso(Ouagadougou), involving five (5) health districts. We conducted semi-structured interviews with key informants. The factors influencing the implementation were analyzed retrospectively after the end of the program.

2.4 Sampling and recruitment

For in-depth interviews (IDIs), we used purposive sampling to ensure a comprehensive range of perspectives and experiences regarding the implementation of the intervention. Key informants from all relevant groups were thoughtfully selected to participate in the study. The central region of Burkina Faso was chosen to ensure the inclusion of a substantial number of key informants who had been actively involved in the program.

To achieve representativeness of each group, we included all five (5) districts within the selected survey area. Systematically, we incorporated all health facilities and members of associations that had implemented the intervention in the following health facilities: Bogodogo, Boulmiougou, Kossodo, Paul VI, and Samandin.

Individuals with valuable knowledge and experience in the implementation of the community TB program were invited to participate in the interviews. The interviews were conducted until data saturation was reached, signifying that no new information or perspectives were emerging, ensuring a comprehensive exploration of the subject matter.

2.5 Participants

he interview participants encompassed a diverse group of stakeholders involved in the Community TB program. These included the coordinators of the association networks or associations, the presidents of the associations and the teams responsible for implementing the program, such as program managers, monitoring and evaluation managers, and financial officers. In addition, representatives from the Ministry of Health, including those in charge of health programs (NTP, PADS: health support program) and those responsible for monitoring and evaluation, were interviewed.

Health workers from all the Diagnosis and Treatment of TB Centers (DTCs) were actively enrolled in the study to capture perspectives from various healthcare settings. Furthermore, the study involved animators of associations, traditional healers, and TB patients. In this study the terms of "animators, community health workers (CHWs) were used to design them.

2.6 Data collection

All participants were contacted by e-mail and then by telephone. They were invited to take part in face-to-face interviews. Prior to the interviews, participants gave their consent and all interviews were recorded.

We used semi-structured interview guide tailored to each category of interviewee. These guides were created in accordance with the themes of our conceptual framework, with a primary emphasis on implementation factors. Alongside the recordings, we also took comprehensive notes during the interviews to complement the gathered data. Furthermore, we established a data extraction grid for gathering pertinent information from program documents.

The interviews were conducted until data saturation was reached. They were carried out in either French or Moore, the local language, based on the participants' language preferences. To enhance the reliability and validity of the data, we employed a triangulation approach by also gathering information from program documents, such as activity reports and progress reports. This enabled us to cross-reference and validate the insights obtained through interviews with data from official records.

2.7 Ethical considerations

The study received authorization from the National Ethics Committee for Health Research of Burkina Faso under reference number 2017-4-40 on 3rd May 2017. Before conducting each interview, participants were fully informed about the purpose of the study, and their participation was entirely voluntary. They were assured that they had the right to stop the interview at any time and for any reason, without any repercussions.

Informed consent was obtained from each participant before the interviews. The interviews were digitally recorded to ensure accurate representation and were later transcribed verbatim for analysis. To protect the participants' privacy, anonymity was strictly maintained, and no identifying references were included in the transcripts or any study-related materials.

2.8 Data analysis

All interviews underwent directed thematic analysis, with each interview serving as the unit of analysis. We transcribed the audio recordings of the interviews verbatim in French, and used NVivo Software version 12 for analysis.

We adopted a deductive approach for thematic analysis, creating codes and themes aligned with the dimensions of the adapted CFIR framework. Initially, we comprehensively reviewed all transcripts and took notes to gain a deep understanding of the data.

Next, we established nodes based on the seven domains of the adapted CFIR framework, including sub-nodes for the constructs. These sub-nodes were directly integrated into the previously established nodes for barriers/obstacles or facilitators. For transcript segments that didn't align with any CFIR constructs, we generated new codes. We then categorized the collected data within the CFIR domains and constructs, following the deductive approach.

Moreover, themes that couldn't be categorized within the CFIR constructs were related to the characteristics of the organizations/institutions involved and the support system in place (recruitment, training, and technical assistance). We systematically integrated this additional information into our conceptual framework.

The first author and a specialized assistant proficient in interview methodologies conducted the interviews. In tandem, a comprehensive codebook was devised in alignment with the selected conceptual framework. The coding process was executed in accordance with the guidelines stipulated in this codebook."

3 Results

We conducted key informant interviews with a total of twentythree program implementers, representing various levels, such as health center staff, and community representatives.

The results are organized in accordance with the seven dimensions outlined in our conceptual framework. The data are presented within these dimensions, which encompass the following: the program's characteristics, the outer setting, the inner setting, the characteristics of the involved actors, the Characteristics of Civil Society Organization, the implementation process and the support system.

Within each dimension, we have categorized emerging factors that could have influenced the implementation of our intervention as either barriers or facilitators. These factors offer insights into the challenges and enabling factors encountered throughout the implementation process.

3.1 DOMAIN 1: the program's characteristics

3.1.1 Factors arising from the characteristics of the program that have facilitated its implementation

The community-based TB program was successful in its implementation due to its characteristics. This was a key domain, with three constructs emerging as important to implementation: origin, adaptability, relative advantage, design Quality & Packaging.

3.1.2 Origin

The program was developed by the stakeholders involved in the fight against TB in the country. The Ministry of Health, in collaboration with its national and international partners, participated in writing the project proposal for funding request to the Global Fund (GF).

3.1.3 Adaptability

During the interviews, the majority of participants highlighted the program's adaptability. Despite its complexity, involving multiple actors from various domains, the community TB program demonstrated a capacity to adjust to local conditions, thus facilitating its optimal implementation.

"I believe the program remained flexible. At times, we made adjustments and modified the organization within associations, for example, to ensure continued implementation." Program Manager, SR1

However, it was evident that the adaptability of the program was a subject of debate, as actors from the Principal Recipient (PR) did not share the same opinion.

"...we had the impression that with this program, everything was tightly structured, from the indicators to the strategies...we didn't have much flexibility..."—Program Manager, Principal Recipient (PR).

3.1.4 Relative advantage

This community-based TB program, which leveraged associations, was aligned with the objectives of the National TB Program. The primary aim was to proactively seek out TB cases within the community and improve patient management.

Overall, healthcare providers and TB patients expressed profound appreciation for the services offered by Community Health Workers (CHWs) and were highly receptive to the support they received. A significant advantage of the program, as underscored by their feedback, was the direct assistance provided by CHWs. These encompassed activities such as actively screening for suspected TB cases in the community, delivering health-related education, and providing valuable psychological support to patients dealing with stigma.

"Prior to the engagement of associations, the district had never managed to reach 50 patients per year; however, with their participation, we are now able to reach 100 patients per year". DTC worker 3

3.1.5 Design quality & packaging (perceived excellence in how the intervention is bundled, presented, and assembled)

The initiation of the project engaged a wide range of community stakeholders, encompassing traditional healers, members of civil society, political and religious figures, as well as individuals who had previously experienced TB. These diverse groups, each esteemed in their own right, played pivotal roles in supporting the project's implementation through advocacy and awareness campaigns, rendering their contributions indispensable in facilitating the entire process.

"What worked exceptionally well was the involvement of all community components; there was a sense of synergy in our efforts...when the religious leaders spoke, their influence resonated throughout the places of worship, and it was truly remarkable."—Animator X

He elaborates further, stating, "...having personally experienced TB, I can relate to the right words to convince a suspected case or a treatment-refusing patient to seek assistance at the health centers... moreover, these individuals serve as tangible proof that TB can be successfully treated when the treatment plan is diligently followed..."

According to certain interviewees, the program's adherence to the existing healthcare system structure played a pivotal role in facilitating its implementation.

"It was well-designed...from the peripheral level to the central level....there were established community structures to execute the work...and at each tier of the healthcare system, specific supervisors were assigned for every type of community actor."—PR ME Officer

3.2 DOMAIN 2: the outer setting

In the CFIR framework, the outer setting refers to the economic, political, and social context in which an intervention takes place, including formal and informal support systems. Our evaluation focused on networking, patient needs and resources, and external policies and incentives as defined in the CFIR framework. Networking refers to the level of familiarity between the implementers of the intervention within an organization and external entities.

3.2.1 Factors in the outer setting of the community tuberculosis program that facilitated implementation

3.2.1.1 Patient needs & resources

Community awareness and care activities were tailored to meet the specific needs of patients.

"We honor the decisions made by TB suspects and patients. In many cases, we go to their homes as necessary, offering psychological

support and educating their families about issues related to stigma."— Animator BS2

3.2.1.2 Cosmopolitanism or the level of networking of the implementing

Cosmopolitanism or networking among implementers has contributed to program facilitation. Some civil society organizations have secured extra funding from external partners to address program implementation gaps.

"We secured additional resources for the monitoring and evaluation aspect of Round 8 of GF funding, originally not part of the plan. This allowed us to provide implementing associations with computers and software."—Program Officer 1

3.2.1.3 External policy & incentives

The external political environment strongly supported community involvement in health promotion activities. The Global Fund (GF), a major donor in the fight against HIV, TB, and malaria, motivated countries by offering dual-track funding for both the public and community sectors. Significant funding was dedicated to support community efforts against TB.

The government of Burkina Faso displayed substantial commitment by allocating 25% of GF-received funds to community activities. This commitment was evident in the engagement of associations at the district level and throughout Burkina Faso's healthcare system.

"During Round 8, substantial resources were allocated for program implementation, and it's worth noting the commitment of political leaders. Their availability and active participation in regional review workshops were clear indicators."—Program Officer 3

3.2.2 Factors in the outer setting of the community tuberculosis program that hindered implementation

3.2.2.1 Peer pressure

Certain associations, previously involved in grant implementation, were excluded this time. Despite their voluntary community services, this exclusion created competitive pressures detrimental to the implementation process.

There was also contention over the role of PR assigned to PAMAC by some civil society leaders. Arguments arose, suggesting that this program did not originate from civil society.

"At the national level, disputes occurred, and it was thanks to UNDP's support that PAMAC managed to assume the PR role there." Program Manager, BS2

3.2.2.2 Patient needs & resources

The implementation of community care faced a significant obstacle due to the limited financial means of certain populations. Many patients couldn't fully access the services provided by Community Health Workers due to their extremely constrained resources. Challenges included difficulties in transportation to healthcare facilities and obtaining sufficient food for medication.

Additionally, irregular funding and the misallocation of resources (material, financial, and human) between central and

peripheral levels posed vulnerabilities to the optimal implementation of the community program.

"It's challenging; the associations lack consistent resources for transportation during home visits. The willingness is there, but resource limitations create difficulties. Sometimes, we (health workers) chip in to assist the facilitators (laughs)."—DTC Nurse

3.3 DOMAIN 3: the inner setting

In the CFIR framework, the inner setting refers to the structural attributes and cultural aspects of the environment that can impact implementation (12). Key CFIR constructs relevant to the inner setting in our study included readiness for implementation, networks and communications, available resources, compatibility, relative priority of the intervention, goal setting and feedback structures, as well as leadership commitment and the implementation climate.

3.3.1 Factors in the inner setting of the community tuberculosis program that facilitated implementation

3.3.1.2 Readiness for implementation

Readiness for implementation encompasses leadership involvement, which includes commitment, participation, and accountability of leaders and managers, as well as the availability of resources and access to information and knowledge.

Respondents highlighted that the Principal Recipient's (PR) extensive experience in managing community programs, the competence of its staff, its institutional affiliation with the United Nations Development Program (UNDP), and its collaboration with the National TB Program (NTP) significantly facilitated the implementation process.

"We had a PR who had previously been involved in implementing the community program during round 4. This prior experience proved to be highly beneficial," noted a Ministry of Health official.

3.3.1.3 Access to knowledge & information

The initial training not only equipped the actors with knowledge about tuberculosis (its signs, manifestations, and means of combat) but also provided insights into health program management.

Communication within the program's internal environment was robustly established. A mechanism was put in place to enable the exchange of information in both upward and downward directions. Numerous meetings were conducted at the program's outset, and regular meetings were scheduled throughout its duration to ensure efficient communication.

"I believe that communication was effective; informative meetings were held, and all stakeholders at the central level were kept well-informed about the program's progress," affirmed SR2 Program Manager.

3.3.1.4 Available resources

The availability of adequate resources (human, material, and financial) facilitated the successful implementation of activities. With its experience, the Principal Recipient (PR) was well-equipped to carry out this intervention.

"I believe that PAMAC had the experience; during round 4, PAMAC was the sole Sub-Recipient, making them the most knowledgeable and competent. There were no competitors at that level. Another important factor is that PAMAC was already accustomed to collaborating with associations in the fight against HIV and TB". monitoring and evaluation officer

3.3.2 Factors in the inner setting of the community tuberculosis program that hindered implementation

3.3.2.1 High staff turnover

The high turnover of program staff has had a negative impact on implementation. The loss of qualified human resources was a real handicap to successful implementation.

3.3.2.2 Leadership of PR

The selection of PAMAC as the Principal Recipient (PR) was met with varying levels of acceptance among stakeholders. PAMAC was not seen as a typical civil society organization, but rather as an international agency. This raised concerns about the contested role PAMAC played as PR. The perception of PAMAC as an international agency might create an unsuitable working climate for the PR's leadership.

The institutional affiliation with UNDP made it appear like a UN agency...thus, some community leaders disagreed with PAMAC as the Principal Recipient."—Community leaders

3.3.2.3 Poor collaboration between civil society organization and health facilities

The community program also encountered challenges at the peripheral level. The data collected indicates poor collaboration between DTC health workers and animators. In certain districts, animators were perceived as "rivals," leading to interpersonal conflicts that often disrupted activities."...we had difficulties with our DTC manager...he didn't want to see us in the health center...for him, anyone who didn't receive training at the health school had no place here..."—facilitator SR1

Furthermore, in specific districts, health workers demanded cash payments from CHWs before conducting sputum analysis. They perceived the referral activities of community actors as an additional burden to their workload.

"The situation was particularly concerning in some DTCs; it's quite perplexing. "We refer suspected cases to them, and they ask us to stop because it increases their workload," said one animator.

Another animator added." This has resulted in sputum samples lying on the ground, rotting, because they don't have time to analyze them" Association's Leader.

The interviewees described a challenging working climate characterized by the Principal Recipient (PR) having to compensate for the shortcomings of other community actors. Moreover, a significant number of health workers held a negative perception of the associations (lack of trust, underestimation of their capacity, etc.). These factors contributed to additional challenges for the community program, in addition to the increased workload reported by healthcare providers.

"It's true that after an awareness campaign conducted by the associations, we would see a significant increase in the number of

people coming in; as soon as we noticed a large crowd, we knew that there had been sensitization somewhere."—DTC officer

3.3.2.4 Weak institutional and organizational capacity

Not all the associations working with PAMAC had the capacity to carry out the activities. They lacked the necessary institutional and organizational systems to effectively implement the program's activities.

"I believe that even the largest structures had to develop a capacity building plan, and even then, it was the PR team that did most of the work...but that was one of PAMAC's missions...so we didn't complain..."PR's responsible

3.4 DOMAIN 4: the characteristics of the implementing actors (PR, SR, associations, health workers, NTP actors)

3.4.1 Factors in the characteristics of the implementing actors (PR, SR, associations, health workers, NTP actors) that facilitated implementation

Organizations consist of individuals (implementers) who bear responsibility for and can influence the implementation of an intervention. We have examined the concepts of knowledge and beliefs, along with self-efficacy, within the context of CFIR. Knowledge and beliefs pertain to an individual's attitudes and the importance they attach to the intervention, as well as their understanding of the facts, truths, and principles associated with it (13). The majority of CHWs appear to be highly motivated by their work, recognizing its significant impact on the health of the community they serve.

Individuals, depending on the type of association (traditional practitioners, TB patients, religious and customary) to which they were affiliated, had varying levels of knowledge and beliefs about the importance of the program (knowledge and beliefs about the intervention). The implementation of such an intervention appeared to carry greater significance for actors at the central level (PR, NTP, PR) than for those at the peripheral level (implementing association, DTC agent).

"We strongly believe in the contribution of associations to the fight against tuberculosis in Burkina Faso. The impact of their contribution has been demonstrated in other countries, and we have faith in its effectiveness here as well." NTP agent

"Most associations just make noise. Furthermore, they are accustomed to seeking easy money, similar to what happened during the days of HIV...DTC agent

3.4.2 Factors in the characteristics of the implementing actors (PR, SR, associations, health workers, NTP actors) that hindered implementation

Some actors felt that the involvement of associations led to an increase in their workload. On the other hand, some actors were willing to put in extra effort to handle the influx of cases referred by the associations.

During the interviews, issues regarding the compatibility of Global Fund procedures with community life were evident. These procedures were found to be ill-suited to the functional capacities of the associations. One of the major obstacles was the collaboration with the health system. Despite being theoretically planned, in practice, the associations were not given due consideration.

"...because civil society and public services should work together, but I had the impression that the civil part was always underestimated...the public part always underestimated the civil society part, as if the civil society should make efforts to adapt to what was done at the public level, but not the other way around, to adapt a little to what civil society does..."—PR manager

3.5 DOMAIN 5: the implementation process

3.5.1 Factors in the implementation process of the community tuberculosis program that facilitated implementation

The process from operational planning to implementation was participatory, with health and civil society actors collaborating closely on the community program. This inclusive approach to planning considers the concerns and inputs of all stakeholders involved.

"It was very enlightening for me because I observed that the process was highly participatory—it brought together the various stakeholders and enabled them to synchronize their efforts and understand each other better right from the beginning". SR_3 program Manager

At the operational activity level, the animators collaborated with the district health workers to plan and carry out the activities.

"We mutually agree and validate a work plan for each quarter» Association leader.

Furthermore, half of the interviewees expressed strong belief in their ability to achieve the objectives. The training they received before the activities began, along with their own experiences, instilled confidence in their capabilities to accomplish the set objectives.

"It wasn't easy, but we put in the effort. We were confident in our actions, so we were determined to achieve our objectives. We had prior experience in similar activities, and on top of that, we received training. We believe we can only succeed in fulfilling our mission." Association Facilitator

3.5.2 Factors in the implementation process of the community tuberculosis program that hindered implementation

Some interviewees expressed the view that the project did not align with a need expressed by the community. Moreover, they believed that the donor had exerted significant influence to impose its vision, which included the selection of indicators, intervention strategies, recruitment of associations, and provision of technical assistance.

"...the primary obstacle lies in the concept of the project; based on my experience in community work, this is the main difficulty I

have observed. It was not a need expressed by the population, yet the project was introduced to support them...". Program officer SR3

The project design did not consider some of the outcomes and lessons learned from the implementation of previous projects.

"Interestingly, there were previous projects, like FORESA, that laid the foundation for community intervention in TB, but to my surprise, their outcomes and experiences were not taken into account in the current project design."—NTP officer

All managers reported that the significant involvement of the donor in the program's management had a negative impact on the implementation. It occasionally led to ambiguities in the desired management procedures as per the Global Fund's requirements.

But I also believe that working with the Global Fund was not always easy; we received numerous emails and requests, asking us to justify various aspects. It was quite challenging, with frequent meetings required to respond to the emails from the Global Fund. PR officer

Some actors felt that the involvement of associations led to an increase in their workload. On the other hand, some actors were willing to put in extra effort to handle the influx of cases referred by the associations.

During the interviews, issues regarding the compatibility of Global Fund procedures with community life were evident. These procedures were found to be ill-suited to the functional capacities of the associations. One of the major obstacles was the collaboration with the health system. Despite being theoretically planned, in practice, the associations were not given due consideration.

"...because civil society and public services should work together, but I had the impression that the civil part was always underestimated...the public part always underestimated the civil society part, as if the civil society should make efforts to adapt to what was done at the public level, but not the other way around, to adapt a little to what civil society does..."—PR manager.

3.6 DOMAIN 6: the characteristics of civil society organization

3.6.1 Factors in the characteristics of civil society organization that facilitated implementation of the community tuberculosis program

The results revealed that individuals affected by the illness (infected or affected individuals, traditional healers) were more engaged in the activities without necessarily expecting funding from the program.

"We have annual action plans, and we try to implement our activities using resource mobilization strategies. However, more often than not, we rely on our own resources from incomegenerating activities, membership fees, and other means."— Association member representing patients.

Associations made up of people affected by the disease, such as TB patient associations, show greater resilience and determination in the fight against the disease.

"The fact of being infected or having lived with someone who is infected provides the basis for commitment; they understand better

what the disease means. This situation can be motivating enough, which makes me stay committed with or without money."—NTP officer

The data further highlighted the strong involvement of traditional healer's associations in the implementation. This was evident from the statement of a CDT agent: "The associations of traditional healers worked even without funding—seeing patients regain their health was enough for them. Their work was recognized several times by the highest authorities of the Ministry of Health with a medal and an incentive bonus. On World TB Day, they were always awarded."

3.6.2 Factors in the characteristics of civil society organization that hindered implementation of the community tuberculosis program

According to the respondents, all associations were not able to address the challenges that awaited them. The existence of the association is not supported by a vision, by well-established objectives

"we don't have any specific objectives, we are really open, if there is funding in such and such a field, we just orient our objectives and we will take the funding". Association leader

Our results highlight an institutional and organizational weakness in most of the associations. The lack of human resources has prevented them from having loyal and trained staff. The turnover of staff was the important barriers to good implementation.

According to one program officer, "our inability to maintain trained staff has been our fundamental problem...what do you want we don't have the money to motivate them because of the frequent gaps in funding, so they will go in search of a better job offers".

3.7 DOMAIN 7: the support system

3.7.1 Factors in the support system of civil society organization that facilitated implementation of the community tuberculosis program

The technical assistance provided by the PR's technical team and the National TB Program (NTP) has played a crucial role in enhancing the capacities of both the associations and the facilitators.

"We were well supported by PAMAC; whenever we asked for technical support, they were there."—Association Facilitator Z

Our interviewees also mentioned the technical support provided by the PR and the Sub-Recipients (SRs) through a Fiduciary Management Agency (FMA) recruited by the Global Fund (GF). "The GF came to help us secure funding to work…we learned a lot from them…with their support, our financial reports were accepted by the GF and they provided funding for us."—SR Manager

All the animators received comprehensive training and acquired the necessary knowledge to effectively carry out community TB control activities. They found the initial training to be highly valuable in enhancing their skills and enabling successful implementation of their work. Moreover, they benefited from regular supervision by health workers.

"PAMAC, in collaboration with the NTP, provided us with training, and now we receive regular supervision from CDT officers."—Association Facilitator

This program provided a valuable opportunity for associations to enhance their organizational and institutional capacities. The implementation of interventions to combat tuberculosis also increased the visibility of these associations.

"...this program has brought us numerous advantages; it's the first program that has supported and strengthened us at all levels...our relationship with the health services has significantly improved..."—Association Leader

3.7.2 Factors in the support system of civil society organization that hindered implementation of the community tuberculosis program

The system for recruiting associations and facilitators faced criticism from our respondents. They found the recruitment criteria to be inappropriate for community organizations, and many interviewees described the rules as "bureaucratic."

"For instance, the extensive documentation required favored larger associations similar to NGOs, even though it is widely known that they may not always be the most effective workers. Instead, they might be more focused on seeking funding than actual implementation," shared a member of Association Y.

An NTP officer also added, "As a result, some genuinely capable organizations find themselves excluded because they may not meet all the specified requirements. This system is not well-suited for community organizations; it's too modernized and, to be honest, we don't quite understand it." Table 2 summarises the factors that have influenced the implementation of the program.

4 Discussion

Our study aimed to identify the factors that facilitated or hindered the implementation of community TB program in Burkina Faso. The conceptual framework method was used to identify the obstacles and factors that facilitated the implementation of the community TB control program.

The community TB program discussed in this study exhibits various characteristics that influence its implementation, distributed across seven distinct domains. In domain 1, the results suggest that facilitating factors prevail. The origins of the program are rooted in close collaboration among stakeholders involved in tuberculosis control in the country, including the Ministry of Health and national and international partners. This cooperation from the stage of funding proposal to the Global Fund laid the foundation for a participatory approach and ongoing collaboration. In addition, the implementation process coordinated by a multidisciplinary team (PR, SR) was very useful to the implementation. This allowed for the training and supervision of animators in charge of operational activities, all of which helped to reframe and correct shortcomings in order to deliver quality services. These

TABLE 2 Factors Influencing the Implementation of the Community Program.

Domains CFIR	Facilitating factors	Barriers/obstacles
1. The program's characteri	stics	
Origin	- Program was developed by the stakeholders in fight against tuberculosis of country: The Ministry of Health, in collaboration with its national and international partners	
Adaptability	The program was modified to adapt to the local context.	
Relative advantage	Recognition of the undeniable benefits of community intervention by health professionals (reduction of multiple tasks; improvement of indicators in health facilities). Compatibility with CDT objectives The proximity of the intervention to the communities	
Intervention source	The project was initiated by the beneficiary country (Burkina Faso).	 The project does not address a need expressed by the population. The project failed to consider lessons learned from comparable initiatives. The project was driven by the donor, influencing the selection of indicators, intervention strategies, recruitment of associations, and provision of technical assistance.
Evidence des résultats	The project results were noticeable (increase in the number of people screened, decrease in the number of lost to follow-up cases). CDT Agents	
Design quality and packaging	The project setup involved groups of people due to their reputation (traditional healers, civil society actors, political and health authorities, former TB patients). The program followed the structure of the health system, involving community actors at all levels.	Involvement of a large number of associative structures.
2. The outer context		
Needs and resources	- Community awareness and care activities were tailored to meet the specific needs of patients.	
Cosmopolitanism	- Some civil society organizations have secured extra funding from external partners to address program implementation gaps.	
External policy and incentives	 The external political environment strongly supported community involvement in health promotion activities. At the international level, the requirement to involve communities in the fight against diseases is recognized. dual-track funding for both the public and community sectors. Significant funding was dedicated to support community efforts against TB. 	
Pression des pairs		Certain associations, previously involved in grant implementation, were excluded this time this exclusion created competitive pressures detrimental to the implementation process. contention over the role of PR assigned to PAMAC by some civil society leaders. Arguments arose, suggesting that this program did not originate from civil society
Patient Needs & Resources		Many patients couldn't fully access the services provided by Community Health Workers due to their extremely constrained resources Challenges included difficulties in transportation to healthcare facilities and obtaining sufficient food for medication irregular funding and the misallocation of resources
3. The inner setting		
Readiness for Implementation	The Principal Recipient's (PR) extensive experience in managing community programs, the competence of its staff, its institutional affiliation with the United Nations Development Program (UNDP), and its collaboration with the National TB Program (NTP) significantly facilitated the implementation process.	
Access to Knowledge & Information	- The initial training equipped the actors with knowledge about tuberculosis and provided insights into health program management. - Communication within the program's internal environment was robustly established. - Numerous meetings were conducted at the program's outset, and regular meetings were scheduled throughout its duration to ensure efficient communication	

(Continued)

TABLE 2 Continued

Domains CFIR	Facilitating factors	Barriers/obstacles
Available Resources	The availability of adequate resources (human, material, and financial) facilitated the successful implementation of activities	
High Staff Turnover		The high turnover of program staff has had a negative impact on implementation The loss of qualified human resources was a real handicap to successful implementation.
Leadership of PR		- PAMAC was not seen as a typical civil society organization, but rather as an international agency - the contested role PAMAC played as PR - The perception of PAMAC as an international agency might create an unsuitable working climate for the PR's leadership
Collaboration		Poor collaboration between civil society organization and health facilities
Institutional and organizational capacity		- Weak institutional and organizational capacity of some CSO
4. The Characteristics of the	e implementing actors (PR, SR, associations, health workers, NTP actors	s)
Motivation	The majority of CHWs appear to be highly motivated by their work, recognizing its significant impact on the health of the community they serve.	
Knowledge and beliefs about the intervention	- Individuals, depending on the type of association (traditional practitioners, TB patients, religious and customary) to which they were affiliated, had varying levels of knowledge and beliefs about the importance of the program - greater significance for actors at the central level (PR, NTP, PR) than for those at the peripheral level (implementing association, DTC agent).	- Some actors felt that the involvement of associations led to an increase in their workload. On the other hand, some actors were willing to put in extra effort to handle the influx of cases referred by the associations The procedures of GF were found to be ill-suited to the functional capacities of the associations
5. The Implementation pro-	cess	
	- The process from operational planning to implementation was participatory, with health and civil society actors collaborating closely on the community program - At the operational activity level, the animators collaborated with the district health workers to plan and carry out the activities. - half of the interviewees expressed strong belief in their ability to achieve the objectives.	- The project did not align with a need expressed by the community The donor had exerted significant influence to impose its vision, which included the selection of indicators, intervention strategies, recruitment of associations, and provision of technical assistance The project design did not consider some of the outcomes and lessons learned from the implementation of previous projects.
		- The significant involvement of the donor in the program's management had a negative impact on the implementation It occasionally led to ambiguities in the desired management procedures as per the Global Fund's requirements
6: The Characteristics of Ci	vil Society Organization	
	 Associations with individuals affected by the illness (infected or affected individuals, traditional healers) were more engaged in the activities without necessarily expecting funding from the program. Associations made up of people affected by the disease, such as TB patient associations, show greater resilience and determination in the fight against the disease. strong involvement of traditional healer's associations in the implementation 	 All associations were not able to address the challenges that awaited them. The existence of the association is not supported by a vision, by well-established objectives The lack of human resources has prevented them from having loyal and trained staff The turnover of staff was the important barriers to good implementation.
7: The support system		
	- The technical assistance provided by the PR's technical team and the National TB Program (NTP) has played a crucial role in enhancing the capacities of both the associations and the facilitators. - The technical support provided by the PR and the Sub-Recipients (SRs) through a Fiduciary Management Agency (FMA) recruited by the Global Fund (GF). - All the animators received comprehensive training and acquired the necessary knowledge to effectively carry out community TB control activities. - The initial training to be highly valuable in enhancing their skills and enabling successful implementation of their work - Regular supervision by health workers. - A valuable opportunity for associations to enhance their organizational and institutional capacities.	They found the recruitment criteria to be inappropriate for community organizations, and many interviewees described the rules as "bureaucratic."

results suggest that the community program as designed had great potential for successful implementation.

The adaptability of the program was also highlighted in domain 1, where it is noted that despite its complexity involving diverse actors from various domains, the community TB program has demonstrated great flexibility in adapting to local conditions (9, 14–16). This flexibility greatly facilitated the optimal implementation of the program by considering the specific needs and challenges of each context (11, 12, 17). For example it seems that the possibility of flexible working hours or tasks are the indicators perceived by the actors as being associated with high management support (18). Several experiments have reported that program that allow for adaptation are more successful (19).

In terms of knowledge, beliefs and self-efficacy, the community relays had sufficient knowledge to carry out activities and were very enthusiastic about taking part in the program. They found the initial training very useful, enabling them to carry out their work successfully. All traditional healers are aware of the importance of primary health care and recognise the value of their involvement and the services they provide. It is therefore imperative to strengthen their commitment to this program. This will educate and inform them on how to help community members who are ill and when they should be referred to health facilities. The results of our study suggest that the successful implementation of this type of program is linked to the positive or negative attitudes of the stakeholders towards the program, training, self-confidence (the feeling of being able to meet the requirements of the program) and the enthusiasm of the stakeholders (20).

The external context, reveals that implementation has been facilitated by strong political and financial support from the Global Fund. The commitment of the Burkina Faso government to allocate a significant portion of the budget received from the Global Fund for community activities reflects a clear political will to involve the community in tuberculosis control.

Domain 3, centered on the internal context, emphasizes the importance of readiness for implementation. The extensive experience of the Principal Recipient (PR) in managing community programs, along with its close collaboration with the National Tuberculosis Program (NTP) and institutional anchoring with the United Nations Development Program (UNDP), has contributed to facilitating program implementation.

In domain 5, which deals with the implementation process, a participatory and collaborative approach among health and civil society actors has been a key element in achieving program objectives. Collaboration between animators and healthcare workers at the district level has allowed for effective planning and execution of activities (14).

However, despite these facilitating factors, the study highlighted challenges related to the characteristics of civil society organizations. Some associations lack qualified human resources and a well-established vision, which hampers their ability to effectively manage program activities.

In terms of the support system, it is mentioned that technical assistance provided by the PR's technical team and the National Tuberculosis Program (NTP) has played a crucial role in strengthening the capacities of associations and animators.

However, some criticism is raised regarding the recruitment criteria for associations and animators perceived as bureaucratic.

One of great difficulty was the increase in workload due to the increase in attendance at the DTCs after the associations' awareness sessions; no system of compensation for the additional workload was put in place, which led to conflicts between animators and health workers in some DTCs. Martin Muddu's study on barriers to integrating hypertension and HIV care made this same finding and confirmed that it was a barrier to program implementation (17). Terry and al (2020) study suggests a better alignment between workload and person adequacy (12, 17). The track record of most associations in the fight against HIV made it difficult for them to be adopted not only by communities because of stigma, but also by some health center staff, as they were seen as having accumulated financial resources from the multiple HIV program they ran. This could be an explanation for the financial compensation imposed by some DTCs workers. However, in other districts, instead of expecting financial compensation, an organization was set up to pay for community services (transport costs, motivation, etc.) during the unfunded periods. In this case, we have seen an increase in the level of implementation rather than a halt in community activities due to irregular funding.

In this study, the peripheral level faced several challenges. Although our program is compatible with the needs of the NTP, it would seem that the idea of the project was not perceived as an expressed need by the population according to several interviewees. This could affect the participation of the community and also the ownership of the project by the associations. In this situation, sustainability could be threatened. This suggests mixed positive or negative perceptions of the intervention among the implementing actors. Indeed, studies have shown the links between innovation uptake and needs. It is crucial for providers that the intervention meets their needs (20). The operational planning process to implementation was participatory, with health and civil society actors working together on the community program. But the actors in these structures at the peripheral level seemed to be on the fringes of the planning. This led to a problem of ownership of the program. The study by Tonny Zitti in Mali made the same observation (11). It is therefore normal that we have seen a refusal to accept community intervention in some DTCs.

Although the country was able to sign a financing agreement with the GF, financial resources were absent or very insufficient on the ground to carry out the activities, demonstrating the weakness of the structures in complying with the donor's financial management requirements. This was due to poor governance and financial management at the level of the implementing associations (12, 13). The lack of funding within the association for the implementation of activities has mainly affected the implementation of operational activities; timebound interventions based on the availability of subsidies can erode the confidence of the community in organizations that employ them, further compromising the effectiveness and acceptability of such interventions in the long term (10). In the literature, the availability of financial resources has been shown to favor the implementation process (13, 14). However, this situation alone could not explain the difficult implementation;

financial resources can better contribute to the implementation only if other conditions are met, such as the commitment of strategic actors, understanding of the project and the availability of financial (18, 21).

According to other studies (18, 19), insufficient or irregular payment has a considerable impact on the quality of outreach services. In addition, it leads to the turnover of trained facilitators, which can jeopardize implementation (21). All providers had adequate knowledge to conduct community-based TB activities. The facilitators found the initial training very useful in equipping them to carry out their work (14). But they were dissatisfied and demotivated by the irregular payment for their services. In the districts, the lack of knowledge and information on the involvement of associations in the fight against tuberculosis on the part of certain health workers (Physicians, nurses, etc.) prevented some associations from carrying out their activities successfully (13).

The PR was ready to coordinate the implementation of the community TB program, but the other structures (SR, SMEO) that were to accompany it did not have all the required skills. Hasson et al. have pointed out that the recruitment of structures is a moderating factor in the implementation of a program (22). In this sense, we propose that special attention should be paid to the inclusion of such organizations in a program.

4.1 Lessons learned and implications of this study

The form of community involvement used in this study has been well-received and has contributed to improved outcomes in TB control. However, its heavy reliance on external funding poses limitations on its scalability and long-term sustainability. It would be beneficial to mobilize national resources to support such community interventions. Furthermore, involving local actors (districts, health centers, implementing associations) in the entire process, from project design to implementation, is crucial for fostering ownership, which is essential for successful implementation.

The success of this program is significantly influenced by factors such as the characteristics of the involved structures, the support system, and the presence of strong leadership. Adapting the program's comprehension level to match that of the associative structures is vital for genuine ownership and meaningful engagement with the project.

4.2 Limitations of the study

Our study was conducted in only one out of thirteen health regions, making generalization challenging. However, the contextual analysis we performed included a wide range of participants from various sectors, including ministries of health, national and international NGOs, civil society, and all entities directly and indirectly involved in the implementation.

Another limitation was the time gap between the end of the project and the study, which may have introduced recall bias. To mitigate this, we used a diverse group of interviewers and extensively relied on program documents (reports, funding requests, etc.).

Using the CFIR for the analysis also has limitations, as certain areas might have been missed since the framework was not initially used to construct the interview guides. However, we made this choice to explore if new themes could emerge. The deductive analysis allowed us to identify and classify emerging themes, and these new categories could be used for similar community programs in the future. Additionally, as the CFIR was developed from a study in a medical setting, we sought a framework more suited to the community context.

5 Conclusion

In conclusion, our study conducted a comprehensive examination of the obstacles and facilitators encountered in the implementation of a community-based tuberculosis program in Burkina Faso. The results of this research shed light on several key factors that either contributed to or hindered the success implementation of program. Measures should be taken to mobilize national resources, strengthen the capacities of associations, and promote local ownership of the program. Special attention should also be given to improving financial management and resolving issues related to the recruitment and compensation of community health workers. For such community-based tuberculosis programs to succeed in Burkina Faso and in similar context it is essential to address these obstacles and facilitators.

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 humans were approved by the Comité d'éthique pour la recherche en santé du Burkina Faso (Burkina Faso Health Research Ethics Committee). The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent to participate in this study was not required from the participants in accordance with the national legislation and the institutional requirements. Written informed consent was obtained for some participants who could read and write. For those who could not, a translation into the local language was conducted and verbal informed consent was obtained.

Author contributions

FD: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Writing – original draft. OS: Conceptualization, Methodology, Supervision, Validation,

Writing – review & editing. SK: Conceptualization, Methodology, Supervision, Writing – review & editing.

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Training in eight low-and middle-income countries: lessons learned from a pilot study using the WHO-TDR dissemination and implementation massive open online course

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Introduction: Non-communicable diseases (NCDs) are a leading cause of morbidity and mortality in low-and middle- income countries (LMICs). Despite this, a lack of funding, training and mentorship for NCD investigators in LMICs exists. In an effort to gain knowledge and skills to address these gaps, participants from the Global Research on Implementation and Translation Science (GRIT), a consortium of studies in eight LMICs and their networks, attended the dissemination and implementation (D&I) massive open online course (MOOC) developed by the Special Programme for Research and Training in Tropical Diseases at the World Health Organization to strengthen D&I capacity building. Here, we report on the pilot of this MOOC, which was implemented during the SARS COVID-19 pandemic from April- November 2020. Methods: Participants completed pre-and post-training questionnaires to assess self-reported D&I competencies, general research skills, and research mentor access and quality. D&I competencies were measured by use of a scale developed for a US-based training program, with change in competency

Abbreviations

D&I, Dissemination and Implementation; GRIT, Global Research on Implementation and Translation Science; LMICs, Low and middle-income countries; MOOC, Massive open online course; NCDs, Non communicable diseases; TDR, Training in Tropical Diseases; WHO, World Health Organization.

scores assessed by paired t test. We used univariate statistics to analyze the data for all other outcomes.

Results: Of the 247 participants enrolled, 32 (13%) completed all course requirements, 21 (9%) completed the pre-and post-surveys and are included in the analysis. D&I competency scores suggest improvement for those who had complete pre- and post-assessments. Trainee's average score on the full competency scale improved 1.45 points (0–5 scale) from pre- to post-test; all four subscales also showed evidence of improvements. There were small but not significant increases in competencies for grant writing, proposal/ manuscript writing and presentations from pre- to post-test assessment. 40% of trainees reported access to a research mentor and 12% reported access to a D&I specific mentor. Participants reported barriers (e.g., unstable internet access and challenges due to COVID-19) and facilitators (e.g., topical interests, collaboration with colleagues) to completing the MOOC.

Conclusions: Although COVID-19 affected program usage and completion, the MOOC was feasible. We also had signals of effectiveness, meaning among LMIC participants completing the course, there was improvement in self-report D&I competency scores. Recommendations for future D&I trainings in LMICs include (1) adding more topic specific modules (i.e., NCD research, general research skills) for scalability; (2) fostering more collaboration with participants across LMICs; and (3) establishing partnerships with D&I mentors for course participants.

KEYWORDS

implementation research, dissemination & implementation research, capacity building, massive open online course (MOOC), non-communicable chronic diseases

Introduction

Non-communicable diseases (NCDs) are the leading cause of mortality worldwide that disproportionately impact low and middle-income countries (LMICs) (1). With 80% of deaths from NCDs occurring in LMICs, the role of local research capacity and relevant research informing policy and practice is crucial (2). Despite this, there has been a particular lack of funding, training and mentorship for NCD investigators in LMICs (3).

The Special Programme for Research and Training in Tropical Diseases (TDR) at the World Health Organization (WHO) developed the Massive Open Online Course (MOOC), which aims to disseminate implementation research concepts (4). The primary goal of the course is to strengthen capacity building and improve training opportunities, targeting local public health researchers, practitioners and policy-makers (4). The course delivers dissemination and implementation (D&I) research education in LMICs where access to formal learning pathways, such as university courses in implementation research, may be limited (5). Investing in research capacity and training in LMICs reduces disease burden by building local research capacity and ensuring that those who are being trained are best equipped to address the needs of their communities (6–9).

MOOCs have steadily gained popularity given the accessibility, affordability, and effectiveness of the courses (4, 10, 11). The TDR MOOC on Implementation Research (IR) has shown to improve participant knowledge and understanding of implementation research and increased participants' ability to apply the course concepts to professional practice (12). While this MOOC was

developed with a focus on infectious diseases of poverty, the course concepts can be applied to strengthening implementation research capacity for NCDs and other disciplines (12, 13).

The goals of this paper are to describe the pilot evaluation outcomes of one of the 2020 MOOC-D&I trainings conducted by the Global Research on Implementation and Translation Science (GRIT) consortium as part of the GRIT's ongoing mentorship and capacity building programs, and share barriers, facilitators, and recommendations to enhance future D&I training opportunities in LMICs.

Methods

TDR MOOC on IR

The TDR MOOC on IR is a step-by-step online training for public health researchers and decision-makers that focuses on design and implementation of research projects (12). Core concepts of implementation research are addressed in five modules including: (1) identifying the challenges of various health settings; (2) assessing the appropriateness of existing disease control strategies; (3) developing new interventions and strategies by working with communities and stakeholders; (4) specifying implementation research questions; and (5) designing rigorous research projects, including how to identify implementation outcomes, evaluating effectiveness, and making plans to scale-up implementation in real life settings (12). The course includes homework assignments, the requirement of completing and

passing at least four quizzes and a final assignment with a peerreview component. The five modules were open to participants from May 11, 2020, to Sept. 25, 2020. The final exam was available to take after the five modules were completed until October 23, 2020, and participants were required to complete the peer-review assessment by November 6, 2020. Participants completed an electronic survey at the beginning and conclusion of the MOOC to evaluate the change in knowledge and self-assessed competencies. Subsequently, participants were asked to share barriers and facilitators to completing the MOOC. Participants who completed all course components received a MOOC certificate of completion.

Participants

There were two sets of participants in this study. The first were participants from the Global Research on Implementation and Translation Science (GRIT) Consortium funded by the National Heart Lung and Blood Institute. 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 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 (3, 6). Specifically, all countries have partnership between D&I mentors and hypertension physicians in the U.S. and in country. Members from all countries were invited to GRIT workshops about implementation science and hypertension care, and all countries have developed formal and informal infrastructures of mentoring in D&I and research in general (14). The MOOC was an added structure in which consortium members decided to engage to support enhancing D&I knowledge for GRIT members.

The invitation to participate in the MOOC was open to all consortium members. Additionally, GRIT participants were encouraged to share the announcement with their respective networks. The second set of participants were not part of the GRIT Consortium and were recruited through snowball sampling through the GRIT network. We did not have inclusion or exclusion criteria. Our recruitment email invited anyone interested in the MOOC with a brief description of the course, timeline and expectations. Enrollment was open from April 6 to May 5, 2020 and the course ran from May 11, 2020 to November 6, 2020.

Measures

This was a pilot study aimed to see if training D&I via an online platform was feasible across eight LMICs. The primary outcome of this study was competency in D&I research. Surveys were distributed via Qualtrics (15). We also examined four secondary outcomes including: (1) D&I mentor access and quality; (2) general research mentor access and quality; (3) general research skill competencies, in manuscript writing, proposal writing, making scholarly presentations, and grant writing; and (4) a qualitative

assessment of barriers and facilitators to completing the MOOC. While the TDR MOOC does not have a formal mentorship as part of the course, GRIT members are connected formally or informally with their D&I members in either delivering interventions or enhancing capacity building in D&I and hypertension care. Additionally, unique to this training was the expectation that results from the MOOC training could be used as potential future research ideas as part of GRIT capacity building efforts.

The current study is a single-group, pre-post study design to assess changes in D&I research competencies, measure mentor access and quality, and describe general research skills among participants in the TDR MOOC. Additionally, barriers and facilitators to completing the course were examined. Researchers originally developed the competency measure for D&I trainings in the United States (5, 8, 16). Others have subsequently used this measure to assess D&I competencies for the WHO MOOC internationally (10, 17). The 43 item self-report measure is organized into four subscales: (1) definitions, background, and rationale, (2) theory and approaches, (3) design and analysis, and (4) practice-based considerations (5, 8) using a 5-point Likert scale (i.e., Not at all to Extremely).

A secondary outcome of this study was D&I mentor access and quality, measured through three questions added to the original survey. The first question asked trainees whether they had access to a D&I mentor (answer options: yes, no, not sure). If the trainee had a D&I mentor, they were asked two follow-up questions. The first follow-up question assessed the quality of the mentoring ("how would you rate the overall quality of the mentoring you received from your D&I mentor?"). Trainees answered using a 7-point Likert scale with anchoring verbiage at 3 points (1- very low, 7-very high). The second follow-up question assessed the degree to which the D&I mentoring met their expectations: "to what extent do you feel your D&I mentor is meeting your expectations?" Trainees answered using a 7-point Likert scale with anchoring verbiage at 3 points (1-Not at all, 7-Completely).

A third outcome examined the general research mentor access and quality, with three additional survey questions. The first research mentor question asked trainees whether they had access to a research mentor (answer options: yes, no, not sure). Trainees with a research mentor were asked a follow-up question about mentoring quality and the degree to which the mentoring met their expectations. The same questions, with answer options, that were asked to assess the quality of the mentorship and met expectations for their general research mentor were asked for those with a D&I specific mentor.

A fourth outcome measured general research skill competencies, in manuscript writing, proposal writing, making scholarly presentations, and grant writing. Trainees rated their level of competency for each of these items using a 5-point Likert scale (1 not at all to 5 extremely).

The final outcome examined was barriers and facilitators to completing the MOOC. Trainees who completed the MOOC were asked: "what enabled you to complete the MOOC?" Trainees who completed some but not all of the MOOC were asked: "what enabled you to complete some of but not all the MOOC components?" Trainees who did not complete all of the

MOOC were asked: "what prevented you from being able to complete the MOOC?" All trainees were asked: "What changes/ support would help future participants complete the MOOC?" The questions pertaining to barriers and facilitators were openended and included in the post-assessment survey.

MOOC participant demographic information was also collected. Specifically, participants provided their gender, age, education, country, work position, work location, and GRIT participation.

Analysis

Quantitative analyses were conducted in Stata 16.1. A paired t-test was used to determine if trainees' D&I competencies and general research competencies changed from pre- to post-test. The trainees' average total D&I competency score and their average scores for each sub-scale were calculated (8, 10). The analytic sample for our primary outcome only included trainees with complete pre- and post- D&I competency measures; those with missing data were excluded. Chi-square tests, Fisher exact tests, and independent two sample *t*-tests using demographic variables were obtained to determine if the trainees without complete D&I competency measures differed from those with complete pre- and post-measures. Some respondents had missing demographic variables and could not be included in the comparison assessment. Demographic variables was 5 and the highest was 9.

The results from that analysis suggest that there were no meaningful differences between those with complete D&I competency scores and those without. As such, only the results for trainees with complete pre- and post-test D&I competency measures are reported. Similarly, the analytic sample for the fourth outcome measuring general research competency only included respondents with complete pre- and post-data for that measure. There were more respondents with complete pre- and post-data for general research competency compared to the D&I competency completers. The same diagnostic tests were run on the general research competency completers and non-completers. No meaningful difference was found between the two groups.

A univariate statistic was used to analyze the data for the second and third outcomes. Data for those outcomes came from the pre-test survey data. Observations with missing data were removed. Finally, the qualitative data for the final outcome, barriers and facilitators, were analyzed using thematic analysis to identify themes, patterns and areas of overlap in participant's open ended survey responses (18).

Results

MOOC participation

247 individuals from the GRIT Consortium and ancillary networks enrolled in the MOOC; 116 (47%) completed the pre-assessment survey, 101 (41%) attempted any quizzes, 59 (24%) completed all quizzes, 35 (14%) completed the final exam, and 32 participants (13%) completed all course requirements, but

only 21 (8%) completed both pre and post-surveys and therefore these are the ones included in the analysis.

Table 1 outlines the demographic characteristics of the trainees who completed both the pre- and post-competency measures

TABLE 1 Demographic characteristics of trainees.

	pre/po competer	omplete ost D&I ocy (<i>n</i> = 21) (%)	At least one item in pre-test survey (n = 116) n (%)		
Gender					
Male	9	(43%)	61	(53%)	
Female	12	(57%)	49	(42%)	
Other	0	(0%)	1	(1%)	
Missing	0	(0%)	5	(4%)	
Education					
PhD/MD	2	(10%)	18	(16%)	
Master's degree	16	(76%)	61	(53%)	
Some graduate school	0	(0%)	4	(3%)	
Bachelor's degree	3	(14%)	27	(23%)	
Some college	0	(0%)	1	(1%)	
Missing	0	(0%)	5	(4%)	
Country					
Ghana	3	(14%)	9	(8%)	
Guatemala	0	(0%)	4	(3%)	
India	0	(0%)	4	(3%)	
Kenya	0	(0%)	10	(9%)	
Malawi	5	(24%)	22	(19%)	
Nepal	4	(19%)	10	(9%)	
Rwanda	7	(33%)	45	(39%)	
Vietnam	2	(10%)	7	(6%)	
Missing	0	(0%)	5	(4%)	
Work position ^a					
Academic	7	(33%)	36	(31%)	
Clinician	2	(10%)	10	(9%)	
Leadership	0	(0%)	17	(15%)	
Research (other)	6	(29%)	27	(23%)	
Multiple positions	3	(14%)	9	(8%)	
Other	2	(10%)	8	(7%)	
Missing	1	(5%)	9	(8%)	
Work location	-	(570)		(0,0)	
Ministry of health	3	(14%)	14	(12%)	
Research center	5	(24%)	25	(22%)	
University	12	(57%)	54	(47%)	
WHO	1	(5%)	1	(1%)	
Community health center	0	(0%)	3	(3%)	
Hospital	3	(14%)	28	(24%)	
Other	0	(0%)	8	(7%)	
	1	(5%)	9	(8%)	
Missing GRIT participants	1	(3/0)	, ,	(0/0)	
TREIN	6	(29%)	16	(14%)	
HyTREC	13	(10%)	19 74	(16%)	
Not part of GRIT		(62%)		(64%)	
Missing	0	(0%)	7	(6%)	
Previous D&I training	7	(220/)	20	(220/)	
Yes	7	(33%)	38	(33%)	
No	14	(67%)	73	(63%)	
Missing	0	(0%)	5	(4%)	

^aValues sum to more than 100% because respondents could select multiple work locations.

bSample size for the age was (n = 111).

(n=21) and the demographics for all participants that initially enrolled in the MOOC (n=116). Most of the trainees with complete pre-and post-D&I competency measures were female (57%); had a master's degrees (76%); were from Rwanda (33%) and Malawi (24%); were not GRIT Consortium members (62%); did not have previous D&I training experience (67%); and the average participant age was 35 ± 4.5 .

D&I competencies

The self-reported D&I competency scores improved for those with completed pre- and post-competency measures (see Table 2). Trainees' average score improved on the full scale by 1.45 points., the, The definitions, background, and rationale subscale improved by 1.36 points. The theory and approaches subscale improved by 1.63 points. The design and analysis subscale improved by 1.45 points. practice-based considerations subscale improved by 1.37 points.

Participants reported that access to D&I mentoring was low (not reported in Table). Only 12% (n=14) of the MOOC trainees who completed the pre-survey (n=116) indicated that they had a D&I mentor. Of those that had a D&I mentor, 63% reported the quality of mentoring was above average, with 21% rating the quality as "very high." 71% reported a 4 or 5 out of 7 regarding that their mentor met their expectations for mentorship, where 4 reflected moderately meeting expectations.

Access to general research mentoring was reported by the participants as being higher compared to D&I mentoring. Forty percent (n = 46) of the MOOC trainees that completed the presurvey reported having a research mentor. Around 52% of those with a research mentor rated the mentoring quality as above average. Similar to the D&I mentoring, 46% reported a 4 or 5 out of 7 reflecting that the mentor met expectations for mentorship, where 4 represented moderately meeting expectations.

Research competency scores among those with complete pre- and post-survey responses (n=33) varied. While the scores generally improved from pre- to post-survey, the differences were not statistically meaningful. Participant manuscript writing scores remained constant between pre- and post-test [3.48 ± 0.97 vs. 3.48 ± 1.03 , t(32)=0.00, p>0.05]. Proposal writing improved slightly from [3.42 ± 0.90 vs. 3.45 ± 1.12 , t(32)=0.19, p>0.05] Scholarly

presentation scores improved 0.18 points $(3.58 \pm 1.17 \text{ vs. } 3.76 \pm 1.12, t(32) = 1.00, p > 0.05$. Grant writing scores improved also increased 0.18 points $[2.24 \pm 1.03 \text{ vs. } 2.42 \pm 1.12, t(32) = 1.18, p > 0.05]$.

Barriers and facilitators

Participants reported major barriers preventing them from completing the course including lack of time, other work commitments or additional responsibilities placed on them due to the COVID-19 pandemic, and lack of stable and consistent internet connection. Participants identified time management skills, an interest in the topics addressed by the course, and recognizing the opportunity to learn as driving factors in completing the course. Additional facilitators included collaborating with other participants, supervisors and colleagues; the course flexibility (i.e., pre-recorded sessions to adapt to participant's schedule as opposed to live sessions); and increased time to work on the course due to personal or professional changes during the COVID-19 pandemic.

Course recommendations

Participant recommendations for future MOOC sessions included: (1) greater mentorship from the GRIT stakeholders throughout the course; (2) greater collaboration among participants across LMICs; (3) having the ability to retake modules or quizzes for greater understanding of a specific topic; (4) incorporating an NCD module or more NCD related examples; (5) minimizing website navigation challenges; (6) facilitating access to a reliable internet connection; and (7) more course flexibility. To enhance flexibility, participants suggested having a flexible deadline for the peer assessment, having all modules accessible at the beginning of the course with a final deadline, and having extra time for assignments.

Discussion

This study examined the experience of participants from eight LMICs in one of the 2020 TDR MOOCs on IR. Using the data

TABLE 2 D&I competencies pre- to post test change.

D&I research competency areas (1 = not at all, 5 = extremely, $n = 21$)	Pre-test Mean ± SD	Post-test Mean ± SD	95% CI mean difference
Full scale	2.12 ± 0.93	3.57 ± 0.97	1.04-1.86*
Definitions, background, and rationale	2.54 ± 0.93	3.90 ± 0.94	0.93-1.79*
Theory and approaches	2.01 ± 0.98	3.64 ± 1.06	1.08-2.17*
Design and analysis	1.94 ± 0.95	3.39 ± 1.02	1.07-1.83*
Practice-based considerations	2.08 ± 1.02	3.45 ± 0.94	0.97-1.78*
General research competency areas (1 = not at all, 5 = extremely, $n = 33$)			
Manuscript writing	3.48 ± 0.97	3.48 ± 1.03	-0.34-0.34
Proposal writing	3.42 ± 0.90	3.45 ± 1.12	-0.30-0.36
Scholarly presentations	3.58 ± 1.17	3.76 ± 1.12	-0.19-0.55
Grant writing	2.24 ± 1.03	2.42 ± 1.12	-0.13-0.49

^{*}p < .001.

from the pre-and post-assessment surveys, the self-reported D&I competencies were analyzed as well as barriers and facilitators to completing the course, which provide recommendations and implications for future MOOCs. Although there was a low retention rate in the MOOC, participants completing the post survey showed improvements in their D&I competencies. Participants reported low access to D&I mentors, limited access to general research mentors, and low self-reported competency for manuscript and scientific writing.

Existing literature on previous MOOCs have generally shown lower completion rates (10, 19-23), including a systematic review reporting the majority of MOOCs in the study reported completion rates of less than 10% (23). The course completion rate in this MOOC (13%) was likely impacted by a couple of variables. First, internet access was a major barrier for retention in this study, which has been shown in similar studies (10). MOOCs, by design, enroll large groups of students, including both active and passive participants. Reconceptualizing retention to only include participants who substantively engaged with the course might provide a more accurate picture of program metrics (19). Third, the timeline in which we started the MOOC was challenging. Enrollment took place in April 2020 with a course start date in May 2020, right before several of the participating countries started the lock down to prevent further spread of the SARS-CoV-2 virus. Fourth, as soon as the cohort started the training, the MOOC website moved to be hosted by another company and the transition posed some issues with access to the videos. With the larger movement towards online courses and trainings, future guardrails to develop and maintain websites for online learning will be important (20-22).

Due to the global uncertainty of the COVID-19 pandemic, coupled with TDR platform issues, the first module was extended three months until the end of July 2020. The remaining modules adhered to the original timelines, with a spacing of two weeks between each module. During this period, 53% of enrolled participants no longer engaged in course activities. When asked about the barriers for participation in the post-assessment survey, participants shared that the lack of stable internet, other work commitments and responsibilities, and needing more time to complete the course were key barriers that affected their participation in this course. These barriers have been reported by participants from previous MOOCs (10, 13, 17), but they were likely intensified by the COVID-19 pandemic and associated lockdowns.

This was a pilot study aiming to see if we could provide capacity building in D&I using a MOOC platform in LMICs. The results indicate strong evidence of improvement with self-reported D&I competencies similar to previous courses (10). The subscale that had the largest change was theory and approaches and the subscale with the least change was definitions, background and rationale and practice-based considerations. These results differ from other D&I trainings where a majority of participants reported the largest change in the definitions, background, and rationale subscale (8, 10). The difference in results may be related to the composition of participants, where 33% of participants in this study had previous D&I training before the course. The general research competency scores in

manuscript writing, proposal writing, and giving scholarly presentations did not change in a meaningful way from pre-to-post test. These findings suggest that general research capacities, not specific to D&I, should be targeted by future capacity-building activities, particularly grant writing. Accordingly, the TDR WHO has developed a flexible and interactive D&I toolkit to support capacity building and proposal writing (24).

The need for increased mentoring and guidance was a prominent theme in the recommendations submitted by the participants, as only 14% reported having a mentor in D&I research. Even though every country has a D&I consultant, the limited access to D&I mentors may be a reflection of very few researchers being trained in the emerging field of implementation science in LMICs. Evaluation of other D&I trainings in high resource settings have shown the importance of networking and mentoring, as well as time, for the development of academic outcomes (8, 25), and previous MOOCs with added support beyond mentorship (i.e., meetings for participants to discuss modules, Q&A sessions, discussion forums) demonstrated an increase in participant engagement (10, 26). Future D&I capacity trainings in LMICs should include greater mentorship and support throughout the course as it could contribute to higher course completion and improved overall D&I competency reporting (7, 27). It is also worth noting that many participants were not a part of the GRIT Consortium, but rather recruited and enrolled through collaboration with GRIT Consortium members, demonstrating that MOOCs are an effective tool to extend trainings beyond existing consortiums and partnerships.

Limitations

The major limitation of this paper is the small number of participants that completed the course. Additionally, evaluation data was comprised of only self-report data and, therefore subjected to bias and social desirability. Lastly, we did not follow up with participants to ask whether they were able to apply what they learned. The lack of opportunity to practice what they learned has been a challenge described by participants in previous MOOCs (25, 28).

Future directions and implications

Despite the challenges and limitations, partnering with the Special Programme for Research and Training in TDR MOOC is a feasible and scalable strategy to increase D&I training in LMICs. The use of D&I competency metrics allows for further evaluation on how to design training in D&I. In the future, research partners may add specific modules, such as hypertension care and D&I grant writing. Some of this is already being done as part of capacity building initiatives (17, 29). In moving forward, setting up and strengthening a collaborative practice whereby mentoring and peer collaboration across countries could be beneficial to all in enhancing the capacity for D&I research training (29).

Conclusions

This was a pilot study, and as such, the main hypothesis was to see if we could foster D&I capacity building in LMICs using the TDR MOOC platform. Using pre-post surveys, augmented by the analysis of the open questions from the trainees, this study follows similar designs of other capacity building efforts and adds to the literature in capacity building in D&I in LMIC, showing that self-report D&I competencies improved after the training.

Data availability statement

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

Ethics statement

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent from the participants was not required to participate in this study in accordance with the national legislation and the institutional requirements.

Author contributions

AB and PL conceived the study and oversaw implementation of the course. AR helped coordinate the course and drafted the manuscript. AR drafted the paper. CH analyzed all data, and helped to draft and edit the manuscript. MPF helped draft and edit the manuscript. AB, MPF, MW, LP, HN, MR, AM, KA, MH, VD-R, PL and JG all provided feedback on manuscript sections. All authors contributed to the article and approved the submitted version.

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Conflict of interest

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

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What contributes to the longterm implementation of an evidence-based early childhood intervention: a qualitative study from Germany

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Background: Rigorous research trials have demonstrated that early childhood interventions can reach socially disadvantaged families and can have a lasting impact on the healthy development of their children. However, little is known about the internal and contextual factors that contribute to the long-term implementation of such interventions. In this study, we investigated the development of the home visiting program Pro Kind. The program was adapted from the evidence-based US-American Nurse-Family Partnership program and was implemented in Germany in 2006. Using an exploratory approach, we examined factors contributing to the long-term implementation of this program.

Methods: Qualitative interviews with program implementers (midwives, social workers, program managers) of the Pro Kind program and key stakeholders in two cities in Germany were conducted. Interview guides were developed to assess participants' perceptions and experiences on how the program had developed over time internally and in the interaction with its environment. Data were collected between March and September 2021. Drawing on the Consolidated Framework for Implementation Research (CFIR), data was coded according to the principles of thematic analysis.

Results: A total of 25 individuals (11 program implementers, 14 key stakeholders) were interviewed. The identified factors related to three out of five domains of the CFIR model in our analysis. First, regarding the *intervention characteristics*, the evidence of effectiveness and the relative advantage of the implementation of the program compared to similar interventions were viewed as contributors to long-term implementation. However, the program's adaptability was discussed as a constraining factor for reaching the target group. Second, concerning the *inner setting*, stakeholders and program implementers perceived the implementation climate, the leadership engagement and the program's size as relevant factors for networking strategies and program visibility. Third, as part of the *outer setting*, the degree

Abbreviations

CFIR, consolidated framework for implementation research; COREQ, consolidated criteria for reporting qualitative research; ECI, early childhood intervention program; NFP, nurse-family partnership; RCT, randomized controlled trial.

of networking with external stakeholders was highlighted of great importance for the program.

Conclusions: We identified several factors of particular importance for the long-term implementation and sustainability of an early childhood intervention at the practice level, particularly in the local context in Germany. These findings should inform the design of impactful, scalable, and sustainable early childhood interventions targeting disadvantaged families.

KEYWORDS

sustainability, evidence-based interventions, implementation, early childhood interventions, qualitative research

1 Introduction

Children exposed to early childhood adversities, such as poor socioeconomic conditions, maltreatment and neglect or unhealthy family functioning, are at increased risk for poor physical and mental health and low educational success (1-3). A promising approach to reach and support socially disadvantaged families is home-based interventions in early childhood. Research trials show lasting effects of these interventions on mother and child health outcomes (4-8). However, less is known about the factors that contribute to the "survival" of such interventions in real-world settings after initial project funding has ended (9, 10). Discrepancies between research settings and the context in which the interventions are implemented are a fundamental challenge for sustaining evidence-based public health interventions. Furthermore, over time interventions evolve due to factors such as changing populations, policies, available resources, and organizational structures, which may have positive (refinement of program delivery) or negative implications (loss of fidelity, discontinuation of program) (11). The identification, description, and understanding of internal and external factors, as well as how they interact to influence long-term implementation, is hence essential to maintain program continuation and effectiveness, further optimize the intervention benefits, and prolong program sustainability (6). By long-term implementation we mean the continuation of a public health program after the initial, project-based implementation that was supported by external (research) funding. Long-term implementation has also been described as program sustainability (10). Research on implementation processes and sustainability is needed to plan proactively for program continuation and to support programs in unfolding their full potential (12, 13).

There is a wide range of terminologies for relevant constructs, and an abundance of frameworks and models identifying factors that are important for the implementation process of health interventions (14, 15). Regarding the evaluation of early childhood interventions, previous research has revealed that contextual factors, as well as the dynamic interplay between the program and its environment, play a crucial role (16, 17). Previous studies mostly investigated earlier stages of implementation, focusing on constructs such as fidelity, dosage and quality of early childhood interventions (18, 19). However, for a comprehensive evaluation of the success of early childhood

interventions, it is essential to understand the adoption, scale-up, and sustainability of interventions that have been in place within communities for some years (20). To date, only a few studies have investigated factors that are related specifically to long-term implementation of early childhood interventions, focusing mainly on settings in the US (21-24). The factors identified in these studies include the consideration of the powerful role of context (e.g., community characteristics, addressing service context) as well as the impact of other factors such as program delivery (e.g., service dosage, staffing, program flexibility) (21, 22). For instance, in the Nurse-Family Partnership program (NFP), a large home visiting program from the US, analyses of implementation and outcome data helped the identification of issues specific to certain contexts (23). The results of a mixed method analysis of participant attrition showed, for example, that home visitors in high retention sites adapted the program more completely to their clients' needs and used less directive and prescriptive approaches. Hence, a flexibilisation of the program led to adaptations of the program guidelines, nurse education, visit frequency, content, and location of visits (24).

In this study, we investigate the long-term implementation of the prenatal and infancy home visiting program Pro Kind (25, 26). The program is based on the NFP program (27) and was adapted to the German context. The aims of the program, which focuses on psychosocially and economically disadvantaged families, are to enhance maternal and child health and to reduce the risk of child abuse and neglect. Professional home visitors (midwives or social workers) support first-time mothers from pregnancy to the child's second birthday. The home visits start during the second trimester of pregnancy and are generally then scheduled for every other week. The home visitors work with the families following a structured topic guide covering a wide range of issues including e.g., maternal health, healthy family routines, and life-course planning. In sum, the key features of the Pro Kind program are its tightly defined target group criteria (only first-time mothers, socially disadvantaged, start during second trimester of pregnancy), its thematically comprehensive and structured approach and its duration. These elements are essential for achieving the desired outcomes for children and families (27).

The development of the Pro Kind program is closely tied to changes that occurred at the national level at the time of its conception. A national early childhood intervention program (ECI) was initiated in 2006 (28, 29). In this context, the Pro

Kind program was one of several pilot projects to receive additional funding at the federal state level. It started in 2006 with a multicenter randomized controlled trial (RCT) in 15 sites located in three federal states (Bremen, Lower Saxony, Saxony) and ended in 2012. After this phase, the program materials were revised substantially in close cooperation with the National Center for Early Prevention. The key features mentioned before were, however, kept. The overall sustainability of the Pro Kind program was low across the sites, as it was continued in two of the original sites.

Alongside the evaluation of program outcomes (26, 30–35), the implementation of the Pro Kind program was closely monitored to examine implementation differences (36) and the association of participant characteristics and process variables with program attrition (37). However, investigations on the long-term program development that assess different implementation levels are still needed, considering the different natures of the local implementation settings.

Therefore, we aim to explore factors that shape the long-term implementation of Pro Kind. The findings will enable us to illustrate and contrast factors contributing to the positive as well as negative program development and intervention performance.

2 Materials and methods

2.1 Study design

We conducted semi-structured interviews with program implementers (midwives, social workers, program managers) and key stakeholders (e.g., representatives of youth and welfare services, pediatricians). Qualitative methods were used to gain insights into participant's perspectives about the program development and its integration into local community structures over time. Ethical approval for the study was obtained from the ethics committee of the University of Bremen, Germany (reference number 2021-05). Participation in the interviews was voluntary, and all participants provided written informed consent. This study was conducted in line with the Consolidated Criteria for Reporting Qualitative Research recommendations (COREQ, Supplementary File 1) (38). The research team characteristics are presented in Supplementary File 2.

2.2 Selection of sites and site characteristics

The interviews were conducted at two German sites, Bremen and Brunswick. These cities were selected because they were the only sites, where the Pro Kind program was still being implemented since 2006. The city of Bremen has over 563.000 inhabitants and is located in Northern Germany. It is surrounded by the larger federal state of Lower Saxony, where the city of Brunswick, with about 248.500 inhabitants, is located.

The implementation conditions between the two sites differed already at program initiation. During the trial phase, 80 families in Bremen and 35 families in Brunswick took part in the Pro Kind program, reflecting the different sizes of the cities. At both sites,

the program was delivered through established local social service organizations. However, in Brunswick the program was integrated into the structures and processes of the youth and welfare office to a greater extent than in Bremen. This affected in particular the procedures in recruiting families, laying with the youth and welfare office in Brunswick. With its three employees and a relatively small number of cases (about 10), the program in Brunswick has been scaled down over the past years, whereas in Bremen the number of cases has increased to 140.

2.3 Sampling

At study onset, the research team (TB and MLS) presented the study aims and procedures to the Pro Kind staff from both sites at an annual network meeting. The program managers facilitated contact between the research team and the midwives and social workers who were implementing the program. The sampling of the Pro kind staff was purposive in that we wanted to prioritize interviews with staff who had been working with the program for several years. Potential key stakeholders in the field of early childhood interventions were initially identified by the program managers, the interviewed staff and the research team. Thereafter, snowball sampling was applied to identify further stakeholders, continuing until no additional interview participant could be identified or data saturation was achieved. In an effort to counterbalance the snowball approach, we conducted internet searches to try and identify further potential interview participants that were not mentioned by the program implementers.

The interviews were conducted between March and September 2021 and the interviewer (MLS) did not know any of the interviewees prior to the study.

2.4 Interview guide and data collection

Using an exploratory approach, the research team discussed the key domains of program implementation with the program implementers at their annual network meeting and developed topic guides for each target group (program implementers and stakeholders). The topic guides were designed to assess interviewees' perceptions and experiences on how the program has developed over time internally and in the interaction with contextual factors (see Supplementary File 3 for the original interview guides and the English translations).

Depending on the COVID-19 regulations, the interviews were either conducted online (using the platform *GoTo* Meeting), by telephone or face-to-face. Where possible, the interviews took place face-to-face at the partner organization's workplace, in a closed room during normal operating hours. Regardless of the format, only the interviewee and the interviewer were present during the interview. Before the interview, all participants received the study information sheet and a consent form. The interviewees were interviewed once and did not receive any incentives for their participation. The interviews were conducted by the same researcher (MLS). The mean interview duration was

42 min (range 23–70 min). All interviews were conducted in German and were digitally audio-recorded and later transcribed verbatim. Samples of the transcripts were double-checked by reading the text while listening to the audio-recordings (MLS). Selected interview quotes were translated into English for this manuscript by MLS and CS, and TB cross-checked the translations (see Supplementary File 4 for the original quotes and the English translations).

2.5 Data analysis

Interview transcripts were coded in MAXQDA (version 2020). The analysis followed the phases of thematic analysis (39). To identify patterns in the data, we employed a hybrid inductivedeductive approach. Despite the exploratory nature of our data collection, the inductive analysis revealed certain themes and codes that increasingly aligned with a widely implementation framework known as the Consolidated Framework for Implementation Research (CFIR). The CFIR offers a comprehensive typology categorizing barriers and facilitators associated with implementation (40). It comprises 39 constructs organized into five domains: Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Processes. Initially, all interviews were coded inductively by MLS. To obtain different perspectives on the coding scheme, two research assistants independently coded two interviews. Where differences occurred, MLS and the research assistants discussed the codes and the coding scheme was adapted accordingly. After the first round of coding, a second round was carried out by MLS to refine the codes. The codes were then collated and classified under the domains of the CFIRmodel. An example of the coding frame used to classify codes under the CFIR-domains is provided as Supplementary File 5. In the last step, underlying themes deemed to be of central meaning for the long-term implementation of the program were identified. The results were presented to the research team and the Pro Kind program managers several times to discuss major themes and key findings.

3 Results

3.1 Sample characteristics

A total of 25 persons, one man and 24 women, aged 29–68 years, took part in the interviews. Four were from Brunswick, and 21 were from Bremen. Eleven of the interviewees were program implementers (midwives, social workers, and program managers). Their experience of working with the Pro Kind program ranged from 5 to 16 years. The remaining 14 were stakeholders with a range of professional backgrounds, including social work, pediatrics and psychology, who were working for institutions related to early childhood interventions (e.g., child and youth welfare services, counseling centers, social security office, job centers).

3.2 Factors relating to long-term implementation organized under the CFIR-domains

Factors related to long-term implementation were found in three of the five CFIR-domains: Intervention Characteristics, Inner Setting, and Outer Setting. The specific factors mentioned for each of the three domains are presented hereafter (in italics) using quotes from the raw interview data.

Figure 1 depicts an overview of the three domains, the related factors (within the big bubbles) and subfactors (within the smaller bubbles) which are each highlighted as facilitating (+) or hindering (-) factors, or both (+/-). We did not identify factors in the data that could be assigned to the CFIR-domains Characteristics of Individuals and Processes.

3.2.1 Intervention characteristics

The main facilitating factors that emerged included the evidence of the effectiveness of the program and the relative advantage of the implementation of the program compared to other interventions in the field.

Based on their experience during program delivery and the client's positive feedback, most program implementers were convinced that the families benefited from program participation. One stakeholder reported on the feedback from the families as follows:

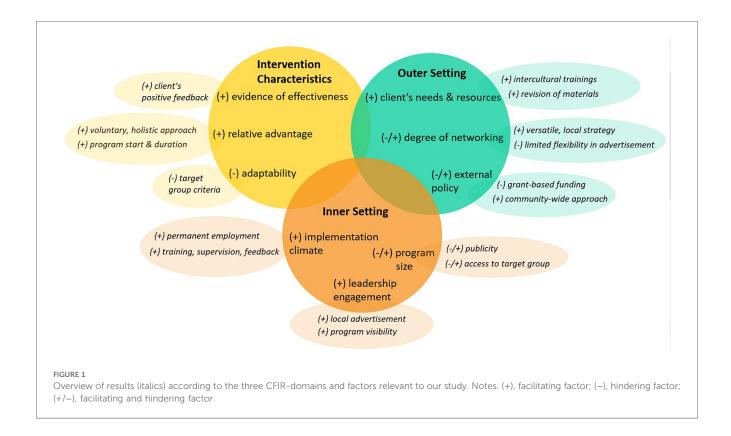
"Especially families, who at first were somehow resistant, because they could not really grasp the program at first, said afterwards that it was really good." (stakeholder#1, Bremen)

This view was shared by many other interview participants and reinforced the stakeholders' and program implementers' general belief in the program's approach. Targeting first-time mothers, starting early during pregnancy, and providing a relatively long program duration that allows a strong working alliance (between home visitor and mother) were viewed as obvious advantages compared to other local programs in the field of early childhood interventions by program implementers and stakeholders. In addition, the holistic and voluntary approach of the program was highlighted as particularly important. However, these core components of the program lead to relatively narrow target group criteria, and this also resulted in criticism of the program's lack of *adaptability*. For example, several stakeholders regret that the program is limited to first-time mothers only, thus withholding it from other mothers with needs:

"... but they already have a clearly defined target group. And many of my clients, for example, don't fit in at all. So it's not always first-time mothers who need this support. It is often second and third-time mothers (...)." (stakeholder#2, Bremen)

3.2.2 Inner setting

Several home visitors positively emphasized aspects related to the *implementation climate* within the organization. Permanent



employment contracts for midwives, which are often not offered by comparable employers, were perceived as an appreciation of the program providers and their work fostering commitment to the program. Additionally, opportunities for further training, supervision, feedback, and case consultations on a regular basis were reported to contribute to a positive learning climate. An external stakeholder commented on the working conditions as follows:

"... the impulse of the professional support and (...) the relatively conducive working conditions of the professionals, right? So professional advice, regular training, regular permanent employment of colleagues in contrast to the family midwives (...) in all other states, family midwives are not employed, but work on a fee basis, which is a disaster for this work." (stakeholder#5, Bremen)

The implementation processes, both at the organizational level and individual level with clients, could thus be continuously reviewed and, if necessary, adjusted through the assistance and input of program providers. This ensured the sustainable quality assurance of intervention delivery, as well as the satisfaction and commitment of employees, fostering retention within the organization in the long-term.

Furthermore, leadership engagement emerged as a strong facilitating factor for long-term program implementation. The active engagement of program managers in advertising the program personally, their involvement in the adaptation of intervention materials (also at national level), as well as their participation in various local events of early childhood

interventions were reported and highlighted by various interview participants:

"And Pro Kind is actually also active in smaller projects. So, I have already experienced that the management participated in the designing of the flyer in simple language, or I mean that they were also there when these cards for smartphone use and childcare were somehow developed, that they were also present and actively contributed." (stakeholder#4, Bremen)

The commitment of the program managers to the program and beyond, to the promotion of early childhood interventions, was valued by stakeholders, leading to an increase in the program's visibility and fostering a trusting relationship between stakeholders and the program managers. Consequently, it promoted closer collaborations, especially regarding the referrals of families to the program.

One factor that links the inner and the outer setting is the critical role of the program's size at the two sites. It can be viewed as both, a facilitator and a barrier to long-term implementation, depending on the location. As it started with a larger team and more families, the Bremen site had a significant increase in funding and therefore in personnel. This enabled the program managers and the midwives to invest more time in networking at the city district level with the overall goal to establish collaborations with stakeholders who refer families to the program. Particularly the wide access to the target group is seen as an important prerequisite to survive in the long-term. According to stakeholders, the size of the program also played a

central role in gaining publicity, to be recognized as an established partner. Responding to a question about the program's position in the local network of early childhood interventions, a stakeholder refers also to the program's size:

"I experience Pro Kind as one of the big players. So, then I immediately think, okay, big organization, many colleagues, widely known too, and very established, in my choice of words." (stakeholder#6, Bremen)

Due to a decreasing, smaller program size at the other site, in Brunswick, this facilitating process could not be initiated yet, with a negative consequence for its visibility. In this context, the program manager reported a shortage of staff, especially local midwives, and a different funding scheme hindering the program's growth at this site. Accordingly, the program size has played a significant role in its reach, ability to act and, thus, long-term implementation.

3.2.3 Outer setting

Regarding the aspect *clients' needs and resources*, the program implementers emphasized the constant social change, mainly through immigration, which resulted in ongoing diversification, also of the target group. Accordingly, working materials were revised and provided in easy-to-understand language, and program implementers were trained in intercultural competencies. Despite these efforts, one stakeholder, for example, still saw a need to expand the language diversity in the team:

"... what I experience again and again (...) is the language, the language barrier. So, in many families, the mother tongue is present, there is little German proficiency. And of course, not all midwives have these language skills. And I think we need to look again at the employees, can we also hire people who speak one language or another. (...). I think that would probably also be Pro Kind's wish." (stakeholder#3, Bremen)

While acknowledging room for improvement, program implementers emphasized that directing attention and adapting to clients' needs aimed to enhance the working alliance and ensured the quality of program delivery—both are considered facilitators for long-term implementation.

There was a broad agreement that the *degree of networking* with other external stakeholders was essential for getting access to the hard-to-reach families, and to provide appropriate support. The program implementers rely on the cooperation with local stakeholders in order to integrate the families into the existing community structures, such as childcare, counseling services, or activities for mothers in similar situations and to promote their self-efficacy. One program manager summarized the importance of networking as follows:

"So, networking is very important. Pro Kind without networking wouldn't work at all (...). Access is only possible through our stakeholders. And then there are specific issues. That means we see ourselves as guides for specific issues. Meaning we can tell the families that they can go there for

the problem (...) and that we work together to ensure that the families manage to receive the help and support they need." (program manager#1, Bremen)

Further, in Bremen the versatile, extensive networking through participation in workshops, expansion of local working groups, in addition to low-threshold networking through personal contact in local city districts, facilitated a general expansion of the network. This was reflected in the consistent comments of the site's stakeholders, who perceived the program as being present, well-known and established in the local network. One stakeholder noted:

"... by being present as a program not only in individual districts, but throughout Bremen, it is well known and thus also an established partner in the municipal network." (stakeholder#4, Bremen)

However, in Brunswick, networking was perceived to be a central challenge. A fixed recruitment procedure, organized by the youth and welfare services, limited the ability of the program implementers to get in contact with other stakeholders who could refer families to the program. It also provided limited flexibility in the way of advertising the program. Home visitors were concerned that recruitment through the youth and welfare services could lead to families being wary about participating:

"It is more difficult to motivate women to join the project. Because I tell you now, in the eyes of the young mothers, who may have already had experiences with the youth and welfare office as a child, the similarity with outpatient child protection service is too large." (home visitor#1, Brunswick)

In this context, the staff reported a stagnation and decline in the network, and thus, a decrease in the number of participating families. Besides the difficulties related to this recruitment regulation, further challenges in cooperation between the Pro Kind program and the local youth and welfare services were evident. Staff from both institutions reported difficulties in communication, lack of clarity about each other's roles and functions, and recurring tensions in the joint assessment of child protection. These difficulties were vested in the contrasting approaches and priorities of the two institutions. While both were interested in a constructive cooperation to ensure the best support for families, the Pro Kind staff placed greater value on the voluntary and preventive nature of the program. This also included a trustworthy relationship with mothers, respecting their privacy concerns. In contrast, the youth and welfare offices have a strong child protection mandate and emphasized the need for close exchange of information about critical cases.

As a part of *external policy*, the program managers, in particular, expressed uncertainty about the program's grant-based funding situation, which posed challenges to long-term planning:

"We have to re-apply every year, check again and that takes a lot of energy as well." (program manager#2, Bremen)

One key factor repeatedly mentioned by different participants in Bremen was the integration of the Pro Kind program in a community-wide approach to foster child health in disadvantaged families. This community-wide approach combined several preventive interventions and was accompanied by a large research project. The political decision to implement a community-wide approach secured extra funding for the Pro Kind program and led to an increasing number of families that could be served. At the same time, the pressure to relax the eligibility criteria increased.

4 Discussion

In this study, we examined key factors related to long-term implementation of the home visiting program Pro Kind at two different sites in Germany.

Applying the CFIR-model to the analysis, we found relevant factors related to three of the five CFIR-domains: Intervention Characteristics, Inner Setting and Outer Setting. Our findings also highlight the dynamic interplay between program factors (e.g., target group criteria), organizational factors (e.g., program size) and the context of implementation (e.g., degree of networking).

Looking at the intervention characteristics, stakeholders and program implementers viewed the evidence of effectiveness and the relative advantage of the implementation of the program compared to similar interventions as contributors to long-term implementation. However, criticisms pointed to the lack of the program's adaptability as a constraining factor for growth, primarily because of the program's tight target group criteria. Concerning the inner setting, the implementation climate and the leadership engagement were perceived as relevant factors for staff qualification, continuity and the visibility and credibility of the program. In addition, the program's size emerged as an underlying factor that shaped the capacities for intensive networking, activities to increase visibility and access to the target group. Concerning the outer setting, next to the external policy and efforts to meet the clients' needs, the central importance of the degree of networking was highlighted. In particular, the program's relationship with the youth and welfare services emerged as challenging, mainly related to difficult access to families, tensions in communication, and different priorities.

Drawing on research on the sustainability of public health interventions, the factors and subfactors we identified from the data largely align with the three primary influences on sustainability highlighted in numerous studies: Characteristics of the intervention, factors in the organizational setting, and factors in the community environment at each intervention site. Thus, the importance of shifting the primary focus away from funding sources when designing sustainability research is highlighted (10, 41).

To some degree, there is an inherent tension between evidence of effectiveness, which relies on program integrity, and a program's adaptability and flexibility. In the field of implementation research on early childhood interventions, this challenge is well-recognized, as addressing this issue requires an understanding of theories, components, contextual influences (e.g., variation of risk exposures in families) that contribute to the effectiveness of a program (16). In the case of Pro Kind and NFP, the tightly defined eligibility criteria, the structured approach during the visits and the long program duration are hypothesized to be key elements for program effectiveness (27). Extending the target group criteria to include multiparous women has not been investigated within the RCT of the Pro Kind program, but has also been raised in other studies evaluating the NFP program (23, 42). However, this adaptation could result in reduced or no effectiveness and would entail larger changes to the program's content. Current research from the NFP is therefore investigating whether the program can be adapted to meet the higher acuity and overlapping needs of multiparous mothers (43).

Our results highlighted that a positive implementation climate, characterized by regular feedback, training, and supervision of staff, is crucial for successful implementation. This is because, as prior research shows, such a climate enhances the providers' abilities, readiness, and competencies to deliver early childhood interventions effectively (16, 17, 44, 45). Consequently, these factors influence the quality of implementation of early childhood interventions.

Our findings regarding the role of intensive networking in facilitating access to targeted families and addressing the families' needs by linking them to other resources in their communities, is in line with findings from other studies (46–48). These studies indicate that home visitors are likely to be more effective in retaining clients and in serving families with multiple needs when collaborating closely with those providing other relevant services in the local communities they serve. Moreover, continuously engaging stakeholders throughout the ongoing implementation processes might foster the fit between the intervention and the local context and the maintenance and improvement of interventions within care settings (9, 11).

Our findings also point to the critical program size, which enables or prevents program implementers to engage in intensive networking. This intensive networking is not only important for the practical work with families but also for the visibility in the stakeholder network and for political influence to sustain or increase funding. There is certainly no fixed rule for the critical size of a program and it would also be a limiting factor for a countrywide implementation if a program like Pro Kind could only be offered in larger cities to achieve an adequate size. Nevertheless, small-scale program sites may need specific strategies or extra support from other program sites for intensive networking.

As our findings confirm, the collaboration between early childhood interventions and youth and welfare services, particularly the child protection service is vital to maximize the benefits of the intervention (49). The issues reported at both sites are mostly in line with recent findings indicating the need to address misalignments of the priorities and working styles of the institutions involved (50) and the stigma associated with child protection services as well as to establish adequate communication channels between the programs to enhance collaboration and serve the same families adequately (42, 51).

4.1 Practical implications

From the themes that emerged from our analysis concerning the lack of adaptability, the program's size, and the degree of networking, several practical implications can be derived. These are particularly directed towards researchers and practitioners involved in program development and implementation, who must respond to continuous environmental changes to ensure the ongoing success of these programs. Adaptability is certainly a necessary trait of an intervention that tries to survive in a rapidly changing environment. As one approach for regular small-scale adaptations, internal discussions program about appropriateness of the program materials and possibilities for further education could help an intervention remain relevant. With regard to alterations and changes that concern the whole intervention, implementation research has suggested that adding new components to an existing intervention can help to improve effectiveness (52, 53). However, changing the core components, such as the eligibility criteria, may have consequences for the appropriateness of the intervention content and the effectiveness. Ideally, such an adaptation should be accompanied by a process and outcome evaluation (54). If program implementers decide to keep the integrity of the original model, then a strong emphasis on the program's effectiveness and relative advantage over other programs may counterbalance the lack of adaptability. While contextual factors, such as external policy-making or future austerity cuts, are rather out of control for program implementers, investment in local networking seems advisable because it may be a decisive factor for maintained funding. Regarding the critical size of the program, it may be specifically important for small-scale program sites to develop strategies for effective networking. For a preventive intervention that relies on voluntary participation and a trusting working alliance with the families, it may be important to keep a critical distance to the child protection service and to be viewed as working independent from it. Nevertheless, such intervention programs need to be reliable partners for the youth and welfare services when coordinated action is necessary. Proactive role clarification and clear process descriptions for coordinated action may help to resolve this tension.

4.2 Limitations

The findings of this study should be interpreted considering the following limitations. Firstly, the results reported here draw upon only two sites in Germany, which may limit their generalizability. Using the CFIR-model as a theoretical framework in our analysis however helped us to present our findings on a conceptual level, thereby adding to the transferability of the findings. Secondly, although the CFIR-model is comprehensive in scope, it does not pre-specify the importance or relationship between the individual factors. Consequently, while we highlighted the factors that came through as the most relevant ones according to our analysis, we cannot claim any causal relationships between them. Due to our

exploratory data collection approach, we used the CFIR-model for guiding coding, data analysis, and reporting our results. It might have been however advantageous to incorporate the CFIRmodel into the data collection process earlier for capturing the factors more comprehensively. Thirdly, the number of interviews was not balanced between the two sites since we recruited only a small number of interview participants at the site where the program size decreased over time. Further insights into potential challenges of long-term program implementation from the stakeholders' perspective would have been beneficial for our analysis, but we did not identify any additional stakeholders who felt competent to discuss the program. However, considering the qualitative nature of our study, we gained fruitful information about hindering factors by including additional participants from a different context. Furthermore, following an exploratory approach, we did not collect data at the sites where the program ended after the initial study phase in 2012. This limits the generalizability of our findings. Lastly, it is possible that the snowball sampling may have resulted in a selection bias. Starting with the program implementers led us to interview stakeholders that were in close collaboration with the program. Despite additional internet searches conducted to counterbalance the snowball approach, we may have missed other stakeholders at the outskirts of the network who may have had different or more critical views on the program.

5 Conclusion

In this qualitative study, we identified factors of particular importance for the long-term implementation of the Pro Kind program. We highlighted issues about the program's adaptability and the critical role of intensive local networking under consideration of different program developments at two German sites. Presenting our results on a conceptual level by using the CFIR-model as a theoretical framework and giving practical implications on the program, organizational and context level may inform future adaptations, enhancements and design of early childhood interventions for socially disadvantaged families.

Data availability statement

The datasets presented in this article are not readily available because the informed consent signed by the participants did not include their agreeing to their qualitative data being shared publicly. Requests to access the datasets should be directed to Tilman Brand, brand@leibniz-bips.de.

Ethics statement

Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

SK, MS and TB conceptualized the study. MLS conducted, coded and analyzed the interviews. MLS drafted the manuscript with contributions from TJ and CS. All authors contributed to the article and approved the submitted version.

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Conflict of interest

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

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023. 1159976/full#supplementary-material

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Identification and development of implementation strategies: the important role of codesign

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Background: To date, implementation strategies reported in the literature are commonly poorly described and take the implementation context insufficiently into account. To unravel the black box of implementation strategy development, insight is needed into effective theory-based and practical-informed strategies. The current study aims to describe the stepwise development of a practical-informed and theory-based implementation strategy bundle to implement ProMuscle, a nutrition and exercise intervention for community-dwelling older adults, in multiple settings in primary care.

Methods: The first four steps of Implementation Mapping were adopted to develop appropriate implementation strategies. First, previously identified barriers to implementation were categorized into the constructs of the Consolidated Framework for Implementation Research (CFIR). Second, the CFIR-ERIC matching tool linked barriers to existing implementation strategies. Behavioral change strategies were added from the literature where necessary. Third, evidence for implementation strategies was sought. Fourth, in codesign with involved healthcare professionals and implementation experts, implementation strategies were operationalized to practical implementation activities following the guidance provided by Proctor et al. These practical implementation activities were processed into an implementation toolbox, which can be tailored to a specific context and presents prioritized implementation activities in a chronological order. Results: A previous study identified and categorized a total of 654 barriers for the implementation of a combined lifestyle intervention within the CFIR framework. Subsequently, the barriers were linked to 40 strategies. Due to the fact that many strategies impacted multiple barriers, seven overarching themes emerged based on the strategies: assessing the context, network internally, network externally, costs, knowledge, champions, and patient needs and resources. Codesign sessions with professionals and implementation experts resulted in the development of supported and tangible implementation activities for the final 20 strategies. The implementation activities were processed into a web-based implementation toolbox, which allows healthcare professionals to tailor the implementation activities to their specific context and guides healthcare professionals to prioritize implementation activities chronologically during their implementation.

Conclusion: A theory-based approach in combination with codesign sessions with stakeholders is a usable Implementation Strategy Mapping Method for developing a practical implementation strategy bundle to implement ProMuscle across multiple settings in primary care. The next step involves evaluating the developed implementation strategies, including the implementation toolbox, to assess their impact on the implementation and adoption of ProMuscle.

KEYWORDS

implementation, strategies, methodology, lifestyle intervention, older adults, codesign, Implementation Strategy Mapping Method, primary care

1 Background

Implementation science focuses on translating evidence-based programs (EBPs) into practice (1). Methods or techniques that are employed to overcome barriers and enhance the adoption, implementation, sustainment, and scale-up of such EBPs are called implementation strategies (2). Implementation strategies are designed to target barriers at different levels, such as the intervention, recipient, organizational, policy, and professional levels (3). Numerous studies describe theories and taxonomies and present implementation strategies tailored to specific levels (3). Evidence-based, detailed implementation strategies are crucial for the successful implementation of EBPs in daily practice (4). However, most studies lack an adequate description of the strategies and how to match them to barriers, which makes it difficult to select optimal strategies and to understand whether and how strategies could be effective for overcoming barriers and supporting the implementation of EBPs (1, 5).

Notably, it is not expected that every setting has similar barriers for implementation; instead, various combinations of barriers are likely to emerge, which may change over time (6, 7). The lack of guidance makes it challenging to translate the strategies to specific contexts for different EBPs (5, 8). Selecting appropriate implementation strategies and mapping and tailoring them to address the barriers in the specific context require a systematic approach. Using an Implementation Strategy Mapping Method encompasses the implementation practice and results in transparent strategies; this enables researchers or implementers to assess whether the developed strategies align with their specific context.

Today, several Implementation Strategy Mapping Methods guide the process of selecting and developing implementation strategies (8), each containing three general steps. First, determinants that could facilitate or hamper the implementation of an EBP within the local context should be assessed. Second, change methods (e.g., behavioral, organizational, or system change) to address these determinants must be identified. At last, implementation strategies need to be developed or selected that incorporate these change methods (5).

One of the most frequently used Implementation Strategy Mapping Methods is "Implementation Mapping" (9). Implementation Mapping, described by Fernandez et al. (9), addresses the need for a theory-based method to influence determinants for implementation. Nowadays, Implementation

Mapping is widely used in implementation science for selecting and developing implementation strategies. Implementation Mapping describes five tasks to select, develop, execute, and evaluate strategies based on existing theory to enhance the alignment between context and implementation (9). The tasks are iterative, involving continual revisiting of previous steps throughout the process to ensure all adopters and implementers, outcomes, determinants, and objectives are addressed.

To enhance the alignment of implementation strategies with the context of EBP implementation, Fernandez (9) emphasized the need to engage stakeholders in a collaborative process at each step of Implementation Mapping (9). The context in which an intervention is implemented plays a significant role in deciding whether a strategy will be effective. Moreover, strategies that align with the context will contribute to improved implementation and adoption of an EBP (1, 10), achieving more contextually adapted strategies. The experiences of stakeholders can complement implementation science expertise and provide valuable information for identifying implementation challenges and developing possible ways to target these challenges. There are different ways to engage stakeholders in the development of implementation strategies. Codesign is a method that seeks to optimize the alignment of implementation strategies with the context. Codesign involves the collaboration of both trained and untrained individuals in the creative design and development process (1).

In the literature, there are hardly any studies that fully and systematically describe the selection and development of implementation strategies following the crucial steps of an Implementation Strategy Mapping Method, including attention to stakeholder engagement in the identification of barriers and in the selection and development of implementation strategies (11). With this study, we aimed to provide a transparent description of the strategy development process for implementing a combined lifestyle intervention across multiple settings in primary care following Implementation Mapping as an Implementation Strategy Mapping Method, ensuring attention to specific contexts by engaging relevant stakeholders throughout the process.

The combined lifestyle intervention is called ProMuscle, which aims to maintain the independence of older adults. ProMuscle is a 12-week program that combines resistance exercise training with dietary consultations to increase the daily protein intake. Over the years, ProMuscle has undergone further development and

has shown promising effects on physical functioning, strength, and muscle mass among community-dwelling older adults (12). Given the rapid aging of the population, the implementation of combined lifestyle interventions like ProMuscle holds significant potential in contributing to the maintenance of physical independence among older individuals. Ultimately, this could have a positive effect on the prevalence of chronic diseases and reduce healthcare costs.

Therefore, the current study aims to develop implementation strategies using codesign sessions with relevant stakeholders to facilitate the implementation and adoption of ProMuscle across multiple settings in primary care.

2 Methods

2.1 Study design

A qualitative inductive, codesign approach was used to develop theory-based and practical-informed strategies that could align with different contexts. The reporting of this study adheres to the Standard for Reporting Implementation Studies (StaRI) checklist (13).

2.2 Setting

This study is part of the PUMP-fit study, which is centered on implementing ProMuscle in the Netherlands. The primary objective of the PUMP-fit study is to increase the adoption of ProMuscle by selecting and evaluating theory-based, context-tailored implementation strategies. This study was conducted in the Region Foodvalley in the Netherlands. The Region Foodvalley is a collaboration between eight municipalities, local healthcare organizations, universities, and research institutes. Its target is to provide a better nutritional environment for the residents of the region. Within the Region Foodvalley, more than 200 healthcare professionals (HCPs; including physiotherapists and dieticians) work within primary care settings across eight municipalities.

The implementation strategies were developed for, and in codesign with, these professionals because they are the target population for implementing ProMuscle in primary care.

2.3 Participants

Physiotherapists and dieticians working in the Region Foodvalley were recruited through various channels, including the interest list of the PUMP-fit study, social media announcements, calls for participation in newsletters of professionals' associations, and local initiatives. Healthcare professionals were included if they were physiotherapists or dieticians involved in treating older adults within primary care.

Moreover, implementation experts from the Netherlands were personally invited to participate in this study. Specifically, their involvement aimed to provide input on the conceptualization of implementation strategies.

2.3.1 Sample size

Codesign studies share similarities with focus group studies in qualitative research, as high-quality interactive discussions among the cocreators are pivotal for a successful process. Although qualitative research lacks existing rules regarding recommended sample sizes, recommendations have been made to recruit cohorts of 6–12 participants for focus group studies (14). Considering these factors, a recommendation of 10–12 participants for the codesign process is advised, which may also account for dropouts due to the process being conducted over multiple sessions.

2.4 Procedure

In this study, the Implementation Strategy Mapping Method, "Implementation Mapping", was adopted (9). As this study aims to describe the development of implementation strategies, the first four of the five steps of Implementation Mapping were followed. Due to the variations in primary care settings across the Netherlands, it is expected that the context in which ProMuscle is implemented will present diverse contextual determinants; hence, it is anticipated that the implementation strategies will vary for each setting. Therefore, the involvement of various stakeholders during the whole process was perceived as an essential step to align the strategies with the context. Stakeholder involvement was incorporated in various ways into these steps. The procedures for each step are described below.

2.4.1 Step 1. Identifying barriers and theoretical constructs

A preliminary aspect of the PUMP-fit study was the identification of barriers and facilitators of the implementation of a combined lifestyle intervention. Determinants influencing the implementation of ProMuscle in community care were identified by a recently performed scoping review; detailed descriptions of these determinants can be found elsewhere (15). In short, a literature review, including stakeholder consultation, was conducted to identify determinants influencing implementation of combined lifestyle interventions community-dwelling older adults. The identified barriers were categorized into the constructs of the Consolidated Framework for Implementation Research (CFIR) (16). The CFIR consolidates implementation determinants from various implementation theories and comprises five major domains (namely, intervention characteristics, outer setting, inner setting, characteristics of individuals, and process) made up of 39 constructs that influence the implementation of innovations into practice. Eventually, to validate the identified barriers and facilitators in the literature, 19 relevant stakeholders were consulted. During (group) interviews, 13 physiotherapists, 3 dieticians, and 3 community-dwelling older adults were asked about determinants for implementation, eventually prioritizing the identified barriers.

In addition to mapping and prioritizing the determinants described by Implementation Mapping, relevant implementation models addressing behavioral change (17, 18), organizational

change (19), and implementation effectiveness (20) were consulted to establish links between the emerged CFIR constructs and the underlying theoretical constructs. By linking determinants to theoretical constructs, relevant theories were identified, allowing for the adoption of uniform definitions. Eventually, this linking of determinants to underlying constructs provides further direction for justifying possible strategies, which is part of the next steps (21).

2.4.2 Step 2. Linking barriers to strategies

Two methods were used to link the identified barriers to implementation strategies. First, existing taxonomies, models, and theories described in the literature were studied to select implementation strategies. After that, stakeholders were consulted to contribute to the development of additional strategies.

2.4.2.1 Linking to existing taxonomies described in the literature

The first taxonomy used to select strategies was the Expert Recommendations for Implementing Change (ERIC) taxonomy (22). The ERIC taxonomy is a widely used compilation of 73 implementation strategies consisting of definitions sourced from a wide range of implementation experts. To link the identified barriers to possible implementation strategies, the CFIR-ERIC Matching Tool was used (5). The CFIR-ERIC Matching Tool was developed in collaboration with implementation experts (5). These experts rated the importance and feasibility of compiling 73 implementation strategies to barriers categorized by the CFIR framework (5). The tool allows users to select the identified CFIR determinants. Hereafter, a list of relevant strategies is presented per identified determinant for implementation. For each strategy, the tool provides the percentage of experts who ranked that particular strategy in their top seven. This percentage can be interpreted at two levels of endorsed strategies, namely, Level 1 endorsed ERIC strategies (i.e., more than 50% of the experts ranked this as one of their top seven strategies for that barrier) and Level 2 endorsed ERIC strategies (i.e., between 20% and 50% of the experts ranked this as one of their top seven strategies for that barrier) (5, 23). The research group determined that, for the continuation of this study, the top three strategies with the highest agreement or three strategies with an agreement higher than 50% would be used.

Although the CFIR-ERIC Matching Tool provides a convenient global overview of appropriate implementation strategies, the ERIC taxonomy is not exhaustive, and additional efforts are needed to do justice to all identified barriers (24). The research group hypothesized that some barriers might be rooted in the specific behavior of healthcare professionals or older adults receiving the intervention and that these aspects were underrepresented in the ERIC taxonomy. Therefore, an additional literature search was conducted to incorporate behavioral change strategies. Implementation taxonomies and theories, including the taxonomy of Kok et al. (25), Greenhalgh et al. (26), and the Theoretical Domain Framework (17), were consulted to identify implementation strategies targeting behavior.

2.4.2.2 Developing new strategies in codesign

In addition to selecting implementation strategies based on taxonomies and theories described in the literature, input from involved healthcare professionals was retrieved during two codesign sessions. Codesign sessions were scheduled with 10 healthcare professionals (physiotherapists and dieticians). In total, two 90-min online (due to the COVID restrictions) codesign sessions with healthcare professionals were held. At the beginning of the sessions, healthcare professionals were informed about ProMuscle through a short presentation. Under the supervision of a researcher, healthcare professionals discussed possible effective strategies to overcome barriers for implementing ProMuscle. To obtain full objectivity, healthcare professionals were unaware of the implementation strategies identified from the literature. In the end, if strategies from the literature were not mentioned by healthcare professionals, the researcher would propose them to the healthcare professionals to explore whether they could also be considered effective strategies.

2.4.2.3 Triangulation

The strategies retrieved from both the literature and codesign sessions were described in a matrix. Where possible, the research group matched the strategies proposed by healthcare professionals to those from the literature and combined them into the matrix. The strategies that remained and could not be combined with the strategies from the literature were treated as new and added to the matrix.

2.4.3 Step 3. Evidence for implementation strategies

Proctor et al. stated that providing theoretical justification for implementation strategies can address their potential working mechanisms, giving insight into how and why a strategy might facilitate change (2). Theoretical justification can take various forms: empirical, theory-based, and pragmatic (2).

Empirical evidence is considered evidence from research or an individual's knowledge and experience with strategies that have been proven effective.

Theory-based evidence refers to the theoretical knowledge gained in a research field or concerning a specific subject.

Pragmatic justification is derived from clinical expertise, experiences, or the needs of relevant stakeholders concerning overcoming barriers. Although pragmatic evidence does not provide empirical or theoretical evidence for strategies, it can provide insights into the rationale for identifying factors that should be addressed and how strategies could address them (2, 27). In the context of the present study, the research group sought evidence for the identified implementation strategies in scientific literature. The literature that described theories and taxonomies linking specific implementation determinants to strategies was used. First, studies that investigated individual strategies were sought in the database of EPOC and implementation science journals. If the effectiveness of specific strategies was not examined in the literature, theory-based justification was sought in existing theories for the underlying constructs identified in step 1. Also, studies

reporting implementation strategies in similar contexts were consulted.

In addition to seeking empirical evidence and theoretical justification, we aimed to derive pragmatic justification during the codesign sessions with healthcare professionals. Healthcare professionals discussed possible effective strategies to overcome barriers for implementing ProMuscle and provided insights into the effectiveness of the strategies based on their clinical expertise and needs. Also, pragmatic justification for the strategies was obtained during meetings with implementation experts and researchers, as well as through interviews with older adults, drawing on their experiences and needs.

2.4.4 Step 4. Operationalizing implementation activities

The next step in developing appropriate implementation strategies involves operationalizing the implementation activities in full detail. The literature emphasizes the needs and challenges of specifying and reporting implementation strategies (2). Guided by the recommendations for specifying and reporting implementation strategies outlined by Proctor et al. (2), the operationalization of the implementation strategies considered seven dimensions: actor, action, action targets, temporality, dose, implementation outcomes addressed, and theoretical justification. These dimensions should be fully described to facilitate measurement and reproducibility.

With respect to the current study, a matrix was developed to describe all seven dimensions of each proposed implementation strategy.

For this step, codesign with stakeholders was established in an iterative way through consensus meetings with the research team, meetings with two implementation experts, and interactive work sessions with healthcare professionals, including physiotherapists and dieticians. During two 90-min codesign sessions, healthcare professionals were divided into groups. Across the sessions, five groups worked with themes containing several overlapping strategies to make sure all strategies had been covered and to limit workload per codesign session.

The matrix was continuously supplemented with input from healthcare professionals, implementation experts, and research groups during the sessions, resulting in a complete matrix that incorporated input from stakeholders and the literature.

2.4.5 Step 4b. Development of an implementation toolbox

To meet the needs of professionals, implementation materials, in the form of an implementation toolbox, were developed (Implementation Mapping step 4). It was important to create a practical tool to assist healthcare professionals and provide them with the ability to tailor the implementation strategies to their specific context. As mentioned earlier, the research group was aware of the different settings in which ProMuscle would be implemented, consequently leading to different contexts and barriers.

During the development of the implementation toolbox, the research group consulted 1 implementation expert and 10 professionals to create a practical tool for healthcare professionals implementing ProMuscle. The described implementation activities were presented to an implementation expert. Also, based on the experiences of the experts, the most practical way to present the activities in an online platform was discussed. Moreover, the presentation of the tool was designed to be user-friendly and inviting for professionals to use it.

3 Results

3.1 Population

The research team, along with Dutch implementation experts (n=2) and HCPs, i.e., physiotherapists (n=8) and dieticians (n=2) working in the Region Foodvalley, participated in the interactive codesign sessions to provide input for the development of implementation strategies. Table 1 presents the participation of stakeholders across each step.

TABLE 1 Participants of the codesign sessions presented for all four steps of the chosen Implementation Strategy Mapping Method.

Gender	Profession	Work experience (years)	Step 1	Step 2	Step 2*	Step 3	Step 4	Step 4b
	Research group		X	X	X	X	X	X
Female	Physiotherapist	13	X	X		X	X	
Female	Physiotherapist	6	X	X		X	X	
Male	Physiotherapist	37	X	X		X	X	
Female	Physiotherapist	14	X	X		X	X	
Male	Physiotherapist	16	X	X		X	X	
Female	Physiotherapist	39	X	X		X	X	
Female	Physiotherapist	4	X	X		X	X	
Female	Physiotherapist	8	X	X		X	X	
Female	Dietician	7	X	X		X	X	
Female	Dietician	25	X	X		X	X	
Female	Implementation expert					X		X
Female	Implementation expert							X

Step 1, identifying barriers and theoretical constructs; Step 2, linking strategies to barriers; Step 2*, assigning strategies to overarching themes; Step 3, evidence for strategies; Step 4, operationalizing implementation activities; Step 4b, development of an implementation toolbox.

3.2 Outcomes

Implementation strategies for facilitating the implementation of ProMuscle in primary care were selected, described, and operationalized using four adapted steps of Implementation Mapping. In all four steps, different ways to engage stakeholders were included, as presented in the following. Figure 1 visualize the steps including the methods used to retrieve input and the involved stakeholders. Because of the fact that ProMuscle will be implemented in multiple settings, a significant number of barriers and linking strategies emerged. Therefore, an extra step, assigning strategies to themes, was added to step 2 (Figure 1).

3.2.1 Step 1. Identifying barriers and theoretical constructs

In a previous study (15), determinants influencing the implementation of combined lifestyle interventions were identified through a literature review and interviews with relevant stakeholders. A total of 654 determinants were identified, representing all CFIR domains, that could influence the implementation of combined lifestyle interventions similar to ProMuscle (15). Relevant stakeholders like physiotherapists and dieticians validated and prioritized these determinants during interviews. This resulted in 10 main barriers for the implementation of a combined lifestyle intervention in primary care. The top 10 most common determinants are as follows:

"other personal attributes," "knowledge and beliefs about the intervention," "readiness for implementation," "network and communication," "implementation climate," "design quality and packaging," "costs," "patient needs and resources," "cosmopolitanism," and "engaging" (Table 2).

These determinants were linked to theoretical constructs. Some theoretical constructs were similar for multiple determinants. Moreover, most determinants could be linked to multiple theoretical constructs. Table 2 presents all 10 determinants with underlying constructs. The models used to link the determinants to constructs were the theoretical domain framework (17), implementation effectiveness model (28), health belief model (29), and social cognitive theory (30).

3.2.2 Step 2. Linking barriers to strategies 3.2.2.1 Linking to existing taxonomies described in the literature

The selected constructs from CFIR in the previous step were entered in the CFIR-ERIC Matching Tool, and this method resulted in multiple strategies advised for the specific determinants. The initial step involves excluding strategies deemed not applicable because they did not align with the context for implementing ProMuscle. For example, the strategy to make billing easier was a level 2 endorsed strategy for the construct "costs." However, the combined lifestyle intervention ProMuscle is not reimbursed, and recipients are required to pay for participation. Therefore, the research group decided that this strategy

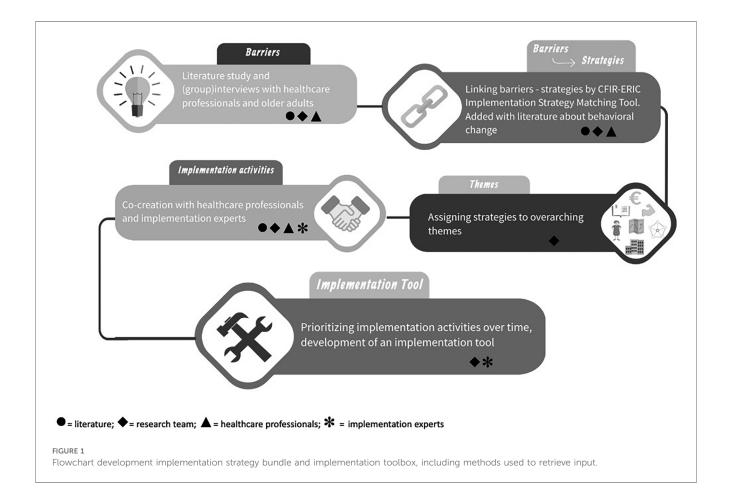


TABLE 2 Identified determinants influencing the implementation of combined lifestyle interventions linked to theoretical constructs.

Domain	Construct	Definition of the CFIR construct	Theoretical construct	Theory
Characteristics of individuals	Other personal attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values,	Attitude	Theory of planned behavior, social cognitive,
		competence, capacity, and learning style	Self-efficacy	Social cognitive theory, TDF
			Skills	Implementation effectiveness, TDF
			Knowledge	TDF
Characteristics of	Knowledge and beliefs	Individuals' attitudes toward and value placed on the	Attitudes	TDF
individuals	about the intervention	intervention as well as familiarity with facts, truths, and	Commitment	Implementation effectiveness model
		principles related to the intervention	Knowledge	Social cognitive theory
Inner setting	Readiness for	Tangible and immediate indicators of organizational	Commitment	Social cognitive theory
	implementation	commitment to its decision to implement an intervention	Social norms	Implementation effectiveness model
			Resources	TDF
Inner setting	Network and communication	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization	Organizational commitment	TDF
Inner setting	Implementation climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization	Climate for implementation	Implementation effectiveness model, TDF
Innovation characteristics	Design quality and packaging	Perceived excellence in how the intervention is bundled, presented, and assembled	Intervention effectiveness	Implementation effectiveness model
			Resources	TDF
Innovation	Costs	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs	Costs	Health beliefs model
characteristics			Incentives	Implementation effectiveness
			Resources	TDF
Outer setting	Patient needs and	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization	Incentives,	Implementation effectiveness
	resources		Knowledge	TDF
			Motivation,	TDF
			Resources	TDF
Outer setting	Cosmopolitanism	The degree to which an organization is networked with other external organizations	Environmental, leadership	TDF
			Organizational commitment	TDF
			Social norms	Social cognitive theory
Process	Engaging	Attracting and involving appropriate individuals in the	Motivation	TDF, health belief model
		implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities	Incentives	TDF
Process	Innovation participants	Attract and encourage recipients to serve on the	Attitude	TDF
		implementation team and/or participate in the innovation	Commitment	Implementation effectiveness
			Social support	TDF

TDF, theoretical domain framework

would not be suitable for implementation in this phase. However, if ProMuscle were to be reimbursed, this strategy could be considered and added to the strategy bundle if deemed necessary.

For constructs "patient needs and resources," "engaging," and "other personal attributes," the CFIR-ERIC strategy matching tool did not yield (appropriate) strategies to align with the context. In the end, this step resulted in 40 appropriate implementation strategies. Of the 40 strategies, 32 were retrieved from the ERIC taxonomy (22), 5 from the TDF, and 2 from the taxonomy of Kok et al. (25).

3.2.2.2 Developing new strategies in codesign

In addition, the input from healthcare professionals and implementation experts during the codesign sessions was mostly practical and was not specifically linked to implementation strategies as described in the literature and the

ERIC taxonomy. The activities proposed by healthcare professionals align with the action dimension, according to Proctor et al. (2), for most of the strategies that were found in the literature (as presented in Table 3).

For the strategies derived from the literature that were not mentioned by healthcare professionals, the researchers asked whether the remaining strategies could be effective or not. Three strategies that appeared in the literature but were not mentioned by healthcare professionals were "conduct local need assessment," "assess for readiness and identify barriers and facilitators," and "develop academic partnerships." Because the healthcare professionals were not experienced in implementation science, and likely had insufficient awareness for assessing the context (needs, barriers, and facilitators), the research group decided to elaborate on these strategies anyway. Moreover, the three strategies were classified as level 1 strategies according to the CFIR-ERIC Matching Tool.

TABLE 3 Implementation strategies assigned to overarching themes and relating CFIR construct(s).

Theme	Strategy from taxonomies and theories	Actions proposed by HCPs in work sessions	Underlying CFIR domain—construct	
Assessing the	Conduct local needs assessment		Inner setting—readiness for implementation	
context			Outer setting—patient needs and recources	
	Assess for readiness and identify barriers		Inner setting—implementation climate	
	and facilitators		Inner setting—readiness for implementation	
Network internally	Build a coalition	Staff meetings	Inner setting—readiness for implementation	
			Inner setting—network and communication	
	Organize clinician implementation team meetings	Informing and promoting	Inner setting—network and communication	
	Promote network weaving	Maintain collaboration	Inner setting—network and communication	
Network externally	Promote network weaving	Informing and promoting	Outer setting—cosmopolitanism	
	Develop academic partnerships		Outer setting—cosmopolitanism	
	Build a coalition	Forming a network	Outer setting—cosmopolitanism	
Costs	Access new funding	Access funding	Intervention characteristics—costs	
	Alter incentive/allowance	Incentives for recipients	Intervention characteristics—costs	
			Inner setting—implementation climate	
	Develop resource-sharing agreements	Sharing knowledge, space, and materials	Intervention characteristics—costs	
Knowledge	Develop educational materials	Education	Characteristics of individuals—knowledge and beliefs	
			about the intervention	
		Promotion materials and protocols	Intervention characteristics—design quality and	
			packaging	
			Process—engaging	
	Conduct ongoing training	Yearly training	Characteristics of individuals—other personal attributes	
	Conduct educational meetings	Frequent evaluations	Characteristics of individuals—knowledge and beliefs about the intervention	
			Process—engaging	
Champions	Identify and prepare champions	Champions	Characteristics of individuals—knowledge and beliefs about the intervention	
			Inner setting—implementation climate	
			Process—engaging	
Patient needs and	Involve patients, consumers, and family	Engaging older adults	Process—engaging innovation participants	
resources	members		Outer setting—patient needs and resources	
	Prepare patients/consumers to be active	Group coherence, personal approach	Process—engaging innovation participants	
	participants	Setting goals	Outer setting—patient needs and resources	
		Coaching		
	Intervene with patients and consumers to	Share results with recipients	Process—engaging innovation participants	
	enhance uptake and adherence		Outer setting—patient needs and resources	
	Promote adaptability	Intervention fitting the context	Outer setting—patient needs and resources intervention characteristics—design quality and packaging	
	Obtain and use patients'/consumers' and family feedback		Outer setting—patient needs and resources	

To illustrate the elaboration of this step, in the following box (Box 1), we present how the construct "costs" within the domain *intervention characteristics* was linked to implementation strategies.

BOX 1 LINKING CONSTRUCT "COSTS" TO IMPLEMENTATION STRATEGIES WITH

Entering determinant "costs" (intervention characteristics) into the CFIR-ERIC tool resulted in the following strategies: "access new funding" (72%), "alter incentives" (44%), and "develop resource sharing agreements" (32%). Also, for construct *implementation climate*, strategy "alter incentives" was presented. This outcome suggested that a single strategy could address multiple barriers.

3.2.2.3 Triangulation: assigning strategies to overarching themes

The literature search and consultation with healthcare professionals revealed a great number of strategies. During consultation with the research group, it was noticed that some implementation strategies were applicable to multiple determinants. Therefore, it was hypothesized that some strategies would affect multiple barriers. In addition, the large number of strategies could burden healthcare professionals (31). As a result, the research group aimed to identify overarching themes within the strategies and introduced an extra step within the adopted version of Implementation Mapping. A total of four consensus meetings were conducted with the research group to provide an overview, create overarching themes, and assign strategies to the themes. Ultimately, 20 unique strategies were assigned to

7 overarching themes: assessing the context, network internally, network externally, costs, knowledge, champions, and patient needs and resources. Table 3 presents the seven themes, providing a complete overview of strategies derived from the literature and input from healthcare professionals, along with the constructs to which these strategies were linked. Appendix A provides a description of the constructs that eventually fell under the themes. Box 2 presents the description of the theme costs.

BOX 2 DESCRIPTION OF CONSTRUCTS THAT FELT UNDER THEME COSTS

Costs: This theme primarily reflects on construct intervention characteristics. Also, the construct implementation climate is related to this theme, as insufficient time (and money) for the implementation process itself was identified as a barrier for implementation.

3.2.3 Step 3. Evidence for implementation strategies

Eventually, this third step resulted in justification for every strategy, which is extensively described in Appendix B. Empirical evidence was found for activities within the following strategies: "assess for readiness and identify barriers and facilitators" (32, 33), "build a coalition" (34), "conduct ongoing training" (35), "conduct educational meetings" (34, 36), and "intervene with patients and consumers to enhance uptake and adherence" (35). Most strategies could be justified by underlying theoretical constructs or models mostly based on organizational change (19, 20, 37), system change (34, 38–40), and behavior change (17, 25, 41, 42). Also, during the codesign sessions, healthcare professionals and implementation experts provided pragmatic evidence from their own experience with implementation, as well as based on their needs. In previous research, older adults were interviewed, which resulted in pragmatic evidence for implementation strategies concerning the strategies in theme "Patient needs and resources".

To illustrate the improved methodology of developing implementation strategies, the theme *costs* will be described in detail in Box 3. For a complete description of all strategies, including the evidence for each strategy, see Appendix B.

BOX 3 DESCRIPTION OF THE THEORETICAL JUSTIFICATION OF THE STRATEGIES IN THEME COSTS

For theme *costs*, no empirical evidence was found for the three strategies in the EPOC database and implementation journals in similar contexts. This is probably because the insurance and funding possibilities in the Netherlands differ from those in, for example, the United States where most implementation strategy effectiveness studies are conducted. However, Greenhalgh et al. (26) presented several studies where funding contributed to the success or failure of implementation.

Therefore, literature was sought within existing theories and models. The used taxonomies of Michie et al. (17) and Kok et al. (25) did not provide relevant references. The research group conducted a search for studies addressing "funding possibilities," "alter incentives," and "sharing recourse agreements" and their possible underlying theories or working mechanisms for implementation. A review from Dopp et al. was found (40), where strategies concerning funding an EPB implementation were discussed. Dopp et al. highlighted that funding is necessary to cover the costs of care. Grants serve as a means to reimburse the EBPs and incentivize their use (40). Covering the costs leads to decreased expenses for service providers, which ultimately can increase the acceptability of the EBP. Moreover, incentives provide resources (e.g., training, consultation) that may be difficult to purchase for health services.

Consequently, the literature search resulted in theoretical justification for the strategies "assess new funding" (40) and "alter incentives" (34, 40). Healthcare professionals provided practical activities and practice-based, pragmatic justification for the strategies "alter incentives," "develop resource sharing agreements," and "assess funding possibilities."

During the work sessions, healthcare professionals mentioned that costs could be one of the main barriers for implementation. Because the combined lifestyle intervention ProMuscle is not reimbursed by healthcare insurance, older adults, especially those with little financial possibilities, may be unable to participate. Moreover, the costs of the program could also impact the recruitment of older adults. This could be due to the limited knowledge of older adults about the benefits of a program like ProMuscle. Healthcare professionals stated that assessing funding possibilities and informing older adults about the benefits of ProMuscle could contribute to optimal recruitment and adoption.

For theme *costs*, healthcare professionals proposed several implementation activities focused on the costs of the intervention and the time spent on implementation by professionals.

The importance of these activities was highlighted by professionals' experiences. Healthcare professionals expressed that it is important for possible participants to know what to expect and to prevent dropouts due to (unexpected) costs. In addition to implementation activities concerning the costs of delivering ProMuscle (access funding possibilities), healthcare professionals also provided insight into what they needed to be able to implement ProMuscle in their practice (alter incentives). Deliberating with the manager of their practice to make time for implementing the intervention was mentioned as crucial to be able to evaluate, upscale, and sustain the implementation. Also, practical incentives such as promotion materials, protocols, and templates were mentioned as needs by healthcare professionals. Finally, using the current implementation group to exchange knowledge, materials, and even workplace was mentioned (develop resource sharing agreements). Having the ability (time, materials, and facilities) to implement the intervention and ensuring that fellow implementers will be open-minded in sharing resources ensures that healthcare professionals in their network are on the same page. According to healthcare professionals, being on the same page and uniformly delivering the intervention could enhance the success of implementation.

3.2.4 Step 4. Operationalizing implementation activities

The research group translated the retrieved strategies into Dutch and provided global information about the strategies to further operationalize them during the codesign sessions.

The first group of healthcare professionals worked with theme costs, and the second group worked with themes process, intervention, and knowledge. The third group worked with themes network internally, network externally, and patient needs and resources. The fourth group worked with theme knowledge. A fifth group consisting of dieticians was considered a validation group because the other four groups consisted of physiotherapists. The group of dieticians checked whether they agreed with the proposed activities and were asked if they missed specific activities.

Healthcare professionals provided additional and practical input concerning the "actors," "action," "dose," and "justification" dimensions, according to Proctor et al. (2).

The research group complemented the specification with input from the literature. Input from the literature, research groups, and healthcare professionals resulted in fully detailed implementation strategies for all seven themes. A complete description of the strategies for theme *costs* is presented in Table 4. For the remaining themes, the strategies are described in Appendix B.

Themes Assessing the context and champions were seen as important for all other themes. Therefore, the strategies assigned to these themes were considered obligatory to start the implementation.

3.2.5 Step 4b. Development of an implementation toolbox

The research group consulted multiple implementation experts and professionals to create a practical tool for healthcare professionals implementing ProMuscle. Implementation experts mentioned that it was important for the tool to be easy to use. It should not take much time to understand the tool. They emphasized the importance of providing an overview where professionals should not have to perform extensive scrolling. Also, the implementation activities should be presented in chronological order, rather than by theme.

Therefore, the research team assigned every implementation activity to a specific time frame. The activities could be assigned to one or more time frames. The following time frames were used: 8–6 weeks preimplementation, 6–4 weeks preimplementation, 4–0 weeks preimplementation, implementation, and sustainment. This resulted in an online implementation toolbox in which implementation actions are chronologically described and bundled per theme. In this way, healthcare professionals are free to choose which theme would apply to their specific context. Moreover, a function was built to check whether actions were conducted and to add remarks.

The four steps resulted in a full description of 20 strategies, divided over 7 overarching themes. A complete description of all 20 strategies and the barriers they address is presented in Appendix B. The theory-based and practical implementation activities were added to a web-based implementation tool. Figure 1 presents an overview of the conducted steps and the methods used to retrieve input. As shown in Figure 1, the steps of

Implementation Mapping were slightly changed, and an extra step (themes) was added. Moreover, in every step, relevant stakeholders provided input to provide an implementation strategy bundle for healthcare professionals that can be tailored to their specific contexts, and added this bundle in an online toolbox.

Discussion

This paper describes the methodology of developing a theoretically justified and practically tailored implementation strategy bundle to implement a combined lifestyle intervention for community-dwelling older adults across multiple settings in primary care. The Implementation Strategy Mapping Method was guided by Implementation Mapping (9). Initially, the four steps of Implementation Mapping were followed. Because this study focuses on multiple settings in primary care and various contexts were explored, a great number of determinants for implementation emerged, which ultimately led to 40 linked implementation strategies. The addition of an extra step to the methodology was deemed necessary to provide structure to the array of implementation strategies. Moreover, the diverse collection of strategies could enable healthcare professionals to tailor their strategies according to their specific contexts.

Ultimately, the structural approach guided by Implementation Mapping and the embedded codesign with healthcare professionals and implementation experts led to the development of a practical and theory-informed strategy bundle. Through codesign, the strategies were tailored to the context in which they were supposed to be applied. The implementation toolbox serves as a guide for healthcare professionals, assisting them during the implementation and overcoming barriers related to their contexts.

A large number of implementation strategies, totaling 20, were described in detail and included in the final implementation toolbox for healthcare professionals who aim to implement a combined lifestyle intervention. The large proportion of strategies can be justified by the multiple determinants that were found as possible barriers for implementing a combined lifestyle intervention. For the implementation of a combined lifestyle intervention, determinants at multiple levels can affect the implementation results. Therefore, by including multiple strategies in the implementation toolbox, we can ensure that healthcare professionals can tailor strategies aligning with their specific contexts and can adjust them when encountering other barriers during the implementation process.

The inclusion of the extra step assigning strategies to overarching themes in the development of the implementation strategy was prompted by the perceived burden for healthcare professionals. Creating themes resulted in strategy bundles relating to the specific themes. Multiple studies present the development and use of multicomponent strategies (6, 7, 43, 44). Moreover, the use of multicomponent strategies is highlighted by Cooper et al. (45), where various combinations of strategies were found effective for sustaining the implementation of an EBP (4, 43). The wide use of multicomponent strategies in implementation science, and the ones that were investigated and found effective in different trial studies, is grounded in the

TABLE 4 Description of strategies concerning the theme costs following the recommendation of Proctor et al. (2).

Justification empirical evidence, theory- based evidence, pragmatic justification	Pragmatic from experiences of healthcare professionals and theoretical evidence (40)	Theory-based (34, 40)	Pragmatic from experiences of healthcare professionals
Implementation outcome affected	Feasibility, adoption, fidelity, acceptability	Feasibility, fidelity, adoption	Feasibility, fidelity, sustainability
Dose	Depending on the temporality of the funding, new funding can be assessed as many times as needed	A 30-min phone call/online meeting between the researcher and healthcare professionals; during the implementation, monthly evaluation meetings are held; healthcare professionals will discuss (once) the opportunity for extra time with their managers before the start of the implementation	Healthcare professionals contact each other if necessary, before, during, or after the implementation
Temporality	Ideally, before the start of the implementation but can also be conducted throughout the implementation	Before the start of the implementation and and during the implementation, if necessary	Before, during, and after the implementation
The targets	Possible funders of the intervention are healthcare insurance, municipalities, funds, etc. Cofunding gives an opportunity to lower the costs of the intervention for recipients	Improving knowledge of healthcare professionals about the need for facilities during implementation and increasing the opportunity from implementing, facilitated by managers of healthcare professionals	Improving knowledge and facilities of healthcare professionals implementing ProMuscle
The action	Writing calls or granting applications to cofinance the intervention	Researchers will inform healthcare professionals about the implementation and the intervention and healthcare professionals will discuss with their manager for extra time to set up and roll out the implementation	Healthcare professionals reach out to each other to share information, knowledge, and materials
The	нсь	HCP RG	НСР
Name of CFIR domain Definition of the the —construct strategy affected	Access new or existing money to facilitate the implementation	Work to incent the adoption and implementation of clinical innovation	Develop partnerships with organizations that have the resources needed to implement the innovation
CFIR domain —construct affected	Intervention characteristics— costs	Intervention characteristics— costs Inner setting— implementation climate	Intervention characteristics— costs
Name of the strategy	Access new funding	Alter incentive/ allowance	Develop resource- sharing agreements

HCP, healthcare professional; RG, research group.

understanding that implementation is often influenced not only by one determinant but by a combination of determinants.

Moreover, the context in which an intervention is implemented greatly influences the success of implementation (46). Therefore, as addressed by Nilsen et al. (46), the difference in contexts highlights the importance of tailoring the implementation to specific contexts. This is supported by a Cochrane review in which it was found that tailored implementation strategies were more effective than non-tailored strategies (47, 48).

Because this study described strategies for multiple barriers, an implementation plan can be tailored to the specific contexts in which the intervention is implemented (6). In addition, due to input from healthcare professionals, actions for the strategies are very practical and should be applicable to (mostly) every healthcare practice implementing ProMuscle. Also, determinants for all levels of implementation according to the CFIR were considered in developing the implementation toolbox. Therefore, tailoring an implementation plan to specific contexts should be possible.

This paper not only addresses the development but also gives a transparent and complete description of the developed implementation strategies. It is not entirely surprising that most studies lack a description of the selection and development of implementation strategies and stakeholder engagement; developing strategies following one of the Implementation Strategy Mapping Methods is very time-consuming. However, because the strategies are detailed and based on theory and practice, fellow implementers can use this overview of a strategy bundle (Appendix B) in similar implementation processes of combined lifestyle interventions. Future research should focus on the working mechanism (49) of the implementation strategies developed in this study. With the results of this study, knowledge about the strategies could be used to implement other combined lifestyle interventions for community-dwelling older adults. If the implementation toolbox is found effective, it can be more widely deployed, adjusted to other contexts, or investigated for other interventions.

A strength of this study is that an Implementation Strategy Mapping Method by way of Implementation Mapping (9) was used to guide the process of developing implementation strategies. Implementation Mapping is considered a powerful approach because of its collaborative nature (43), which is perceived as critical in implementation (50). In the case of ProMuscle, where multiple barriers were identified that could influence the implementation of a combined lifestyle intervention, it could be suggested that multiple strategies are needed. But also, that for every setting, different (combinations) of strategies are appropriate. Therefore, other Implementation Strategy Mapping Methods could also be used as guidance for the development of the implementation strategy bundle, for example concept mapping, focus groups or conjoint analysis (8). However, because of the novelty of the research area in implementation strategy development models, little is known about the effectiveness of the models regarding the adoption of the implemented intervention (8). Therefore, we used Implementation Mapping, the most well-known and widely used method that incorporates stakeholder input, and adjusted its steps to better align with the scope of our study (multiple settings).

Another strength is the incorporation of codesign with stakeholders during the identification of determinants and the development of the strategies. Codesign was a great contributor to tailor strategies to the specific context of implementing a combined lifestyle intervention in primary care (1). For developing implementation strategies to implement ProMuscle, it was hypothesized that codesign would be beneficial for the fidelity and feasibility of the strategies and the alignment with the context. Also, stakeholder engagement is an effective way to engage healthcare professionals in further implementation and involvement in the implementation trials (11). The codesign sessions were an organic and iterative process during all four steps. During the codesign sessions, healthcare professionals provided input on possible actions concerning the seven themes. These codesign sessions provided practical input, and all proposed activities could be linked to implementation strategies suggested by the CFIR-ERIC tool and other taxonomies. Moreover, the codesign sessions resulted in tailored implementation strategies for all seven themes. Finally, the correspondence between the results of the literature search and the codesign sessions suggests that the developed implementation strategies match the context in which ProMuscle will be implemented.

A limitation of this study was that the CFIR-ERIC Matching Tool was used to identify strategies for the potential barriers. Although the CFIR-ERIC tool is widely used in implementation science, it is based on the experiences of implementation researchers and not all strategies included in the tool are evaluated for their effectiveness (22). However, this limitation was partly resolved by the literature search conducted in step 3. Although little empirical evidence was found for individual strategies, the justification lies in the theory and models underpinning the strategies to overcome specific barriers when implementing a combined lifestyle intervention. Further research should investigate not only the link between determinants and strategies but also the effectiveness of the bundled implementation strategies.

Conclusion

The utilization of an Implementation Strategy Mapping Method, with an important role for codesign in each step, led to the development of theoretically justified and practical implementation strategies to support healthcare professionals to implement a combined lifestyle intervention for community dwelling older adults. A significant number of implementation strategies are fully described and can serve as a first overview for other implementers. The structural method, taking the context into account by incorporating codesign in all four steps, has resulted in a theoretically informed final product, an implementation toolbox. Therefore, the implementation toolbox could be a practical tool that can be tailored to an individual's context for healthcare professionals willing to implement a combined lifestyle intervention such as ProMuscle. Future research will focus on evaluating the implementation strategy bundle, including the implementation toolbox, regarding the implementation ProMuscle in primary care.

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 humans were approved by the Medical Ethics Committee of UMC Utrecht. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

PL: Writing – original draft, Writing – review and editing. BD: Writing – review and editing. AH: Writing – review and editing. CV: Writing – review and editing. D-JB: Supervision, Writing – review and editing. LS: Writing – review and editing.

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Conflict of interest

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Appendix A Description of constructs that are related to the themes

Assessing the context: Conducting local needs assessment was described as a strategy for the internal and external contexts. In addition, assessing readiness and identifying barriers and facilitators were strategies that align with theme *internal context*.

Network internally: Building a coalition, promoting network weaving, and organizing implementation team meetings were strategies assigned to theme network internally. The theme reflects mostly on the CFIR construct network and communication. However, the construct readiness for implementation also aligns with the theme with the corresponding strategy, "build a coalition."

Network externally: Cosmopolitanism, e.g., working with other organizations, is the only construct assigned to theme network externally. Strategies concerning network externally were relatively similar to those concerning network internally. However, it is executed in different levels of the context and focuses on building and enhancing external collaboration with stakeholders. Therefore, actions described for the strategies in theme network externally are different from those described for network internally.

Costs: Theme *costs* reflect mostly on the construct intervention characteristics. Also, construct *implementation climate* is related to

this theme, as insufficient time (and money) for the implementation process itself was identified as a barrier to implementation.

Knowledge: Strategies concerning theme knowledge reflect multiple levels within the implementation. Actions related to knowledge, such as materials, are described for stakeholders, recipients of the intervention, and healthcare professionals delivering the intervention. The strategies in theme knowledge relate to constructs "knowledge and beliefs about the intervention," "design quality and packaging," "engaging," and "other personal attributes."

Champions: Theme champions was linked to one strategy, addressing three constructs. Within the description of the strategies, a champion is mostly named as an actor. Because champions were named as actors for a great number of strategies and were found to have a major role in implementation, the theme champions should be incorporated into the other themes.

Patient needs and resources: More strategies addressed patient needs compared to the other themes. Most strategies in this theme were derived from other literature works concerning behavioral change. Moreover, many healthcare professionals proposed strategies that could be integrated into the intervention, for example, setting goals and motivational interviewing.

Appendix B Description of implementation strategies following Proctor et al.'s recommendation for specifying and reporting implementation strategies.

Justification empirical evidence, theory-based evidence, pragmatic justification	Theory-based (35)	Empirical (30, 31), theory-based (26)	Pragmatic from experiences of HCPs
Implementation outcome affected	Acceptability, appropriateness	Appropriateness, feasibility	Fidelity, patient centeredness
Dose	One questionnaire before the start of the implementation; completing the questionnaire takes up to approximately 10 min	One questionnaire before the start of the implementation; completing the questionnaire takes approx. 10 min	During the intake of the intervention
Temporality	Before the start of the implementation	Before the start of the implementation	Before the start of the intervention
Targets	Identifying the needs of physiotherapists and dieticians implementing ProMuscle	Identifying barriers and facilitators of physiotherapists and deticians for implementation of ProMuscle	Identify the needs of possible recipients of ProMuscle
Action	Researchers develop a readiness tool to assess the different contexts of professionals to assess whether all required materials are available	and facilitators through literature review and consultation with stakeholders; develop the readiness tool based on the previously identified barriers and facilitators; and assess the readiness tool with HCPs	Assessment of the needs of recipients of the intervention to align with the knowledge and needs in the first week of the intervention
Actors	RG	RG	НСР
Definition of the strategy	Collect and analyze data related to the need for the innovation; this assessment could be focused on the description of usual care and its distance from evidence-based care, optinions from stakeholders on the need for an innovation or on special considerations for delivering the innovation in the local context	Assess various aspects of an organization to determine its degree of readiness to implement, barriers that may impede implementation, and strengths that can be used in the implementation effort	Collect and analyze data related to the need for innovation
CFIR domain —construct affected	Inner setting—readiness for implementation	Inner setting— implementation dimate Inner setting— readiness for implementation	Outer setting— patient needs and resources
Name of the strategy	Conduct local needs assessment	Assess for readiness and identify barriers and facilitators	Conduct local needs assessment
Theme	Assessing the context		

(Continued)

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Justification empirical evidence, theory-based evidence, pragmatic justification	Pragmatic from experiences of HCPs, theoretical (38)	Theory-based (32, 38)	Pragmatic from experiences of HCPs	Empirical (32), theory-based (40)
Implementation outcome affected	Feasibility, adoption, fidelity, acceptability	Feasibility, fidelity, adoption	Feasibility, fidelity, sustainability	Adoption, sustainability
Dose	Depending on the temporality of the funding; new funding can be assessed as many times as needed	A 30-min phone call/ online meeting between the researcher and HCPs, during implementation, monthly evaluation meetings are held; HCPs will discuss (once) the opportunity for extra time with their managers before the start of the implementation	HCPs contact with each other, if necessary, before, during, or after the implementation.	Assessing and analyzing stakeholders before the implementation; participate in networks and inform colleagues frequently (once a month depending on the original organization structure)
Temporality	Ideally, before the start of the implementation, but it can also be conducted throughout the implementation	Before the start of the implementation and during the implementation, if necessary	Before, during, and after the implementation	Before, during, and after the implementation
Targets	Possible funders of the intervention are healthcare insurance, municipalities, funds, etc.; cofunding gives an opportunity to lower the costs of the intervention for recipients	Improving knowledge of HCPs about the need for facilities during implementation and increase the opportunity from implementing, facilitated by managers of HCPs	Improving knowledge and facilities of HCPs implementing ProMuscle	Involving HCPs and stakeholders within the organization in the implementation of ProMuscle
Action	Writing calls or grant applications to cofinance the intervention	Researchers will inform HCPs about the implementation and the intervention. HCPs will discuss with their manager for extra time to set up and roll out the implementation	HCPs reach out to each other to share information, knowledge, and materials	Assessing and analyzing which colleagues are necessary for the implementation. Start a network or join an existing network within the organization to inform and collaborate about the implementation of ProMuscle
Actors	HCP	RG HCP	НСР	НСР
Definition of the strategy	Access new or existing money to facilitate the implementation	Work to incent the adoption and implementation of clinical innovation	Develop partnerships with organizations that have the resources needed to implement the innovation	Recruit and cultivate relationships with partners in the implementation effort
CFIR domain —construct affected	Intervention characteristics— costs	Intervention characteristics— costs Inner setting— implementation climate	Intervention characteristics— costs	Inner setting—readiness for implementation
Name of the strategy	Access new funding	Alter incentive/ allowance	Develop resource- sharing agreements	Build a coalition
Theme	Costs			Network internally

(Continued)

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Justification empirical evidence, theory-based evidence, pragmatic justification	Theory-based (37)	Theory-based (36)	Theory-based (36)
Implementation outcome affected	Adoption	Adoption, sustainability	Adoption, sustainability
Dose	Set up a project team before the implementation, conduct monthly meetings during the implementation, and maintain the involvement after the implementation	Analyze current networks before the implementation, join networks during the implementation, and maintain the involvement after the implementation	Analyze current networks before the implementation, join networks during the implementation, and maintain the involvement after the implementation
Temporality	Before, during, and after the implementation	Before, during, and after the implementation	Before, during and after the implementation
Targets	Involving HCPs with the implementation and increasing knowledge about the implementation and intervention.	Involving HCPs with the implementation and increasing knowledge about the implementation and intervention.	Involving relevant stakeholders with the implementation of ProMuscle. Engage stakeholders by providing information about the intervention during meetings
Action	Set up a project team consisting of colleagues involved in the intervention; conduct monthly meetings containing evaluation moments concerning the implementation of ProMuscle	Analyzing whether networks regarding older adults in community care already exist within the organization; join and, if necessary, let other parties join the network who are considered important for the implementation of ProMuscle; stimulate participants of the network to collaborate and share recounses and information about the intervention	Analyzing what networks regarding older adults in community care already exist; join and, if necessary, let other parties join the network who are considered important for the implementation of the intervention; stimulate participants of the network to collaborate and share resources and information about the intervention
Actors	RG CH (HCP)	В	НСР
Definition of the strategy	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	Identify and build on existing high-quality working relationships and networks within and outside the organization, organizational units, treams, etc. to promote information sharing, collaborative problemsolving, and a shared vision/goal related to implementing the innovation	Identify and build on existing high-quality working relationships and networks within and outside the organization, organizational units, teams, etc. to promote information sharing, collaborative problemsolving and a shared vision/goal related to implementing the innovation
CFIR domain —construct affected	Inner setting— network and communication	Inner setting— network and communication	Outer setting— cosmopolitanism
Name of the strategy	Organize dinician implementation team meetings	Promote network weaving	Promote network weaving
Theme			Network externally

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Justification empirical evidence, theory-based evidence, pragmatic justification	Pragmatic (49)	Theory-based (37)	Theory-based (14, 50), pragmatic from needs of HCPs	Empirical (33), theory-based (14, 22)
Implementation outcome affected	Acceptability, adoption	Adoption, sustainability	Acceptability, adoption, feasibility, fidelity	Acceptability, adoption
Dose	Contact institutes before implementation, remain in contact, and share resources/collaborate during and after the implementation	Assessing and analyzing stakeholders before the implementation; participating in networks and informing stakeholders frequently depending on agreements about contact	Develop educational materials for the HCPs before the implementation; HCPs further develop materials during the implementation	Before the first HCPs start delivering the intervention, they follow the ProMuscle course, during the implementation, meetings are held to keep HCPs involved; every 1 year after the implementation, HCPs follow a follow
Temporality	Before, during, and after the implementation	Before, during, and after the implementation	Before, during, and after the implementation	Before, during, and after the implementation
Targets	Involve and engage researchers from research institutes; create resource facilities for the implementation	Involving relevant external stakeholders (e.g., general practitioners, community workers, and policy officers) with the implementation of ProMuscle, Engaging stakeholders by providing information about the intervention during meetings	Improving opportunities and capabilities of HCPs executing the intervention, stakeholders, and recipients of ProMuscle	Improving and maintaining knowledge, skills, and capabilities of HCPs delivering ProMuscle
Action	Contact research institutes like universities. Involve the institutes with the implementation. Explore if there are possibilities to be supported by the institute during the implementation	Assessing and analyzing appropriate and necessary stakeholders from external institutions for the implementation; start a network or join an existing network to inform and collaborate about the implementation of ProMuscle	Researchers develop educational material and courses for HCPs, HCPs prepare materials to inform recipients and stakeholders about the intervention (flyers, presentations, etc.)	One year after the first ProMuscle course, organize a follow-up meeting to get back on the course, content, and background information of ProMuscle
Actors	НСР	НСР	НСР	DO IO
Definition of the strategy	Partner with a university or academic unit for shared training and bringing research skills to an implementation project	Recruit and cultivate relationships with partners in the implementation effort	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	Plan for and conduct training in clinical innovation in an ongoing way
CFIR domain —construct affected	Outer setting— cosmopolitanism	Outer setting— cosmopolitanism	Characteristics of individuals—knowledge and beliefs about the intervention Intervention characteristics—design quality and packaging	Characteristics of individuals—other personal attributes
Name of the strategy	Develop academic partnerships	Build a coalition	Develop educational materials	Conduct ongoing training
Theme			Knowledge	

Continued

Justification empirical evidence, theory-based evidence, pragmatic justification	Empirical (32, 34), theory-based (22), pragmatic	Pragnatic from the needs of HCPs and experience of implementation experts	Theory-based (51), pragmatic from experiences of HCPs and needs of recipients of ProMuscle	Theory-based (22, 39), pragmatic evidence from experiences of HCPs and needs of recipients
Implementation outcome affected	Acceptability, sustainment	Adoption, fidelity	Acceptability	Fidelity
Dose	Before the implementation, set up a network of involved stakeholders; During and after the implementation, continue meeting with the network	Before the implementation, organizations can point out a champion. The champions are informed about their tasks by the research team	Before the implementation, barriers and facilitators will be identified. During the intervention, recipients will be informed and stimulated	In every consult/training during the intervention
Temporality	Before, during, and after the implementation	Before the implementation	Before the implementation and during the intervention	During the intervention
Targets	Engaging stakeholders (e.g., HCPs, general practitioners, community workers, and policy officers) by involving and informing them about the intervention.	To make sure that within an organization, at least one healthcare professional acts as a champion to facilitate the adoption of ProMuscle	Make sure that the intervention aligns with the needs of the recipients of ProMuscle	Make sure that recipients participate and remain motivated during ProMuscle
Action	Assessing involved stakeholders and continued intervention meetings to inform stakeholders about the implementation of the intervention	Within every healthcare practice willing to implement ProMuscle, a champion will be identified. The researchers will provide information about the tasks of a champion through an online guide	Recipients will be interviewed to inform possible barriers and facilitators to participate in ProMuscle. HCPs will inform recipients about the progress during the meetings and stimulate group adherence during the intervention	HCPs will motivate recipients during the intervention with motivational interviewing, goal setting, participation, and/or shifting focus
Actors	IO IO	RG and HCP	НСР	HCP
Definition of the strategy	Hold meetings targeted toward different stakeholder groups to teach them about clinical innovation	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	Engage or include patients/consumers and families in all phases of the implementation effort, including training in the clinical innovation and advocacy related to the innovation effort	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 available evidence- supported treatments
CFIR domain —construct affected	Characteristics of individuals—knowledge and beliefs about the intervention	Characteristics of individuals— knowledge and beliefs about the intervention Inner setting— implementation dimate	Process—engaging innovation participants Outer setting—patient needs and resources	Process—engaging innovation participants Outer setting—patient needs and resources
Name of the strategy	Conduct educational meetings	Identify and prepare champions	Involve patients, consumers, and family members	Prepare patients/ consumers to be active participants
Theme		Champions	Patient needs and resources	

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Justification empirical evidence, theory-based evidence, pragmatic justification	Empirical (33), pragmatic from experiences of HCPs	Theory-based (22), pragmatic from experiences of HCPs and researchers	Pragmatic
Implementation outcome affected	Fidelity	Fidelity, appropriateness	Implementation
Dose	In every consult/training, motivational talks will be held. Before every appointment, a reminder of the appointment will be sent. Once/twice a week, extra information will be sent per email. Information will be sent after completion of the program; the end date is advised to be after at least 1 year	Before implementation, ProMuscle will be discussed with HCPs to assess which elements they can deliver and what elements are evident. The literature will be gathered about the working elements	Before implementation, researchers will interview older adults to assess effective ways to engage possible recipients of ProMuscle and share this with HCPs. During the intervention, HCPs will ask recipients for feedback about the implementation process during the training/consultation and, if necessary, adapt the intervention to their needs
Temporality	During the intervention	Before, during, and after the implementation	Before implementation and during intervention
Targets	Recipients of ProMuscle	Make sure HCPs can match the intervention to the characteristics of recipients without losing the working elements of the intervention	Make sure that the recruitment and the intervention align with the needs of recipients
Action	Sending reminders and extra information to recipients through email/phone and motivational conversations during the intervention	Assess the adaptability of ProMuscle; investigate which elements can be adjusted and which elements should be maintained; measure patient outcomes and collect adaptions during the implementation; tailor the intervention to patient needs	Assessment of effective ways to engage recipients of ProMuscle during interviews with older adults; HCPs give recipients possibilities to give feedback on the intervention and implementation
Actors	НСР	RG IO HCP	RG HCP
Definition of the strategy	Intervene with patients/ consumers to increase uptake of and adherence to clinical treatments. This includes consumer/ patient reminders and financial incentives to attend appointments	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	Develop strategies to increase patient/ consumer and family feedback on the implementation effort
CFIR domain —construct affected	Process—engaging innovation participants Outer setting—patient needs and resources	Outer setting— patient needs and resources Intervention characteristics— design quality and packaging	Outer setting— patient needs and resources
Name of the strategy	Intervene with patients and consumers to enhance uptake and adherence	Promote adaptability	Obtain and use patients/ consumers and family feedback
Theme			

RG, research group; HCP, healthcare professional; CH, champion; IO, intervention owner.



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Partnership-building considerations for implementation science in learning health systems: a case study of the Implementation Science Collaborative in Alberta, Canada

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Introduction: Implementation of health innovations is inherently collaborative, requiring trans-sectoral partnerships between implementation researchers, innovation teams, and implementation practitioners. Implementation science has been shown to improve implementation successes; however, challenges that hinder partnerships to advance implementation science continue to persist. Using a whole-system approach to assess and respond to implementation science partnership barriers may shed light on effective responses.

Methods: We conducted a case study of Alberta's learning health system, using semi-structured group and individual interviews to create a nuanced understanding of the considerations required for implementation research collaborations. We interviewed 53 participants representing 21 offices in the health system, academia, professional associations, and government who regularly plan, evaluate, and/or study health system implementation initiatives in Alberta. Using the Partnership Model for Research Capacity Building, we identified current facilitators and challenges for partnerships for conducting and using implementation science, at different levels of Alberta's health-research ecosystem. Results: Alberta's healthcare system is well set up to readily embed intervention effectiveness and efficacy research. Infrastructure was also in place to strengthen implementation practice. However, weaknesses around exchanging knowledge and skills, providing feedback and mentoring, and accommodating diversity affected the ability of both individuals and teams to build implementation science capacity. Without this capacity, teams could not participate in embedded implementation research collaborations. We report the response of the Alberta Strategy for Patient-Oriented Research SUPPORT Unit to these barriers to provide practical guidance on various program options to strengthen individual- and organization-level implementation science capacity. **Discussion:** This study applied a whole-system approach to assess factors across Alberta's health-research ecosystem, which affect partnerships to advance implementation science. Our findings illustrated that partnership considerations go beyond interpersonal factors and include system-wide considerations. With the results, health organization leaders have (1) a method for assessing organizational capability to readily embed implementation research and (2) a catalog of potential responses to create conditions to readily engage with implementation science in their day-to-day implementation processes.

KEYWORDS

implementation science, relationships, partnerships, research capacity, learning health systems, embedded research

1 Introduction

Increasingly, incorporating implementation science (IS) into change initiatives is recognized as a cornerstone activity of learning health systems and other health organizations committed to continuous improvement and evidence-based care (1–4). Furthermore, the importance of IS capacity has been suggested as a core competency for embedded health systems researchers (1, 5, 6) and implementation practitioners (7). IS is defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and hence, to improve the quality and effectiveness of health services" (8, p. 1). As such, people working in health promotion, prevention, and healthcare embrace IS because it enables innovation teams with evidence-based strategies to best apply and sustain change in the real world (9, 10).

In the context of IS, implementation researchers are defined as people who study implementation methods and generate knowledge to promote the uptake of evidence-based policies and practices (11). However, implementation research is not simply an activity to be undertaken by individuals. To ensure the relevance and applicability of implementation research, the science should be co-produced through close collaboration between implementation researchers and implementation support practitioners (12-14) [i.e., those who use the findings from implementation research to strengthen the implementation, spread, and scale of change efforts (11)]. Indeed, academic-practice partnership is considered a key component of implementation as it contributes to closing the research-to-practice gap (13, 15, 16). Such partnerships provide opportunities to create relevant and applicable knowledge about implementation (13, 15, 16). These partnerships can be between implementers, implementation support practitioners, researchers, healthcare staff, policymakers, patients, and any other party interested in or impacted by implementing innovations. Nevertheless, current studies highlight a persistent gap between implementation research and practice, emphasizing that many implementation research partnerships lack the degree of collaboration required to create actionable implementation recommendations that can be scaled, spread, or sustained (11, 12, 16).

There is growing interest in the IS community to resolve misalignments between implementation researchers and support practitioners that limit the uptake of IS. Training models have been developed to build a cadre of highly trained implementation researchers (17, 18). Similarly, teams continue to develop implementation support practitioner competencies to facilitate the uptake of evidence-based change using IS models and frameworks (19, 20). Team and organization models have been developed to support implementation research collaboration

across the academic-health research ecosystem (21–24). Less attention has been paid to the systems within which individuals and teams work, and what system enablers are required for organizational leaders and staff to readily embed implementation research. Given the importance of academic-practice partnerships in IS, understanding partnership enablers and challenges at the micro-, meso-, and macro-level of the local systems is critical to resolving the implementation research-to-practice gap.

Embedded health researchers are increasingly utilized to facilitate academic-practice partnerships. These researchers are housed as members of health service teams where they collaborate to conduct research in real-world settings (25). Through this collaboration, embedded researchers also help build healthcare professional capacity to utilize evidence as it emerges (26). Embedded health researcher models vary but often these researchers act as conduits between healthcare delivery and academic research teams or may have academic crossappointments themselves (25, 27). Research examining embedded health researcher models in healthcare provides critical insights organizational capacity to enable collaborations (27-31). These studies highlight the characteristics of embedded research partnerships (27), including individual skills required to build research partnerships and use evidence created in embedded research (29). These areas of the literature highlight that factors throughout the local academic-health research ecosystem affect embedded research relationships [e.g., individual skills (28, 29, 32), team dynamics (27, 30), organizational research culture (31, 33, 34), organizational research infrastructure (30, 31, 33, 34), and whole system engagement (30, 31)]. These findings focus on the effect of existing enablers and challenges, rather than on preparing systems to readily embed research. Furthermore, the limited studies that examine such preparation are sector-specific (28, 30, 34, 35), leaving an ongoing gap around how to increase system readiness to embed implementation-specific partnerships. Consequently, guidance is limited on how to enable between implementation researchers collaboration implementation support practitioners.

For this this study, we used a whole-system approach following the definition of Komashie et al.: "...a way of addressing health delivery challenges that recognizes the multiplicity of elements interacting to impact an outcome of interest and implement [ation of] processes or tolls in a holistic way" (36, p. 2). Through this approach, our study provides insights into the factors at various system levels that impact academic–practice partnerships to advance IS. To help build an understanding of how to respond to such factors, we also describe how one organization in Alberta, Canada, chose to overcome the barriers identified in this study and strengthen the provincial health system's ability to

readily embed implementation research. Our research does not aim to evaluate the initiative described. Rather, we use a single case study approach to illustrate the process of assessing and strengthening whole-system readiness to facilitate embedded implementation research partnerships and increase IS capacity.

2 Methods and materials

2.1 Study design

We used a single case study design because of its suitability for exploring complex system factors affecting research collaborations (37–40). This qualitative case study focused on partnership considerations for various potential partners involved in advancing IS in Alberta, Canada's health-research ecosystem.

2.2 Case characteristics

Canada is split into 10 provinces and 3 territories with some governance being the responsibility of the federal government and some of the provincial/territorial governments. Healthcare is funded by the federal government, but provinces and territories are responsible for designing, managing, and delivering health services (41). Alberta's healthcare delivery and some public health functions are managed by a single province-wide health authority, Alberta Health Services (41, 42). Alberta Health Services delivers care through provincial-level programming as well as through five regions, called zones, that provide health programs in locally relevant ways, meeting the needs of urban, rural, and remote settings (41, 42).

The provincial government and Alberta Health Services have heavily invested in health research infrastructure through Alberta Health Services' incoming electronic health record system (43) and Strategic Clinical NetworksTM (SCNs). The electronic health record is a key feature of Alberta's learning health system, as it enables real-time capture of health experiences and outcomes to support learning and improvement (1). The SCNs are large research and innovation teams embedded into the health system to facilitate the uptake of evidence-based care from piloting programs through spread, scale, and sustainment (44). The SCNs partner with provincial and zone-level program offices, operations teams, patients, academic researchers, and other interested parties to conduct research and implement change (45). SCN-University Liaisons use their cross-appointments at SCNs and different Albertan post-secondary institutions to assist with this facilitation (46). The SCN structure provides a key learning health system link between clinicians and researchers to identify and answer key questions with rigor to inform policy, practice, and funding decisions in the health system (47). The SCN staff are highly trained in quality improvement, and many team members have advanced research degrees. As such, the SCNs are understood as the engine driving Alberta's learning health system (47); however, the teams have varying experience with IS specifically.

This environment has a strong embedded research culture and supportive infrastructure in place to conduct intervention efficacy and effectiveness research. However, interest and capacity in implementation research in Alberta are fragmented (22). Besides the SCNs, Alberta also has numerous other health research networks and intermediary organizations [i.e., organizations responsible for knowledge transfer and mobilization (48)] that further support implementation practice and research in the province. One of these intermediaries is the Alberta Strategy for Patient-Oriented Research SUPPORT Unit (AbSPORU). AbSPORU is part of a national strategy funded by Canada's main health research funder, the Canadian Institutes for Health Research. AbSPORU's mandate is to build partnerships and provide research, knowledge dissemination, and implementation services that support moving evidence into practice, specifically to strengthen Alberta's learning health system (22). AbSPORU's mandate is set broadly to respond to health system needs as they emerge. Therefore, the latitude AbSPORU has to support implementation through partnerships and services, however that may look for the health system in a given moment, makes the organization an ideal host for various collaborative initiatives to advance IS (49). At the time of writing, AbSPORU's implementation support services included implementation science training and consultations for implementation planning, evaluation, and research. AbSPORU has also hosted conferences, implementation-specific events, and collaborative discussion forums to bring together various parties interested in and impacted by implementation, build implementation partnerships, and strengthen provincial implementation initiatives. Consequently, AbSPORU facilitates implementation research and practice partnerships with the long-term aim of increasing embedded implementation research.

AbSPORU's implementation support services pre-existed this research. These supports stemmed from a needs assessment completed in 2016, reported by Thomson et al. (49). This assessment found that inaccessible IS evidence, exacerbated by deficient knowledge sharing opportunities for change agents, limited IS capacity in the province (49). In response, AbSPORU built numerous initiatives around four core needs: (1) consultation, (2) community of practice, (3) capacity-building, and (4) contributing to knowledge translation and implementation science. The current study was conducted to assess provincial changes in Alberta's health research context and inform ongoing suitability of AbSPORU programming.

2.3 Participants

Between August and December 2022, we conducted 21 semistructured interviews with 53 participants representing 21 offices in academia or the health system who regularly plan, evaluate, and/or study health system implementation initiatives in Alberta (Table 1). We recruited interview participants based on responses from an online survey administered before 2 years. The original survey was distributed to collect data for a social network analysis of Alberta's implementation community (manuscript development underway). The survey was sent to people involved in planning, evaluating,

and studying implementation in Alberta. The goal of this survey and social network analysis was to learn who in the province was involved in implementation support and/or research and how these actors collaborated or not. Respondents who identified that they had engaged in implementation academic–practice partnerships in Alberta were invited to participate in these follow-up interviews reported in this article.

We held individual (n = 14) and group (n = 7) interviews. Group interviews ranged from 2 to 10 people per interview. The 21 offices interviewed represented a spectrum of experiences with IS, with the majority (n = 10) facilitating implementation, some (n = 6) participating in IS research activities, and others (n = 6) actively conducting IS research.

The nature of implementation work varies across the actors in Alberta's implementation community. Some people work in collaborative teams and others act as sole implementation representatives of offices, academic departments, organizations. Because of this range, we offered to hold group or individual interviews to the participants' preference. People who worked more independently (e.g., academic researchers) most often opted for individual interviews and those who worked on highly collaborative teams (e.g., SCNs) chose group interviews, citing the interviews as opportunities for team members to share and learn from one another. As such, the number of SCN participants appears to be over-represented; however, SCN teams were considered as one interview each, similar to how a single academic or policymaker would represent a lab or a government office, for example.

2.4 Data collection

Semi-structured interviews were conducted either in person or virtually over Zoom and ranged from 30 to 85 min in duration. All interviews were conducted by the lead author with a co-researcher (CA) also attending all interviews to ensure coverage of the interview guide. The same interview guide was used for all interviews. Our interview guide addressed (1) organizations' implementation work history and capacity, (2) criteria and processes for establishing collaborations, (3) facilitators and barriers to collaborations, and (4) recommendations to strengthen future collaborations to advance IS. This guide was developed to contextualize the results of the social network additional implementation and inform what infrastructure would increase engagement in IS partnerships by various potential partners in Alberta. We asked participants to reflect on past experiences collaborating for implementation practice and research to answer the interview questions. Our goal was to identify how to address challenges and strengthen IS capacity in Alberta.

Interviews were audio-recorded, transcribed verbatim, and reviewed for accuracy. We also conducted two member-checking activities to give participants opportunities to clarify their contributions, include any comments, or ask additional questions. Participants were given a summary of their interview responses before analysis to ensure we accurately captured and

understood their answers to the interview questions. Feedback from the first interview summary was clerical in nature (e.g., clarifying the organization structure). We integrated all feedback into the final analysis. Participants were also given a preliminary analysis after all interviews were completed. We asked whether the analysis resonated with the participants and if they had any additional insights to add. Members from four of the interviews responded and confirmed that the analysis resonated. No one had additional feedback on the analysis.

2.5 Data analysis

NVivo 11 qualitative analytic software (50) was used to organize and manage transcripts of the audio-recorded interviews. Directed qualitative content analysis was used to code the interview data both inductively and deductively (51). Deductive coding was guided by the Partnership Model for Research Capacity Building (35) (referred to as the Partnership Model in the remainder of this article) to examine whether the overall system is set up to readily embed implementation research into real-world implementation initiatives. Inductive coding facilitated thematic coding for a more nuanced understanding of partnership considerations.

Each interview transcript was coded by two researchers (SB and CA) who also reviewed each transcript together to check individual biases and bring richer analytic power by analyzing the transcripts through two perspectives (52). Analytic rigor was further enhanced through regular meetings after each interview to discuss emerging findings. After each interview, the dataset was considered, and saturation was suspected nearing the end of our scheduled 21 interviews. We conducted the final two to three interviews already scheduled and confirmed saturation as no new information emerged (53). This approach to coding helped identify barriers and facilitators that could be strengthened to increase partnerships to advance IS in Alberta's health system. Moreover, individual and team-level capacity to engage in IS was assessed based on participants' self-described historical roles in embedded implementation research.

All study participants provided informed consent to be included in this research. The research design was approved by the University of Alberta Research Information Services, Research Ethics Board—Health Panel (ID: Pro00084611).

2.6 Theoretical framework

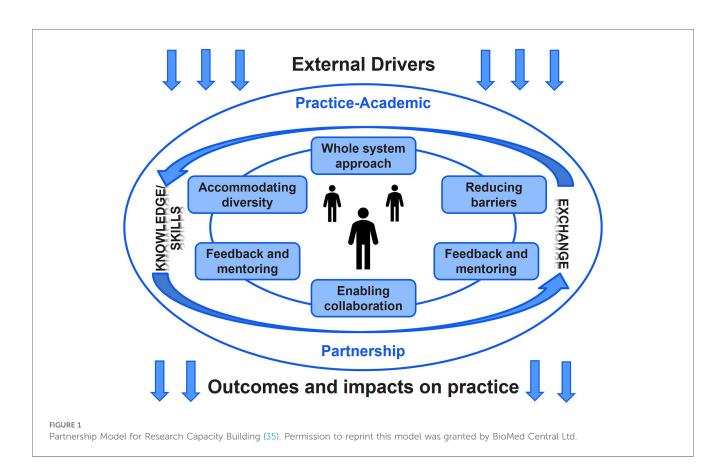
The Partnership Model (Figure 1) is a theory-based model, developed to build health organization research capacity in one health professional group, speech and language therapy (35). The authors of the model emphasize that, "The need for researchers to be aware of how findings will be used and interpreted by healthcare professionals, and for the research to reflect issues relevant to those at the interface of patient care, are both paramount to successful implementation of research outcomes", (35, p. 289). They posit that collaborative research between

healthcare professionals and researchers creates this synergy by ensuring researcher relevance and healthcare professional ability to critically engage with evidence. To achieve this engagement, both individual research capacity and a research-enabling context are required. Together, these two required elements dictate the research readiness of a given health research ecosystem (35).

The model's developers recognize research relevance as vital for successful implementation. However, their work refers to intervention and health outcome research, stopping short of using the model to assess implementation-specific research readiness. The distinction between intervention and implementation research is important as knowledge from both fields inform implementation practice (54). Therefore, engagement in IS partnerships is critical for ensuring the successful uptake of health innovations (54). Despite the narrow scope of the original model, Whitworth et al. claim that the Partnership Model is transferable beyond the domain of speech and language therapy (35). This transferability was an attractive feature for our research team given the model's whole-system view of research readiness and its emphasis on practice-academic partnership. Furthermore, this framework focuses on the contextual factors that underpin an organization's research capacity-building capabilities, a key interest of AbSPORU given its capacity-building mandate. Thus, we used this framework to assess Alberta's capacity to conduct implementation research and use IS in practice. In turn, this study also enabled our team to gauge the usefulness of the Partnership Model to assess IS capacity and context.

The Partnership Model outlines essential components of effective embedded research environments. The model places

particular importance on practice-academic partnership, which enables reciprocal knowledge and skills exchange across partner organizations. Knowledge and skills exchange is considered a key feature of research-ready organizations because it indicates the ability to align the values of different organizations into integrated collaborations. Research-ready systems follow six principles in their research work, represented in boxes in Figure 1, which underpin effective partnerships to increase the research capacity in healthcare settings (55). First, research-ready systems support a whole-system approach that enhances the potential for professionals at different stages of their careers embedded research opportunities and develop organizational research pathways. Second, accommodating the diversity of individual research interests, learning styles, and backgrounds is required to align inter-organization priorities and work processes. Third, facilitating networking opportunities between different parties involved in potential research helps link teams with similar interests who would not otherwise connect through regular day-to-day work. Fourth, enabling collaborations across system levels, sectors, and professions is especially important for organizations supporting intra- and interdisciplinary collaborations, such as implementation research (21-24). Fifth, providing feedback and academic mentoring increases skills for planning, funding, and conducting research. Sixth, research-ready organizations make ongoing efforts to identify and overcome barriers to embedded research [e.g., build funding opportunities for priority research areas (35, 47)]. Finally, the model couches all components in external drivers



and the goal of impacting practice and patient outcomes, represented by the arrows entering and exiting the rest of the model. External drivers differ by the research partner, dictating the shared focus of the collaboration, motivations to collaborate, and conditions within which each partner can contribute to a given academic–practice partnership. Proposed outcomes and impacts are related to the external factors as they create motivation, act as the basis for securing academic–practice partnership resources, and help establish research mandates.

3 Results

We used the Partnership Model of Whitworth et al. (35) as our analytical framework to code the data because it helped provide insights into enablers and challenges to readily embedding implementation research in Alberta's health system. We found that Alberta had many enablers in place to facilitate embedded intervention efficacy and effectiveness research, but that numerous challenges remained for embedding implementation research specifically. Below, we describe the participating teams' and individuals' experiences with collaborating to conduct implementation research and use IS in implementation practice. The remaining results are categorized by the components of the Partnership Model, followed by a summary of AbSPORU's various efforts to increase IS capacity across the province. Each section includes exemplar quotes. For improved readability, and where meaning remained unaffected, we removed non-lexical terms (e.g., um) and grammatical errors.

3.1 Participants' existing experiences with IS collaborations

The participants included implementation researchers, implementation support practitioners, intermediaries, and policymakers. All of the participants stated that they value IS,

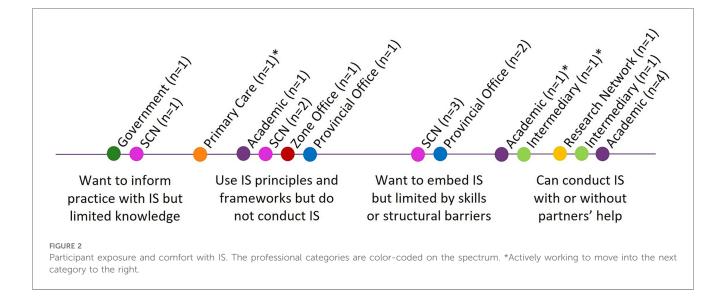
and most teams desired to engage in implementation research collaborations. However, some practice teams were not engaged in implementation research partnerships at the time of the interviews. The scope of each individual's or team's role in facilitating implementation or conducting implementation research varied. The participants also had varying experiences with IS (Figure 2).

Mapping the different teams to the spectrum in Figure 2 uncovered (1) individual and team IS capacity and (2) the strength of organizational mandates or expectations for teams to engage in IS. The spectrum highlighted participating teams' comfort and interest in being involved in IS. At the individual and team levels, this provided important information about what types of supports could be offered to increase IS capacity (e.g., formal training, informal guidance, and mentorship programs). Mapping teams onto this spectrum also provided insights into the organization-level mandates of different teams. For example, different SCNs, indicated by pink dots, fell across the spectrum, demonstrating a weak mandate from the organization for teams to engage in IS.

3.2 Practice-academic partnership

Interview participants described the health-research ecosystem as one that values transdisciplinary research partnerships. However, participants recognized the "messiness" of practice-academic partnerships and the effort it takes to align the different priorities and needs of the different partners:

I do think a lot of it is culture. I think we have to try and bridge what they call two solitudes. I think we have a research thing going and we have a health system thing going, and I think we need to get those closer together. I used to talk about research practice partnerships but again, the challenge there is: how do potential academic collaborators get rewarded for working with those of us in the health system? Because it



does get messy, and it does get a little bit difficult, and it can take people outside their comfort zone. But if we're thinking about young people who are coming into the system who need to establish themselves, we need to be able to uphold our end of the bargain as well (Provincial Office 2).

Building trust and strengthening relationships was paramount for teams across sectors to engage in partnerships to advance IS. Participants emphasized that building trust in relationships takes time and requires an ongoing commitment to delivering on partnership promises. Participants who worked to build relationships with health system teams said

To establish and build relationships with these teams and these individuals and to slowly build trust over time, people need to know that they can come to you, you will be helpful, and you will kind of adapt what your responses are to what their actual needs are. And that's something that takes a lot of time and is something that happens over the course of longer projects or multiple projects. That's really the biggest thing, how we as a team are able to support both the implementation support aspects and then the science aspects of the work going on (Intermediary 2).

I don't feel like you just bring someone on to bring someone on, unless can you get along ... I'm very much an optimist, and I like to see the positive side in any and all people. But I've also been here for a while as an academic, and I have had negative experiences with collaborators ... I tend to try to work on those relationships first ... I want to get to know that person and understand them ... I have a lot of really amazing partners who are open to my crazy ideas ... because I've built up that trust and rapport that IS is necessary and that this should be something that we're invested in, not just doing kind of these one-offs (Academic 6).

[Collaboration] is about lots of things, but the main thing is relationships. It's that trust. What facilitates trust is always delivering, because I've heard so many times from community that, "We wrote a letter of support for their grant and then we never heard from them again ... We're not sure what happened, and so we just don't want to work with them anymore, those university types because they don't deliver". And so, one of the things that I've done is that I have always delivered. It's hard and it takes time, and I'm always late because I'm saying yes to too many things, but I always deliver (Academic 5).

3.3 Knowledge and skills exchange

Knowledge and skills exchange is required to build enough individual capacity to identify opportunities and partner for embedded implementation research. Sometimes people with IS experience were hired to build research capacity within their teams. As one participant shared,

So locally, it has been trying to build capacity with the members, with the primary investigators and their teams within our large team. Also, an example of building capacities is being on multiple grants with our PIs if they are related to implementation. So those have been strategies to express or demonstrate the difference between implementation research or science vs. the application of implementation and support (Academic 4).

Some participants felt that this approach was potentially helpful for capacity-building and networking, as one SCN member said

... building awareness or introducing SCN scientists to academics who are doing IS because, then perhaps there would be more integration between the academics in IS and the SCNs (SCN 4).

However, IS knowledge was most often brought to implementation initiatives in the health system through one-way consultation, rather than through reciprocal knowledge exchange. This consultation model limited capacity-building in Alberta and inadequately supported change initiatives. Participants noted that for teams requiring external IS support, consultants need to be "sufficiently embedded" to understand the context and make useful contributions to the larger change initiative. As SCN team members who had previously worked with IS consultants stated,

When the IS works, it's sufficiently embedded in the day-to-day operations of a project. Whether that's the consultants stay with the project or whether another project lead feels that you know, that's in effect, what we're doing every day is IS and it works well. And that was our experience. If you ask the leaders of that project, they would say that every part of that project is IS. It's not something that we add on or we get kind of input on periodically from an implementation scientist. It is the purpose of the project (SCN 36).

My limited experience previously, not just with Alberta Health Services but with other places as well, is that when implementation scientists fly in and fly out, to consult on a project, it doesn't work. It has to be like a journey that we go through together. Otherwise, other consultants kind of fly in, fly out and they make comments and suggestions without really fully understanding the context and the nuances of each process, then it becomes sometimes a bit confusing, and people just look at that, like, how is that helpful to us? And so, in the end, they just don't use it (SCN 28).

Participants also described the lack of cross-sectoral pathways to communicate implementation research findings or practice lessons learned to other teams in the health-research ecosystem. As one participant said,

We need some sort of platform where somebody could go, they can search for information, where they can learn and just be

able to bounce ideas off of other people that have done something similar in the past. I think that's a gap we need to fill (Provincial Office 3).

A theme that ran through all of the interviews was that the terminology surrounding IS was confusing and in turn limited collaboration. Implementation facilitation, implementation support, quality improvement, dissemination, IS, and conducting IS were often conflated with one another. Participants who had successfully partnered for IS attributed a portion of their success to discussing IS in ways that resonated with partners. As one academic put it,

I've always believed that right from the start of this work, if we can't translate what we're doing as implementation or knowledge translation people, what are we doing? Even our terminology and the confusion around it. So, to me, it's key to be that facilitator and being able to translate to your audience that you're going to be talking to (Academic 4).

Participants from the health system also shared perspectives around terminology:

We had research-trained people, we had trained people, and then we layered design thinking on top of that. We have this tripartite thing, that was all driving towards the same end but they were using different languages to basically describe the same thing. And it really took a lot of work, it was [a senior leader] who did a lot of work in navigating a lot of tension between three groups (Provincial Office 2).

I think what might be useful is that when this area of expertise is being discussed, always gently share the definition of IS. Because I might call it something different as an evaluator, and others might call it something else. A program manager might call it something like "program planning", right? Or others might call it "Plan, Do Study Act cycles". There are so many different terms that kind of coexist in this space. But once you create that understanding that there might be different terms used, but we're all really interested in this. Then you start to understand there are certain frameworks that help understand those key concepts or constructs that you might want to explore as a group, and then develop that shared mental model of something that we're applying to the situation (Primary Care 1).

3.4 Accommodating diversity in a wholesystem approach

Alberta's health system had an existing culture of collaboration, where teams valued bringing in partners with different experiences and at different levels of their careers to jointly conduct research. Participants from across the professional groups included in this study appreciated opportunities for transdisciplinary research relationships. Participants overall felt well supported in

conducting collaborative research that uses a whole-system approach. Moreover, team members did not feel like their organizations forced them to use a whole-system approach, but rather felt that this approach strengthened their ability to engage with IS:

...[O]ther times, you get really good partnerships, and you get people who say, I've got an idea, and you go, well, let's talk about it. And then together, we co-design, and we co-work and we co-develop an IS for implementation research study. And those are the places where it works really well. And that it gets sponsored by our leadership, and so on, and so forth. It very much depends on the approach of a person who comes in and who wants that support, to do that type of work (Provincial Office 2).

Participants were cognizant that to successfully employ a whole-system approach, they needed to accommodate the different experiences that the different partners brought to IS collaborations. Some participants used a network approach, as one participant described,

We don't require participants to do certain things like they can participate as much or as little you know, any projects, again, are reviewed. It is what I call a whole system network. There are different types of networks, there's bottom up, top down or whole system. Whole system, we found, is usually more sustainable (Research Network 1).

Others described common approaches in quality improvement to support a whole system, including,

I think about our use of things like learning collaboratives, etc. as a way to bring all those diverse stakeholders together ... as the start or midway point of implementing some major change, and then having those same stakeholders get together at whatever frequency is needed to live that out (SCN 25).

Despite participants' commitment to a whole-system approach, fundamental misalignments between the work of implementation science and implementation practice diminished participants' efforts to collaborate. Specifically, healthcare staff work in contexts characterized by rapid change and urgency. Conversely, researchers are held to highly systematic and rigorous research planning and conduct standards that require more time than health systems can accommodate. Furthermore, research is often considered by health system teams as an activity outside of their mandated quality improvement initiatives. These misalignments complicate meshing academic rigor with health system expectations for rapid change. As one participant recalled,

We worked with a health system impact fellow to put together an ethics application consent form, assess all the risks, you know, a real good research protocol and push back comes back: "You research people are too slow. You're holding us up. This is just QI. We shouldn't be doing any research part

of it". And then a growing realization that actually putting a research framework around that did make the whole thing more robust, because a lot of the stuff that needed to be thought about was thought about up front. But it was a real struggle (Provincial Office 2).

3.5 Enabling collaboration

As noted in the Section 2.2 Case Characteristics above, many organizations in Alberta have worked to build infrastructure that enables overall embedded health research, resulting in a strong collaborative research culture. Participants commented on the SCNs and local health research funding programs [e.g., Partnership for Research and Innovation in the Health System Program (50)] as key health research collaboration enablers. Some of the departments or organizations represented by the participants also benefited from their leaders having crossappointments and/or co-leadership models, facilitating academic-practice partnerships. One intermediary described this benefit as follows:

I think having co-leads from the system as part of our team has definitely increased our ability to sort of have that influence to apply the science and create those science studies in the system (Intermediary 1).

Despite these enablers and the organization-level research infrastructure in place, health system-based teams are still bound to the needs of their organization and must work within available resources:

If we're reaching out to somebody, then this is a project that is a priority for us. Presumably, we've created some time and funding. So the three things for any collaboration are time, funding, and priority. That's because we're part of the healthcare system. We can't just do whatever we want. You know, if I was an independent academic, maybe I have a lot more freedom to sort of explore areas of interest. But as it is, I have areas of interest, but often they are directed by the organization's need (Provincial Office 1).

3.6 Facilitating networking

While participants understood the value that IS would bring to implementation practice in Alberta, ongoing silos within and across organizations limited networking opportunities. These silos left teams unable to identify and reach out to potential collaborators across sectors. At times, people could meet through personal and professional connections. As one participant said,

My connections, those were really more through being introduced by colleagues, and not through an organized program. And again, maybe there is something like that, and I just didn't know about it. It was through colleagues in [my

faculty], who introduced me to Alberta Health Services folks who are doing work and wanted to collaborate on projects (Academic 7).

People did not suggest that the implementation research community was inaccessible or non-existent, rather it was simply not visible to potential health system teams, as noted by this participant:

I'm not even sure where to go to find the people who know what they're doing in this field, and that are comfortable in working in the messiness of healthcare delivery (Provincial Office 2).

Even participants with cross-appointments at academic centers struggled to find potential partners for implementation research:

There's probably very little broad knowledge of who the IS specialists are. I would say even myself, I am hard pressed to identify people at [my university] that I can refer people to ... so I would say that it's kind of word of mouth (SCN 27).

Importantly, participants never mentioned formalized or facilitated networking opportunities existing to help them meet others working in implementation practice or research.

3.7 Feedback and mentoring

Academic research partners provided regular input into discussions related to research ideas and methods. They also provided vital access to various research funding streams, all of which were important for career trajectory, as described by one participant:

A lot of [my current IS collaborators] were mentors to me as an early career researcher, so some of these were some of my first opportunities at being co-investigators on a grant, seeing what grant writing is like, being part of quite a big team (Academic 7).

However, formal feedback and mentoring are largely reserved for academic trainees, as health system teams leaned on IS consultants.

Despite the benefits of their potential mentorship, some of the academics interviewed were not actively encouraging their students to consider incorporating IS elements into their graduate programs. When asked if their students were engaged in implementation research partnerships, one academic participant said

No, they were not. Yeah, it really was just me and one of my colleagues doing IS ... I can't recall any students who came to me saying that they were interested in IS as a field of study (Academic 7).

Another academic participant commented that students indirectly participated in implementation, through engaged scholarship and intervention research, but none participated as

TABLE 1 Categories of participants involved in the study.

Type of organization	Number of interviews (n)	Number of interview participants (n)
Academics	6	7
Strategic clinical networks	6	35
Provincial offices	3	3
Intermediaries	2	4
Zone offices	1	1
Government	1	1
Primary care	1	1
Research networks	1	1
Total	21	53

implementation scientists embedded in the health system. This participant also noted that direct partnership opportunities were reserved for later-career academics:

They're developing, they're refining, they're adapting their intervention. They're generating the evidence for the interventions that they would be looking to have adopted in practice with ongoing funding from health systems ... but I mean, if technically they're just studying, implementing an intervention, they're not doing that because they're still assistant professors (Academic 5).

3.8 Reducing barriers—AbSPORU supports

Using the Partnership Model showed that at the time of writing this article, Alberta's system was well set up to readily embed efficacy and effectiveness research. Infrastructure was also in place to strengthen implementation practice. However, using the Partnership Model to categorize remarks made in the interviews uncovered weaknesses for embedding implementation research, specifically around exchanging knowledge and skills, providing feedback and mentoring, and accommodating diversity. All of these areas affected individual and team abilities to build IS capacity. Without this capacity, teams were not able to participate in embedded implementation research collaborations.

AbSPORU took a whole-system approach to strengthening system IS capacity and capabilities in Alberta. The organization leveraged existing enablers to develop various IS supports to address ongoing challenges at various system levels. AbSPORU's resulting suite of IS-related initiatives are delivered to strengthen IS capacity and infrastructure in Alberta (Table 2). The foundations of this program are presented in the Case characteristics section above. Below are examples of initiatives that also serve to overcome ongoing barriers identified using the Partnership Model in this study (i.e., individual IS capacity, exchanging knowledge and skills, providing feedback and mentoring, and accommodating diversity). Without these capacities and contextual factors in place, people cannot effectively engage in academic–practice partnerships (35).

To build individual and team-based capacity for IS, AbSPORU offers an IS Certificate program, open to academics and health

TABLE 2 AbSPORU's response to reduce existing barriers to embedding IS.

Barriers according to the	AbSPORU's response to
partnership model constructs	reduce barriers
Knowledge and skills exchange was most often offered through one-way consultation models instead of embedded, ongoing collaboration. There was also no mechanism to share lessons learned across implementation practice and research teams. IS terminology caused miscommunications, limiting conversations around potential IS partnerships.	AbSPORU provides embedded implementation research support where possible. A Lessons Repository was in development to support sharing implementation lessons learned across siloed teams. A Seminar Series offers a light-touch opportunity for people to learn from experts and to share experiences. The IS Certificate aims to clarify and standardize IS terminology across
	academic and health system teams.
Accommodating diversity was limited by misalignments between the priorities and work styles of academic and health system partners.	The IS Collaborative provides methodological guidance to strengthen: (1) IS capacity of people working with and on health system innovations (e.g., SCNs); and (2) proposed IS methods to help align rigor and practicality.
Networking opportunities were scarce for implementation support practitioners and implementation scientists.	The transdisciplinary membership of all IS Collaborative groups provides organic networking opportunities.
Feedback and mentoring were reserved for specific types of academic trainees, leaving others, including health system researchers, with little opportunities to build IS capacity.	The IS Certificate was developed to increase IS capacity for academics and health system staff who work to implement health innovations. The IS Collaborative provides IS-specific feedback for health innovation teams looking to incorporate IS into their work.

system staff wanting to conduct and use IS in their work. They also offer a monthly IS seminar series that brings international IS experts to discuss different frameworks and approaches they have used to partner and support real-world implementation initiatives. Alberta-based implementation support practitioners involved in the scale, spread, and/or sustainment of health innovations are invited to this series. In addition to capacity-building, the IS Certificate Program and seminar series offer networking opportunities for people working in implementation practice and research.

AbSPORU staff also work to provide mechanisms for knowledge exchange. At the time of this publication, staff were conducting foundational research to inform an online implementation lesson repository. The lesson repository is an effort to directly address the identified inability to share implementation knowledge between teams. The repository will also contain contact information so that potential IS collaborators can reach out to people with similar research interests.

Finally, AbSPORU facilitates a transdisciplinary initiative, called the IS Collaborative, that leverages existing IS expertise to build IS capacity locally (22). The IS Collaborative aims to address some individual and team-level capacity needs and strengthen other organization-level elements to overcome widespread barriers to IS partnerships (e.g., silos, work that is misaligned between research and practice). Specific details of the IS Collaborative are reported by Flynn et al. (22) and on the AbSPORU website (57). The most important element of the IS

Collaborative model to note for this article is its transdisciplinary nature. The IS Collaborative includes a Steering Committee and Working Group comprised of Albertans with implementation expertise from sectors across the health continuum. It also includes a Scientific Advisory Board, an international group of leading IS thinkers. Together, these groups offer in-depth IS methodological advice for otherwise research-capable health innovation teams (e.g., SCNs). The transdisciplinary nature of the IS Collaborative supports a whole-system approach to implementation research and practice by providing methodological insight that would help teams develop both rigorous and practical approaches to embedding implementation studies into their health initiatives. The IS Collaborative model is largely consultation-based, but when able, AbSPORU works to find ongoing embedded support that maintains connections with the collaborative. Some participants indicated that consultation models had limited usefulness for conducting implementation research. Nevertheless, AbSPORU proceeded with this model because they did not have sufficient funding to guarantee ongoing embedded support for all IS Collaborative-supported teams. To alleviate this limitation, the IS Collaborative provides consultation to otherwise research-capable teams. Consultants work to build implementation research capacity within these teams, rather than conducting implementation research for them. Consequently, the IS Collaborative works to end reliance on IS consultants over time.

4 Discussion

Our findings illustrate that IS partnership considerations go beyond interpersonal factors and include system-wide considerations. Many of the ongoing challenges for IS partnerships uncovered by this study suggest value in further integration between academia and the health system in Alberta. Without this integration, the province misses tremendous opportunities to leverage its provincial learning health system infrastructure to improve implementation methods. Specifically, our results showed that while Alberta has a very strong learning health system infrastructure in place, individuals and teams lack IS capacity, shared language, and communication pathways required to identify potential collaborators and discuss implementation research opportunities. Without these capacities and structures in place, teams cannot negotiate implementation research designs that balance practical needs with scientific rigor. Consequently, these challenges perpetuate misaligned work styles between implementation support practitioners in the health system and implementation scientists that thwart practiceacademic partnerships.

4.1 Individual and team IS capacity

Our participants emphasized the lack of IS capacity more than any other barrier. Given the extensive enablers in place in Alberta's context, this result verifies other study findings that the lack of IS capacity undercuts the benefits brought from additional research enablers (58). Interview participants had varied levels of capacity and interest even though teams had the same role in the same organization, suggesting that there is no clear mandate for academic or health system teams to engage in IS. An organization-wide mandate to engage in IS is unnecessary, but teams responsible for planning, evaluating, and sustaining change would benefit from IS training as it would help them identify implementation research questions in their work and discuss potential research opportunities with others. In addition, participating in academic-research partnerships strengthens practitioners' abilities to engage with emerging evidence (35). Engaging in implementation academic-practice partnerships can help implementation practitioners develop important competencies related to ongoing improvement. Specifically, these partnerships can help implementation practitioners to (1) keep abreast of implementation frameworks, strategies, and approaches; (2) become familiar with how these frameworks operate within local contexts; and (3) support implementation improvement cycles. These are core competencies for all implementation practitioners (20) and will be vital for those working in learning health systems' contexts that aim to strengthen implementation and sustainment methods, such as Alberta Health Services (47).

The closed nature of the IS community has previously been noted as a barrier for engagement in IS partnerships to advance IS (58). Our results suggest that gatekeeping elements may be present in Alberta's IS research community. Supervisors have good reasons to be cautious about when and where to involve trainees in practice–academic partnership; however, the finding that exposure to implementation research partnerships is more easily accessible for later-career researchers is problematic as other studies have found that active mentorship is the key for students to learn how to balance academic and practice priorities and to build networks for future partnerships (17, 21).

The importance of feedback and mentoring goes beyond supporting academic trainees. Access and exposure to IS increases engagement in IS by other partners, including health system teams (58, 59). The IS seminar series and the multistakeholder panels in the IS Collaborative deliver this exposure to interested researchers housed in academia or the health system. Other programs that aim to strengthen delivery science in learning health systems have reported positive outcomes from mentorship programs (17, 59). Adding a facilitated IS mentorship program for people throughout the health-research ecosystem could enhance the barrier reduction efforts AbSPORU has already put in motion.

Despite this study uncovering barriers that require additional attention, as described above, AbSPORU's current program already includes important components that are helping to strengthen IS capacity in Alberta. Key AbSPORU contributions include its IS Certificate Program and embedded research services. These supports ensure that health system partners receive more than consultation, which the participants indicated

as insufficient. These contributions allow people to acquire and develop key IS skills to use in future partnerships, a key positive impact reported in other embedded research initiatives (60, 61). Consequently, the increased capacity further strengthens the local learning health system (62).

4.2 Connecting and working with IS partners

Even though leaders in Alberta's health system have supported investment in infrastructure to support practice-academic partnership, potential implementation research collaborators struggle to find partners with aligned research interests, a common IS barrier (21, 59). In lieu of any networking opportunities, Alberta's teams turn to personal connections to identify potential partners with IS capacity. Our results corroborate other studies that highlight the importance of crossappointments for practice-academic partnership (30, 35, 62). Previous studies highlight the flexibility that cross-appointments provide for individual researchers to work in both practical and academic spaces (30, 35). Others point to researchers who also hold leadership positions in health systems and the power this can bring to negotiating research designs that balance rigor and practicality (62). Our study adds the power of non-researcher leaders with cross-appointments. Non-researcher leaders with cross-appointments can be critical for building academic-practice partnership simply because of their knowledge of the systems they work within. These leaders can act as brokers who help overcome the barriers associated with identifying and connecting with appropriate partners.

Beyond personal connections, our results suggest that developing an accessible mechanism to connect with other implementation community members would help address barriers to finding implementation partners. AbSPORU initiated building such a mechanism with a component to allow teams to share lessons learned in previous implementation efforts. As such, this mechanism could address both knowledge exchange and networking gaps that currently exist in Alberta.

Our participants emphasized that finding partners with aligned communication and working styles was as important as finding partners with complementary expertise. Ambiguity in IS terminology created barriers for our participants to engage in discussions around potential implementation research partnerships. The challenges created by loose, unclear, or misused terminology is an important issue to address, as shared language helps build partnerships and ensure that research ideas and evidence are accessible to all the partners (21). Further difficulties emerge in research collaborations because of the misalignment of needs and priorities between researchers and implementation support practitioners. This is a well-documented reality (21, 58, 63, 64) that the IS Collaborative aimed to pre-empt by including scientific and practice-based perspectives in all support provided to innovation teams. Integrating these perspectives was a key activity in early IS Collaborative planning (22). Furthermore, the multiple perspective conversations seemingly became a key strength of the initiative as they helped ensure that the resulting IS advice helps innovation teams to develop rigorous and practical implementation research designs. The IS Collaborative is currently undergoing an impact assessment, which will confirm whether this model of feedback helps increase IS ultimately conducted and used in Alberta's health system.

4.3 Enabling IS partnerships

The comments from our health system-based participants align with findings from other studies that fundamental organizational requirements enabling health system teams to engage in implementation research include dedicated time (30), funding (30, 31, 58), and priority or mandate (31, 58, 63, 64). For example, participating health system staff noted that Alberta Health Services encourages them to engage in implementation academic-practice partnerships. However, these health delivery teams were not given protected time or funding for these collaborations. Therefore, teams technically had the permission to engage but the mandate was too weak to successfully inspire implementation academic-practice partnerships. As mentioned above, organization-wide engagement mandates are not necessary, but if organizations want teams to engage in academic-practice partnerships, health system staff require time, funding, and the mandate. Without all three, the low relative priority of these potential partnerships will force teams to decline invitations to engage.

While participants acknowledged the need for funding to engage in implementation research, funding did not emerge as a central barrier to partnership. Indeed, participants cited provincial funding programs (i.e., the Partnership for Research in Innovation in the Health System Program and the Health Innovation Implementation and Spread Fund) (56) as facilitators. Possibly, funding was not considered a key barrier because the interview took place while new IS-specific funding streams were emerging in Canada. Specifically, Canada's federal funding agency, the Canadian Institutes of Health Research, had recently launched its Transforming Health with Integrated Care initiative, which includes an IS team grant component (65). While highly competitive, these new funding streams indicate a growing value of IS and may have helped participants think about barriers beyond funding that affect their partnership abilities.

The rich descriptions by our participants of facilitators and barriers to IS partnerships uncovered strengths and weaknesses throughout the system. As such, our results substantiate other studies that call for a whole-system approach to research capacity-building generally (21, 31) and confirm that developing IS capacity also benefits from a whole-system approach.

The Partnership Model of Whitworth et al. was useful for identifying local parties' capacity to conduct implementation research and subsequently mobilize the findings. The

Partnership Model also helped our research team think through which strengths can be leveraged and weaknesses must be addressed to increase academic–practice implementation partnerships in our local health system. Furthermore, the model helped design implementation support systems. This process of operationalizing the Partnership Model could be useful for other healthcare organizations trying to create conditions to readily embed implementation research and promote IS use in day-to-day implementation processes.

5 Strengths and limitations

Our study included participants representing labs, offices, and organizations across Alberta's health-research ecosystem, providing a rich sample of perspectives. Furthermore, the interview data and analysis were both reviewed by all participants, who were invited to share supplementary insights and feedback. This feedback was incorporated into the final analysis and presentation of the results. Nevertheless, trainees were not included in this study, consequently limiting the results to those that would benefit people in later stages of their careers.

Using the Partnership Model strengthened our analysis because of its alignment with our interests of identifying capacity and contextual factors that affect academic-practice partnerships. Specifically, we used the model to explore and understand IS capacity limitations and contextual factors that exacerbate these limitations. The knowledge created by using the Partnership Model helped us think about potentially beneficial capacity-building interventions. However, the model may not have helped capture other contextual factors the limit of use of IS in practice. Furthermore, the Partnership Model would be less appropriate for teams looking to implement specific interventions. In those cases, well-established IS models and frameworks (e.g., Consolidated Framework for Implementation Research) would be more appropriate for exploring implementation barriers and facilitators.

This research assessed a Canadian health system that is situated in a publicly funded, universal healthcare delivery model. As such, the components of the IS Collaborative model may not be transferable to other contexts. Nonetheless, the Partnership Model proved to be a useful tool for assessing the strengths and weaknesses of local embedded research capacity.

6 Conclusion

Using the Partnership Model to assess challenges across system levels was a useful exercise, as it helped see what strengths could be leveraged and what interventions could increase Alberta's ability to readily embed IS. The IS Collaborative was built to respond to the challenges identified by providing methodological support and building ways for

implementation teams to connect and learn from one another. At the time of this publication, AbSPORU was also delivering other capacity-building programs for individuals as well as developing a cross-sectoral mechanism to share implementation lessons learned. Together, AbSPORU and the IS Collaborative provide insights into developing a whole-system response to the challenges identified in the Alberta context.

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 humans were approved by University of Alberta Research Information Services, Research Ethics Board—Health Panel. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

SB: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. CA: Data curation, Formal Analysis, Investigation, Software, Validation, Writing – original draft, Writing – review & editing. DT: Conceptualization, Funding acquisition, Resources, Supervision, Writing – review & editing. SD: Conceptualization, Methodology, Supervision, Writing – review & editing. KS: Conceptualization, Methodology, Supervision, Writing – review & editing.

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Conflict of interest

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A qualitative study of the implementation and organization of the national Greenlandic addiction treatment service

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Background: Alcohol and cannabis use constitutes the major public health problems in Greenland. Thus, it is important to assess if Allorfik, a new national outpatient addiction treatment service introduced in 2016, was implemented successfully and how it is perceived. Allorfik introduced local treatment centers offering a treatment methodology (motivational interviewing and cognitive therapy) new to addiction treatment in Greenland with limited evidence from Indigenous populations such as the Greenlandic. The present study investigates the implementation of Allorfik from the perspective of those engaged in the process and the field.

Methods: Data consisted of transcribed interviews with 23 individuals from both Allorfik and organizations collaborating with or supposed to collaborate with Allorfik. The theme of the interviews was their perspectives on the implementation process, enablers, and obstacles in the process and how Allorfik was performing at the time of the interview. The interview guide was informed by implementation theory. The transcribed material was analyzed using a general inductive approach.

Results: The analysis resulted in three overall and interconnected themes, namely, implementation, collaborations, and challenges. The implementation was overall considered a success by the interviewees as all components were implemented as planned with a few adaptions, e.g., a treatment guideline update. The collaborations are considered challenging but important to all interviewees. Collaborations seem to rely on personal commitment as opposed to well-defined structures, making it unstable and vulnerable to changes in staff. One of the main challenges highlighted by the interviewees is the number of problems other than addiction among people in treatment, which makes addiction treatment and recovery difficult to achieve. Nevertheless, the high levels of other problems being treated in Allorfik highlights the need for easily accessible therapy as many find that Allorfik is the only place to turn to in times of crisis.

Conclusion: Allorfik seems to have been implemented in accordance with original intentions and plans for addiction treatment service but has also become more than just a service for addiction treatment with easy access in a country with vast distances and limited resources.

KEYWORDS

implementation, alcohol, cannabis, addiction, treatment

1 Background

Alcohol and cannabis use has been one of the biggest health and social challenges in Greenland (1, 2); thus, addiction treatment services are important for a portion of the population. In 2013, Naalakkersuisut (the Government) was imposed by Inatsisartut (the Parliament) to (1) analyze the local need for treatment for addiction and the societal gains in providing the treatment free of charge (3) and (2) to present a plan for Inatsisartut for the future national addiction treatment service in spring 2015 (4). The plan presented was approved and funded through the Finance Act starting in 2016. The central aim of the new national plan was to provide differentiated treatment methods and treatment as close as possible to the homes of the people in need. Alongside, a privately established facility using the 12-Step Model for treatment in the capital, Nuuk, the government thus established a new treatment system, Allorfik, for outpatient treatment of addiction to alcohol, cannabis, and gambling, free of charge for users (4). The plan described that the foundation for treatment methods should be motivational interviewing (MI) and cognitive behavioral therapy; however, access to the 12-Step Model (5) for treatment with approved counselors should be continued. The recommendation of methods of the plan was made with respect to being sensitive to the Greenlandic context; however, with scarce and not easy-toconvert evidence on addiction treatment methods for Inuit or Indigenous people, the recommendation of treatment methods was based on the available medical evidence and best practices from Western societies.

In general, evidence on methods in addiction treatment among Inuit and Indigenous people is sparse; however, a review paper from Andersen et al. examined the treatment for alcohol addiction among Indigenous people (6). This review identified 19 studies, primarily from North America, and tentatively concluded that medical treatment with naltrexone seemed to be effective in reducing heavy drinking, and MI seemed to be an effective psychosocial treatment approach among the Indigenous populations studied. Another important point from Andersen et al. was that although the basis of the review was scarce and the studies included were hard to compare, community-driven approaches, traditional healing methods, and inclusion of other cultural elements seem to be very important in providing good treatment for alcohol use disorders across different Indigenous populations (ibid). A few other examples supporting the use of MI in interventions for people with alcohol addiction in Indigenous populations were found (7, 8). MI (9) and cognitive behavioral therapy (10) were well-established and widely used in other countries, e.g., England (11) and Denmark (12). However, these treatment methods were unfamiliar to addiction treatment in Greenland before the establishment of Allorfik, and in the case of the 12-Step Model for treatment, the efficacy of the methods has primarily been evaluated in Western populations and not among Inuit.

Implementation of a treatment strategy involving both new methods and a new organization nationwide in Greenland can be

considered a huge task, which is a type of task that has not been studied before. Studies on the implementation of addiction treatment so far have primarily focused on, e.g., barriers toward the implementation of evidence-based treatment (13) and the implementation of new elements in the established treatment services, e.g., telemedicine (14) or services for an underserved target group (15); however, studies on the implementation of new addiction treatment services and implementation of new methods nationwide to our knowledge have not been performed yet. Furthermore, the treatment service in Greenland was particularly interesting because of the lack of evidence-based knowledge about treatment in Indigenous populations in general, because the methods of MI and cognitive behavioral therapy specifically were new to addiction treatment in Greenland when implemented, and because of the high impact of addiction on public health and to human suffering in Greenland (1, 2, 4, 16). So far, only a few studies have been published about the functioning and outcome of treatment delivered by Allorfik (17-20). These studies primarily investigated specific aspects of the treatment and the characteristics of people attending treatment, not of the provision and the organization of the treatment service itself. Thus, the study "Evaluation of the implementation of best practice models in the treatment of alcohol and other addictions in Greenland" was initiated, which aimed to evaluate the implementation of Allorfik from a series of angles. The present study was the first sub-study of this overall evaluation, and the following sub-studies will investigate the quality of treatment and how the people in treatment manage after treatment.

The present paper aimed to investigate the implementation process and organization of the new treatment service, Allorfik in Greenland seen through the eyes of those involved, i.e., planners, staff, and collaborators. The objective was to investigate the barriers and facilitators of the implementation process and assess if Allorfik was implemented in adherence with the original plans for a new addiction treatment service according to those involved in the process.

2 Materials and methods

2.1 Setting

Greenland is the home of approximately 56,600 inhabitants with the majority living in the capital municipality, Kommuneqarfik Sermersooq. Greenland was a Danish colony until 1953 and is now part of the Kingdom of Denmark with a self-rule status since 2009. Approximately 60% of the population live in one of the five largest towns (with an Allorfik center), 25% live in smaller cities, and ~15% live in settlements. Almost 90% of the population are Inuit or Inuit descendants, and the largest minority is Danish (21). The infrastructure in Greenland is difficult since no roads connect towns or settlements, and transportations are thus done by air or sea. The public administration is similar to many of the Scandinavian countries, e.g., all health services are free of charge (22).

During a period of 3 years, Allorfik stepwise opened, from South to North Greenland, outpatient treatment centers in the largest town in each of the five municipalities. As of the summer of 2018, Allorfik has established a treatment center in each of the five main cities: Qaqortoq, Nuuk, Sisimut, Aasiaat, and Ilulissat. The implementation of Allorfik centers started in Qaqortoq in November 2016 and ended in July 2018 in Aasiaat. People in need of addiction treatment can be referred to treatment by a social worker or employer or simply seek treatment themselves by contacting their local Allorfik center, free of charge. In addition, people not living in a town with an Allorfik center have an additional series of treatment options via the Internet or telephone or local treatment by a traveling private partner using the 12-Step Model for treatment in smaller towns. Moreover, people living in settlements and towns without an Allorfik treatment center can be temporarily relocated for an intensive day treatment in Nuuk, again with a private partner using the 12-Step Model of treatment method. The 12-Step Model of treatment method in Nuuk implies an intensive daily recovery process oriented towards total abstinence and accepting addiction as a chronic disease, and the counselors' training builds upon the 12-Step Model of treatment (23), the Alcohol Anonymous movement (24) in Greenland, and the Minnesota Model for treatment (5).

After treatment conclusion, a 6-month group-based aftercare program is available for people who have been in treatment, irrespective of the treatment method during treatment (i.e., an offer to both people receiving treatment in Allorfik and for people receiving the 12-step treatment). In 2021 almost 1,000 people were referred to treatment, and 741 treatment courses were completed (25), but the total number of people referred to treatment and completed treatment courses dropped to 753 and 543, respectively, in 2022 (26). The decline in numbers in 2022 was caused by several factors including COVID-19 and a massive water damage to the treatment center in Nuuk, which caused the center to temporarily close and later move its facilities.

From 2018, Allorfik consisted of five treatment centers, a central administration and knowledge center located in Nuuk, and, in addition through a partnership agreement with a private provider, referred persons in need to intensive day treatment in Nuuk. In the local treatment centers, there was a minimum of three counselors available, offering treatment courses. The internal organization of Allorfik has changed a bit throughout the years in Allorfik. In the early days, a cognitive behavioral psychotherapist and, later, two psychologists were employed to support the implementation process. The psychotherapist and the psychologists' main function was to be part of the management group and support the Allorfik centers and the counselors individually, to train new employees, help implement guidelines, and supervise the counselors both in groups and individually. However, after a few years, these positions were no longer staffed, and the supervision and training were instead handled either from within the organization or by experienced external consultants, both from Greenland, by means of visiting supervisors from Denmark and via online support.

2.2 Methodology

The present study's focus on the establishment and implementation process of the treatment service has informed both the study design and analysis. While the implementation of Allorfik had taken place prior to the start of the present study, the focus of the present study was to understand what had influenced the implementation process, seen in retrospect, and not a process evaluation taking place alongside the implementation. According to Per Nilsen's terminology (27), the study used the methodological framework RE-AIM (28) as inspiration for forming this study-especially when developing the interview guide and deciding who to invite for interviews. RE-AIM has five main constructs: reach, effectiveness, adoption, implementation, and maintenance. A central assumption of how the impact of an intervention relies on the combined effect of the five constructs (29). The interview guide was developed around the RE-AIM framework constructs and the descriptions of Allorfik to ensure the inclusion of all elements of implementation and the central treatment elements of Allorfik. The interview guide was discussed with both the author group and the reference group and adjusted accordingly.

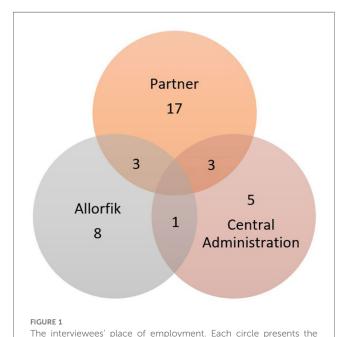
This study has been approved by the Research Ethics Committee for Scientific Health Research in Greenland.

2.3 Reference group

Inspired by community-based participatory research (CBPR) and the previous work in Greenland with community engagement and strength-based research (30-32), the overall study established a reference group. It was not the focus of either the present sub-study or the overall study to have a complete CBPR approach but with inspiration from CBPR to do a study with emphasis on being inclusive and respectful to the community perspectives to research project and to have a transparent process with a strong link to the context of the study. Therefore, the study established a reference group to advise on the project; discuss the research plans, process, and results; and disseminate the results and recommendations, if the study found any. The participants of the reference group were chosen to represent different geographical areas in Greenland and different professions, consisting of five people in total: one from health research in Greenland, two Allorfik staff (not in a managing position), one from the central administration, and one collaborating partner from a municipality. During the first meeting, the overall research plan and the interview guide for this study were discussed. During the second meeting, the participants were presented with the tentative findings of the present study, i.e., quotes from the interviews and preliminary identification of emerging themes to let their perspectives inform the process, analysis, and conclusions of this study. None of the participants in the reference group were reimbursed for their time, and participation was voluntary. Meetings were held within normal working hours and lasted around an hour each.

2.4 Data

The data for the present study consisted of semi-structured interviews with 23 individuals. The interviewees were recruited based on their current or former employment and represented internal Allorfik staff, government officials, and personnel from collaborating partner organizations, e.g., the healthcare system, municipalities, and local NGOs. The interviewees were recruited based on their function in work, and of the 23 interviewees, there is an equal part of people in managing and in employee positions. The interviewees from Allorfik were counselors, counselor group leaders, training and supervision staff, and the director. The interviewees from the municipalities were social workers, department managers, local prevention workers, family center workers, and employment agents who had or could have collaborated with Allorfik. The interviewees from the healthcare system were department leaders, midwives, healthcare workers, and collaborators or potential collaborators with Allorfik. Most people interviewed were geographically based centrally in Nuuk, five were from North Greenland, three were from South Greenland, three were from Middle Greenland, and one person was from East Greenland. Recruitment of interviewees ended as a good coverage of both geographical areas, organizational perspectives were included, and no new perspectives emerged in the interviews. Supplementary Appendix I and Figure 1 provide an overview of the interviewee's places of employment and time of involvement as either a member of staff or collaborator. No people living in settlements were included in interviews as the access to treatment there has not changed substantially with the implementation of Allorfik. Due to the diversity of geographical



total number of interviewees who had experience from

employment with a partner organization, Allorfik, and central

administration and those who had experience from more than one

place with the overlaps.

locations, time of involvement, and the employment positions of the interviewees, the interviews were carried out individually.

During the interviews, the conversations concentrated on the interval of time the individual was involved in or collaborated with Allorfik. A few people had been involved throughout the whole process from initiation until the present day, some had been involved only in the early days of establishing Allorfik, and some were relatively new in their involvement or relation to Allorfik as illustrated in Table 1 in the Supplementary Appendix I. When applicable, the topics of the conversation were the establishment, difficulties, and strengths in the implementation process and how the treatment service was working at the time of the interview. The interviewees were also asked for their perspectives on the suitability of the implemented treatment strategy in this population. The first interview was conducted in January 2021, and the last interview was in October 2021. Due to COVID-19, all interviews were collected over a long period of time through video calls via Zoom or Teams and recorded as video conversations. However, it is only the recorded audio from these conversations that is used for the analysis. The shortest interview lasted approximately 30 min and the longest one and a half hours-most of them lasted ~45-50 min. All interviewees were given the option of performing the interview in either Greenlandic or Danish. One person preferred Greenlandic and was interviewed by a local interviewer, Else Jensen, who also transcribed and translated the interview to Danish for inclusion in the analysis. All other interviews were conducted by first author, Julie Flyger, and transcriptions of the interviews were conducted by Julie Flyger and student assistant, Camilla Dahl Olsen. Julie Flyger has a background in public health and was a young researcher with previous experience and training in conducting interviews. The interview process was supervised by authors Anette Søegaard Nielsen and Christina V. L. Larsen who have extensive experience in conducting qualitative research projects. None of the participants were reimbursed for their time, and participation was voluntary. The meetings were held within normal working hours at a time of their choosing, and all provided informed consent prior to the interview (Supplementary Appendix II).

2.5 Data analysis

Each interview was transcribed verbatim. The data from the interviews were condensed and analyzed using the general inductive approach by Thomas (33). Each transcript was carefully read through, and all meaningful phrases were coded. After the initial coding, all codes were read again looking for patterns, meanings, and common denominators, and after yet another read-through, they were finally organized into themes. All transcriptions and coding were done using NVivo software. The process was a simple thematic analysis inspired by the description of Braun and Clarke (34). The transcribed interviews were read through by the same researcher who conducted the interviews and shared with authors Anette Søegaard Nielsen and Christina V. L. Larsen. The preliminary themes and quotes were

discussed with the reference group as described and discussed in the author group too for the final analysis to be established. In the author group, there were both members of staff and stakeholders to validate the findings, but they were not involved in the process of analysis. The analysis was performed in Danish languages and only the quotes presented in the Results section were translated into English.

3 Results

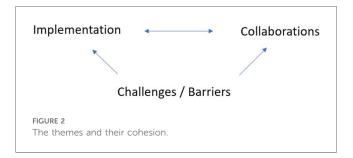
Several interviewees had changed job positions since the initial implementation of Allorfik. Figure 1 provides an overview of the interviewee's employment places during the implementation period and the overlap in experiences. As can be seen, several interviewees had experiences from several places and job positions. Few Allorfik staff have been involved throughout the whole period of implementation. Table 1 in Supplementary Appendix I provides an overview of which period each interviewee presented and talked about. With Greenland having such a small population, it would not be possible to secure the interviewees' anonymity if we referred to the interviewee by means of their job title and place of living, and although all have consented to being quoted, their anonymity was prioritized in accordance with the Science Ethics Committees guidance of good research practices in Greenland. Furthermore, frequent job changes were not abnormal in the Greenlandic society, and the changes in employment some interviewees have had provided different perspectives of Allorfik depending on the period of implementation discussed. In the present paper, when referring to the interviewees, it was thus important to demonstrate if the quote came from the perspective of a member of staff (in this case defined as either being from central administration or an Allorfik employee) or a collaborator (defined as staff from the municipality, healthcare system, or NGO or potential collaborators with Allorfik) as these two angles provide different perspectives on the implementation process and organization.

3.1 Themes

The thematic analysis identified three major themes in the data: the implementation, collaborations, and challenges/barriers and a series of sub-themes. The themes will be elaborated on in the following sections and are very much interlinked as demonstrated in Figure 2.

3.2 Implementation

Many interviewees reported that they found the implementation of Allorfik to be difficult, which to some extent still was. One of the most emphasized encounters in the implementation was the recruitment and retention of staff in Allorfik. One interviewee described a struggle at the beginning of implementation, which was the recruitment of staff who were



trained in or had experiences from another treatment tradition and methodology than what was supposed to be implemented:

I think that has been one of the biggest barriers, it is simply that you have had many of them from the 12-step treatment and it's known that, if you must learn something new and unlearn the old, it is very difficult. (5, collaborator experience)

On top of this, several of the interviewees from Allorfik described how the working conditions were difficult. With the vast distances and difficult infrastructure in the country, some staff described a feeling of being alone and very far away from management, and one described how she had not participated in an annual appraisal and improvement interview in several years. Nevertheless, many of the interviewed staff members also highlighted that Allorfik was an improvement to the previous service and were genuinely happy about their work there:

From the bottom of my heart, it has made me happy that it was the difference I have helped to make. (12, staff experience)

Several staff members expressed how a continuous focus within Allorfik on the quality of treatment resulted in a revised treatment guideline¹ implemented in June 2020, and this revision improved the treatment sessions for both them and the persons in treatment. This change also increased the staff's feeling of job satisfaction. Moreover, the implementation of the improved treatment guideline also seemed to be reflected in an increased quality of the treatment, also noticed by collaborators:

They document their methods and, and use their methods in the records and with the patients, and they are especially good at the motivational interview, so I think it has increased quite significantly, I would say, compared to the first years, which were the definitely not good. So, in that way, I think it, it has been a very big improvement in quality here... so I think they are delivering what they must. But they don't deliver it at a high level because there has been

¹The new guideline was a simplified instruction for the counselors, which aimed to provide the tools for a better guidance through the treatment course for counselors and the people in treatment.

this turnover, so you start over with new staff and so on. But those who are now there and have remained there, they deliver at a level that completely corresponds to the Danish level. (5, collaborator experience)

3.2.1 Management

A key factor in the implementation process seemed to be the stability of the management of Allorfik throughout the years. Several interviewees mentioned how a clear plan for implementation laid out by unchanging management probably was one of the reasons why the implementation of Allorfik had been relatively smooth, quick, and secure:

She had it all designed and if it had been another manager who had started, it would have taken much longer time to build it up. No doubt about it. (18, staff experience)

However, a strong management during the process, concentrated in one central person, situated in the capital also created a risk for lack of communication and decisions being taken that did not consider local aspects, making it difficult for staff and partners to navigate. Some of the informants directly expressed how management had stepped on the toes of some people during the process and missed collaboration opportunities. Nevertheless, the overall impression was that management was given credit for being receptive to potential allies in the implementation process and for having performed a tough job with the changes in staff and also being responsible for many tasks external to Allorfik, e.g., training courses and education of counselors. One person highlighted the difficulties being a leader of addiction treatment services must have involved when most of the staff themselves or a close relative of theirs have had problems with addiction and other problems, due to the high burden of addiction and social problems in Greenland:

... they also have some problems themselves. Psychological, psychological problems and so on, which characterize a lot of the staff.... (5, collaborator experience)

3.2.2 Language

Albeit not being part of the original plans but emerging during the process of implementation was the need for establishing a common treatment "language" or vocabulary within Allorfik: a need that was important for counselors:

It is more than 98% of our,... um..., of those who come for treatment with us, are primarily Greenlandic speaking and that means that it is incredibly important that... um... that they are met not only linguistically but also culturally... and find out, ... um..., what is it that what we need in terms of methods. How do we talk about things? What are some expressions we use? ... or what kind of words are we giving a special meaning here? Which [words] covers some of the

stuff that we'd like to have the opportunity to talk to people about.... (17, staff experience)

3.3 Collaborations

When the interviews turned to the subject of collaboration between Allorfik and the rest of the Greenlandic society, a series of perspectives emerged, of which three were dominant: the healthcare system, the municipalities as collaborating organizations, and the outreach work done by Allorfik.

3.3.1 The healthcare system

The interviewees from the healthcare system all perceived the collaboration with Allorfik as good, albeit not very close. From the point of view of healthcare professionals, there was not much to collaborate on. One person with a healthcare management position reflected on how the healthcare services have not been great at facilitating collaboration, whereas others highlighted the limited resources in the healthcare systems as an important barrier to do more collaboration. Several informants from the healthcare system would like to be able to refer people from the healthcare system directly to treatment Allorfik to avoid non-appearances or needing to involve the municipalities:

So, I don't know if you can somehow work for some kind of referral system. (10, collaborator experience)

A common argument for wishing for a direct referral system and not involving the municipalities was that some treatment seekers and even employees in the healthcare system found that approaching the municipalities indicated a need for social services rather than for addiction treatment:

Many of our employees who actually need a, an, an addiction treatment course, well they don't, they don't really need to come down to their case manager, because they have an income and they have a home and, and things like that but, but they do need to get in to addiction treatment service, because otherwise they lose their job. (1, both staff and collaborator experience)

3.3.2 The municipalities

The informants from the municipalities illustrated how the collaboration with Allorfik varied across the country. The collaborations varied both between different municipalities and Allorfik and within the different municipality units in a single city and the local Allorfik center. The collaboration was perceived as mutual and satisfactory in some places, and the collaboration was described as sparse or non-existent in other areas:

Yes, it was very general, the whole time it has been very superficial I, I have maybe been to three meetings up there in over five years. (10, collaborator experience)

The differences indicated that formal structures for collaborations were not established throughout the country:

We can't really find out, or something like that, how do we cooperate and what do the people who come to Allorfik do, uhm, who refers, how do we refer and various things like that. (3, collaborator experience)

Overall, the collaboration with municipalities seemed to rely on the attitudes of and relations between specific individuals in both Allorfik and the municipality rather than being embedded in formal structures. Thus, when there was a change of staff in either organization, the collaboration often needed to be rebuilt or simply collapsed. However, some informants described the collaboration between Allorfik and social services as running very smoothly in a few specific areas, namely, when there were children involved and to some extent between Allorfik and a municipality's health prevention worker². However, the collaboration between Allorfik and other sectors and institutions was overall described as varying and fluctuating, illustrated by an informant explaining the collaborations varied even within a single city:

Well, my impression is that they have a good collaboration, for example with the hospital. The collaboration with the Family services that, that is also something that must be constantly improved. (3, collaborator experience)

With some of the local Greenlandic NGOs, there does not seem to be any type of collaboration Allorfik, while with others there was a formal agreement and a good relationship. With some collaborators the beginning was difficult but with time the collaboration has improved significantly.

3.3.3 Outreach work

Several informants from the staff, collaborators such as the municipalities, healthcare system, and the NGOs expressed that it was of great importance when employees from Allorfik performed outreach visits to other facilities, meeting both staff and citizens—potential collaborating partners and people in need of treatment:

But, but we are really happy about the cooperation we have around their counselors, who come here and give presentations for the patients and also uh presentations for our staff uh, so that they are also better equipped to, to talk or deal with um this. (1, both staff and collaborator experience)

In continuation, one person from Allorfik described how the opportunities for collaboration were great but depended very much on the person's interests:

²A municipality health prevention worker would typically conduct local prevention and health promotion initiatives and projects, arrange thematic courses, and collaborate with all relevant institutions in the local area.

So, if you want to or if you have the energy for it, there are plenty of opportunities for collaboration. (6, both staff and collaborator experience)

3.4 Challenges and barriers

When the interviewees were asked if they could identify any difficulties for Allorfik—both past and present—a series of angles were highlighted. These challenges have been used in Figure 3 where these have been allocated to the four groups: strengths, weaknesses, opportunities, and threats.

3.4.1 Within Allorfik

One shared experience by the staff of Allorfik was the challenges within the organization itself. At the time of establishment, the challenges were primarily practical and related to the uncertainty of what the new treatment strategy contained: who to hire, where to situate the treatment facilities, and what kind of interior was needed, in addition to unforeseen events such as water damage to a facility. A persistent challenge was, however, the constant staff turnover, which was linked to both the changes in treatment methodology (from the 12-Step Model to MI and CBT) and to contractual restrictions at the government level making it difficult to attract and retain staff:

They have struggled with the huge, huge turnover. (16, staff experience)

Another challenge described by the informants was the difficulties in promoting the success stories from Allorfik, in contrast to the more broadly known narratives of successful 12-step addiction treatment courses, told by influential members of the Greenlandic society about the old treatment system. In some of the interviewees' experiences, this narrative was considered to have heightened some of the preferences of people in treatment for specific treatment methods rather than others. Since some of the leading figures in the Greenlandic society had experiences from the old treatment system in addition to them being involved in politics, some interviewees indicated that this might have put political pressure on Allorfik to question the organization's general way of working and choice of treatment methods.

3.4.2 The people in treatment

The informants described massive levels of problems and challenges among the people seeking help with Allorfik and how these multi-problems impacted the implementation process since they might be hard for the staff to handle. One interviewee pointed to these multi-problems as a driver for the addiction problems:

After all, that is what makes them fall or they become addicts, too, because they have something in their baggage that they have to process. And I think it means a lot, if you want to completely recover from your addiction, that you also, uh, process those things at the same time as you are in addiction treatment (13, collaborator experience)

Strengths

- Meaningful work
- Audits
- Stable management
- Many resources in Allorfik

Weaknesses

- Recruitment / turnover in staff
- Distances
- No fixed structures for collaborations
- The burden of other problems carried by people in treatment

Opportunities

No fixed structures for collaboration

Threats

- Distances
- Lack of resources with collaborators
- Resistance / questioning of Allorfik and its methods

FIGURE 3

Strengths, weaknesses, opportunities, and threats.

Another aspect of offering treatment to a group of individuals suffering from a series of adverse experiences and social problems was that persons in treatment would often prefer to talk about those problems rather than the addiction problems, making the treatment difficult to manage for the counselors. During the interviews, the vast proportion of social problems was highlighted as leading to treatment adherence being unstable in addition to posing a risk of wearing the staff out. Several informants reported how both the social problems, addiction problems, and the linkage of these could not be solved by Allorfik alone but needed the involvement of several other sectors and areas: housing, education, Indigenous identity, and social services to name a few important ones, which are resources that were not always available. Several informants also pointed out that it was not the total amounts of substances used that constituted a problem but rather the pattern of substance use and/or binge drinking that seemed to be firmly rooted in parts of the society:

In other words, we drink fewer liters of alcohol per year, but when we do drink, we drink in the same way. (9, collaborator experience)

3.4.3 No other place to go

Another aspect very much linked to the social burden among the people in treatment, and several interviewees highlighted how the treatment for the addiction transformed into a treatment for all the other painful things in life: If it hadn't been for alcohol uhm addiction treatment, then they wouldn't have been treated at all for all the other sorrows or other pain they had in life, and that's what they got in Allorfik. That it is not only the abuse itself, but also all the pain that is included in that treatment. (14, staff experience)

The informants found that many of the persons in treatment struggled with social problems and some to a point where they could not stay in treatment and thus dropped out. Others would adhere to treatment but simultaneously struggle with social services in childcare cases resulting in staff from Allorfik taking it upon them to help these persons deal with social services. Moreover, some persons in treatment struggled with many difficulties except addiction problems, yet they still sought help in Allorfik, as they found nowhere else to go:

I see it a bit like there is simply not much help to be found anywhere. So just the fact that someone listens and wants to talk to them makes them happy. A place to go. You can't go for the municipality; you can't get hold of the municipality in any way... And we also had in Illulisat at one point, we were almost a crisis center too, if they were upset, they called and asked if they could come and talk. (6, both staff and collaborator experience)

Another interviewee described how Allorfik even sometimes was responsible for crisis management when someone was suicidal:

Yes, that, sometimes they send their citizens up here too um... I've had some like that, I've had a suicidal, a suicidal person. (12, staff experience)

4 Discussion

The overall finding of the present study was that while the process of implementation of the new national addiction treatment had been challenging, it was also considered successful by those involved. The informants found that it overall had led to making the intended services available to those in need. A key feature in the success of the implementation was stable management with a clear implementation plan according to the interviewees. Creating a shared language for treatment within Allorfik was an unforeseen challenge. These findings are not surprising. In general, a well-defined strategy for implementation is key for successful implementation as it provides the tactics for how to do it (35). Still, responsiveness and deliberate adaptations or modifications of elements during the implementation process are also considered valuable for a successful implementation (36). The latter may be especially important in an implementation such as Allorfik's as the establishment process was over a period of 3 years and the context of the implementation must be expected to be both complex and different in each location of implementation. When implementing Allorfik, adaptions were needed when faced with obstacles, for example, implementing new methodologies in treatment that revealed a need for a common language, continuous recruitment of (educated) staff, and building everything from the bottom over vast distances including a shared language in treatment while experiencing a high turnover in staff. A consistent management with a detailed understanding of the implementation strategy ensured that the plan was followed with the adaptations necessary (37).

The present study showed how the implementation of structures for collaborations with other sectors outside Allorfik had been only partly successful. Some collaborations were in effect, other collaborations were never established, and others had stopped because of changes in staff. The analysis illustrated that context and setting very much matter in the implementation (38, 39), and that may be particularly profound when implementing an intervention like Allorfik in a country like Greenland with vast distances and cultural differences on all levels. The healthcare system generally described the collaboration as good but seemed, in reality, to wish for an easy route to securely handing over persons to Allorfik rather than a wish for mutual collaboration. This wish may be an expression of reluctance in the health services towards addressing and getting involved in the treatment of patients' alcohol or cannabis use or a lack of resources to address these issues.

In the municipalities, there were (and still are) several different units within the organizations that were relevant for Allorfik to collaborate with, and while some collaborations were working fine, others were not. This difference seemed to be linked to resources or lack thereof in each place, thus pointing to the collaboration to have been very dependent on individuals rather than structures or procedures. This dependence on the individuals seemed to make the collaborations even more vulnerable with the high turnover in staff that was also described in the analysis. Informants from both internally in Allorfik and from collaborating partners were happy with the outreach work performed by Allorfik; however, this was also described as something that very much relied on the engagement of the individual counselors, which again made this work vulnerable to changes in staff. A high turnover in staff was also found to be a great challenge in the healthcare system (40) and a general problem across Greenland (41) and was thus not limited to Allorfik and probably not controllable by Allorfik either. The high turnover of staff combined with the descriptions of the multiple issues of the persons seeking treatment may pose a risk for staff burnout (42). This was mentioned by some interviewees framed as the job as a counselor might be too demanding for some persons.

The national plan recommended implementing MI and cognitive behavioral therapy as the basis of the new, public system but still continuing to offer the 12-step treatment through a private organization. Implementing new treatment methods presented a challenge to the implementation process since at the implementation start the available staff were originally trained in the 12-Step Model of treatment, and although the treatment context in Allorfik changed, it is well known that it can be difficult to change behavior and habit (43). The tensions generated by different views and experiences with treatment methodology also seemed to be a contributing factor to the high turnover in staff. Furthermore, the shifts in treatment models provided an unforeseen challenge as the known public narrative of good treatment referred to the 12-Step Model of treatment and the old treatment system. Allorfik thus had struggled to present a new success story to the public and change the narrative of treatment. Some interviewees pointed to this as a cause of people seeking treatment, however, a specific type of treatment, and others to how the narrative made the implementation more difficult, as these figures continued to put pressure on Allorfik.

Several informants considered Allorfik to be functioning better than the old treatment layout in various ways and emphasized that Allorfik has succeeded in offering treatment locally. However, the treatment-seeking persons' challenges turned out to be numerous, and it was considered that often the people approached Allorfik to seek help for their struggles in life in general rather than to seek treatment for their addiction problems. The large proportion of people in Greenland with not only problems with addictive behaviors but also suffering from having experienced abuse and neglect in Greenland is well established (1, 44-48). As pointed out by one interviewee, the levels of consumption of alcohol might have decreased over the past decades (49, 50), but the drinking pattern does not seem to have changed for the younger parts of the population (51). This is important to know because while Allorfik provided psychosocial treatment for the persons seeking help there, it would however be difficult for Allorfik to change societal

structures that went beyond the persons entering the doors of the treatment centers.

The planning of the present study was inspired by the RE-AIM framework (28, 29), and although the purpose of this study was not to report on each of the main constructs in the framework, the study results however do reflect them. The present study found that the treatment reached both the intended population and beyond the intended population for treatment with the high turnup of people needing therapy. The interviewees reported that the new treatment was an improvement compared to the old treatment system, but this study cannot provide any further insight into the effectiveness of treatment and leaves this to be investigated in another study. Adoption seems to have been a struggle with the introduction of new methods and the turnover in staff; however, the interviewees report that the treatment service has only had a few adaptations, e.g., a guideline update. Implementation seems to have been a success and the treatment delivered seems to be in accordance with the treatment intended. The people entering treatment have an option of maintenance through the 6-month aftercare program, and in Allorfik, treatment maintenance quality also seemed to be a focus.

4.1 Strengths and limitations

The study has both strengths and limitations. We consider it a strength that the study was based on interviews with many different interviewees, representing different sectors and levels of the Greenlandic community, in addition to consisting of individuals with different experiences and involvement over a long period of time. It can be considered a limitation that almost all interviews were done in Danish, since this perhaps may have led some interviewees to feel insecure or withhold information due to language issues. However, all interviewees were allowed to do the interview in Greenlandic, and in all the Danish-speaking interviews, the interviewer emphasized the importance of speaking freely and using Greenlandic words or phrases if it was useful. All interviews also began with a turn of the table, where the interviewee was allowed to ask the interviewer questions of all kinds to try to make everyone more comfortable in the conversation and reverse the gaze (52).

It is a limitation that the study did not include interviewees from settlements and thus leaves out insight into the very remote local treatment and the people who travel great distances to treatment. This could perhaps have provided different perspectives to the study. However, the treatment services for the people living in Settlements had not changed considerably with the implementation of Allorfik as the new treatment centers were only in the five main cities.

It is a strength that the informants included inform the study with viewpoints that represent a broad picture from different areas and sectors, and not a small glimpse into time from a certain perspective which strengthens the study. The contributions of the reference group have also strengthened the study both when planning the study but also with the discussions around the emerging themes and interpretation of

these, as the reference group both appreciated the aim of the study, contributed with ideas of improvement, and recognized the findings.

It may be considered a limitation that the study did not include any persons in or previously in treatment with Allorfik. This was a carefully considered choice that limited the perspective of this study. The study did not include persons in treatment firstly because the aim to investigate the process of implementation and organization did not correspond with the inclusion of treatment seekers as the treatment attendee's perspective would (hopefully) only provide a perspective of their own species treatment course during a few months and not the whole process of implementing Allorfik. If this issue were to be overcome, the study should have included persons who had attended treatment both before and after the implementation of Allorfik, which might be a particular group of individuals with particular, long-lasting problems. The study could also have included treatment seekers from the entire implementation period and preferably beyond to cover the process of implementation, which would have provided the study with an enormous data material. Lastly, the identification and recruitment of treatment seekers would provide the study with a completely different set of ethical considerations and a whole other perspective on the time and resources needed to complete the study. Thus, the inclusion of patients was avoided as it was deemed unfeasible for this study, but this does not mean that the perspective of the treatment seekers is not of importance. In contrast, the lack of treatment seekers' perspective on Allorfik's organization may hopefully inspire a series of future studies.

4.2 Implications

With this study conducted and the implementation and organization outlined, the ground for continued work and future studies with the evaluation of Allorfik can then proceed. The findings suggest that the services in Allorfik were as intended and described, and thus there is ground for studying other essentials of Allorfik with treatment outcomes such as studies of treatment quality, register-based studies with treatment seekers, and treatment seekers' perspectives of treatment services.

In Greenland, evidence of Allorfik's implementation and organization will be beneficial to both policymakers funding Allorfik and internally in Allorfik, where the findings can be useful in organizational development work. The findings of this study support the possibility of successfully implementing a new treatment service over vast distances and point to some of the elements aiding the success, which could be useful both internally in Greenland for other services and in other Indigenous communities with similar challenges.

5 Conclusion

In conclusion, the implementation and organization of Allorfik seem to have been delivered as intended and promised according to

those involved. The process of implementation has been challenging, and adaptations of the original plan have been made to reach a well-functioning service, but overall, the organization and treatment services intended were the organization and treatment implemented. However, Allorfik also seems to have become more than the addiction treatment service it was planned to be—it has developed into a service with easy access for the citizens in need of help who are otherwise limited by waiting in phone lines, for a referral or the next specialist visit, or simply not available due to limited resources in Greenland. Allorfik had on top of the addiction treatment services developed into a crisis management center for some and a safe space for others to talk about their past and present struggles in life, all while still providing treatment for addiction problems for the people in need.

Data availability statement

Data management and storage were handled by the Open Patient Data Explorative Network. The datasets presented in this article are not readily available because the interview data is in the Danish language only. Requests to access the datasets should be directed to jholflod@health.sdu.dk.

Ethics statement

The studies involving humans were approved by the National Science Ethics Committee in Greenland. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin because COVID-19 enforced all interviews to be conducted via online services. Thus, all participants were orally provided with study information and all participants provided oral consent before initiating the interviews.

Author contributions

JF is the corresponding and main author. CL has contributed to forming the study and when writing the manuscript. EJ has been part of the conduction of the study and the analysis. BN has contributed to forming the study and when writing the manuscript. AN has contributed to forming the study and writing the manuscript. 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.2024. 1219787/full#supplementary-material

SUPPLEMENTARY APPENDIX I TABLE 1

The interviewees, their time of involvement with Allorfik and their position as developer/stakeholder.

SUPPLEMENTARY APPENDIX II

Informed consent for study participants

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External relationships as implementation determinants in community-engaged, equity-focused COVID-19 vaccination events

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Background: While relationships and connectedness among organizations have been included in implementation theories, models, and frameworks, the increased attention to health equity in implementation science raises the urgency of understanding the role of relationships external to the implementing organization. This paper addresses this gap through an exploration of the role of external relationships in community-based, equity-focused interventions.

Methods: This study focuses on an equity-focused, community-based COVID-19 vaccination intervention in Arkansas, drawing upon long-term community-engaged relationships among University of Arkansas for Medical Sciences and the Hispanic and Marshallese Islander communities. We used an exploratory qualitative descriptive design to examine barriers and facilitators to implementation of COVID-19 vaccination events analyzing in-depth qualitative interviews with implementation team members (n = 17).

Results: All participants described pre-existing relationships among the implementing organization, partner organizations, and communities as a key implementation determinant for this equity-focused program. At the interorganizational level, external relationships included formal connections and informal relationships among staff (e.g., communication channels from prior partnerships). At the individual level, strong external relationships with the community were facilitators leveraging long-term engagement, community familiarity, and staff from the communities of focus. Strong external relationships facilitated program reach in underserved communities through three mechanisms: (1) reduced time required to establish functional working relationships among partners; (2) accessibility and cultural congruence of health services; and (3) increased trust among community members. Barriers to implementation also existed in external relationships, but had less influence than facilitators.

Conclusions: Achieving health equity in implementation science requires greater understanding of external relationships as implementation determinants. This exploratory study makes a significant contribution to the literature by describing the types of external relationships that facilitate equitable implementation and identifying the mechanisms through which they may work. We argue that approaches to community engagement drawn from community-engaged research approaches may be useful, as these processes require investment in building/maintaining formal and informal organizational and interpersonal relationships. Further research is needed to understand connections among external relationships and other implementation determinants.

KEYWORDS

health equity, external networks, community engagement, community-based implementation, implementation science

Introduction

Relationships and connectedness among organizations within and across the implementation environment has been included in implementation-related theories, models, and frameworks prior to the inception of implementation science (IS) as a field of study in the United States (US) at the turn of the 21st century (1). Communication channels and social systems are two of the four main elements in Roger's Diffusion of Innovation theory (2), a pillar upon which IS rests. Organizational relationships are also reflected in more recent implementation determinant frameworks (3) as "external networks" (4), "interconnections/linkages" (5), and "inter-organizational networks & relationships" (6). Despite the recognition of external relationships as a critical determinant of implementation (7–12), this construct has not been studied with the same depth as many other constructs within IS frameworks (13).

In the original version of the Consolidated Framework for Implementation Research (CFIR), one of the most widely-cited implementation determinants frameworks, "the degree to which an organization is networked with other external organizations" is identified as a critical implementation factor (14). In the revised CFIR "2.0" (4), the "partnerships and connections" construct broadly captures relationships with external organizations. This construct is situated within CFIR's Outer Setting domain, which captures "macro-level" implementation factors emanating from outside the Inner Setting, or the site where implementation is occurring. Perhaps as a result of the highly interventional nature of implementation research in healthcare, more attention has been paid to the Inner Setting and specifically to constructs and determinants within this category (e.g., available resources, infrastructure, incentive systems) which may be modifiable (or leveraged) within projects designed to improve implementation of a specific intervention or practice within specific healthcare organizations/ locations (3). Other implementation frameworks have provided alternate constructs to focus on macro-level implementation "inter-organizational networks" "community-academic partnerships," in the Exploration, Preparation, Implementation, Sustainment (EPIS) framework (15) and "inter-organizational networks & relationships" in the integrated-Promoting Action on Research Implementation in Health Services (iPARIHS) framework (6).

The limited attention on relationships among implementing organizations and external partners may be due to a perception that they are a more remote implementation determinant and that they are less amenable to rapid intervention. As such, relationships among the implementing organization and organizations and communities external to the implementing organization are a determinant that remains relatively underconceptualized, and to-date few scholars have explored this construct in depth (16). Underdevelopment is a noted challenge for all outer setting constructs, which are "notoriously difficult to evaluate and influence" (13). Extant implementation research frameworks have also predominantly focused on relationships among similar or peer organizations (e.g., healthcare organizations, social services providers) (5, 14). Most published studies assessing external relationships primarily focus on links among peer organizations, such as formal implementation networks (17), quality improvement collaboratives (18), or organizations providing similar client services (19-21). The updated definition of the "partnerships and connections" construct in CFIR 2.0 helps expand the scope of external relationships to include collaboratives, professional societies, referral networks, community-academic partnerships, advocacy groups, and technical assistance organizations (4). While it has been noted that relationships with community organizations in different sectors (e.g., churches, non-profits) can benefit implementation (22, 23), and intersectoral relationships are a common approach in public health programs (24-26), their role is understudied in IS.

Community engagement and equitable implementation

The increased attention to health equity in IS raises the urgency of understanding external relationships (organizational

and/or among individuals) as determinants of implementation (27, 28). It is well-recognized that communities with the highest burden of health disparities are often unreached, or the last to be reached by evidence-based interventions (29-31). The determinants of healthcare organizations' ability to reach disproportionately-impacted communities is understudied in IS (32). A key recommendation for advancing health equity in IS is to engage equity partners in sectors outside of health systems [e.g., employers, housing, school, and faith-based organizations (FBO)] (27). Yet, little is currently understood about the extent to which healthcare organizations are able to engage external equity partners in the implementation of interventions, how best to engage partner organizations, and how these external relationships might improve equity of implementation and outcomes. Thus, when and how healthcare organizations engage underserved communities and the degree of the connectedness among these organizations and communities may emerge as a critical determinant of equitable outcomes.

Relationships between implementing organizations and community organizations are not an explicit component of new, equity-oriented implementation research frameworks (33, 34). While activities to engage communities can be considered as an equity-focused implementation strategy, the nature and strength of external relationships with community groups will likely determine the success of this strategy (35, 36), although recent work by Wallerstein and colleagues highlights that the science has lagged behind practice (37). IS research can draw upon the rich literature on Community-Engaged Research (CEnR) to facilitate our understanding of the role for relationships among community-based equity partners and implementing organizations (4-8).

Trust is another underdeveloped concept in the IS literature but is recognized as critical to building implementation recipients' participation and to Conceptualizations of trust in CEnR have highlighted how relational dynamics contribute to trust-building (39), and establishing partnerships with underserved communities builds trust in healthcare organizations (40). This is also critical for equity in vaccine uptake, as community-engagement has frequently been identified as a critical factor in effectively promoting vaccine uptake and building trust in public health authorities and interventions, especially among marginalized and underserved communities (41-45). Therefore, it is necessary to understand whether, and how, external relationships improve the equity of implementation, relationship strength, and trust.

This paper addresses the gap in research on external relationships in implementation exploring the role of these relationships in implementing an equity-focused COVID-19 vaccination program. We utilized an exploratory qualitative descriptive study design to understand the barriers and facilitators to implementation of COVID-19 vaccination events within FBOs as a way to reach Hispanic and Marshallese Islander (hereafter Marshallese) community members.

Methods

Setting and intervention

The focus of this paper is the implementation of a community-based COVID-19 vaccination program in Arkansas. This program drew upon long-term community-engaged relationships between University of Arkansas for Medical Sciences (UAMS) and the Hispanic and Marshallese communities in the region (46, 47). These relationships originated in 2013 to address social determinants of health and associated chronic disease disparities among the Hispanic and Marshallese communities in Arkansas (41, 46). Since its inception, these relationships have utilized a community-engaged approach, which seeks to build trust among academic researchers, healthcare providers, and communities through direct engagement, honoring those communities' unique contributions at all stages of health interventions. Further details are published elsewhere (46, 48).

As an extension of these formal and informal pre-existing, community-engaged relationships, a COVID-19 response taskforce was developed and led by community-based organizations, and the taskforce met weekly between March 2020 (within one week of the first identified case of COVID-19 in Arkansas) and continued to meet through August of 2022, with daily communication among organizations to address the COVID-19 health disparities among the Hispanic and Marshallese populations in Northwest Arkansas (the details of which have been previously published) (41). The taskforce developed a comprehensive COVID-19 response involving education, outreach, testing, contact tracing, and support for quarantining (46). Vaccination outreach was included as COVID-19 vaccines became available in December 2020. Leveraging these relationships, academic researchers and healthcare organizations implemented COVID-19 vaccination events in community settings, primarily in partnership with FBOs, with a goal of improving reach, increasing attendee comfort, and providing native-language facilitation and education.

To support vaccination outreach programs, the academic medical center, UAMS, received funding from the National Institutes of Health-funded Community Engagement Alliance Against COVID-19 Disparities (CEAL); Racial and Ethnic Approaches to Community Health (REACH), administered by the Centers for Disease Control and Prevention; and the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services. To maximize accessibility of the events, most were held at local FBOs with Hispanic and/or Marshallese congregations on days and times chosen to facilitate attendance and reduce barriers (described in previous publications) (49). Community health workers affiliated with FBOs and/or UAMS promoted attendance by scheduling appointments and providing resources such as transportation to attendees. Events were staffed by members of the implementing and partner organizations. The implementation team included healthcare providers, program staff [many of whom were community health workers (CHWs)], and staff of FBOs.

All vaccines were administered by clinical staff, and all events included bilingual (English/Spanish or English/Marshallese) team members who provided medical translation.

and procedures were approved by the UAMS Institutional Review Board (IRB#262917).

Data collection

Our exploratory qualitative descriptive study examined the barriers and facilitators to implementation of COVID-19 vaccination events within FBOs as a way to reach Hispanic and Marshallese community members. Data was collected at vaccination events held between July 2021 and September 2021. For transparency, our diverse research team and co-authors' selfidentified positionalities include five men, six women, six identifying their race/ethnicity as non-Hispanic White, three identifying as Marshallese and Pacific Islanders, one identifying as Hispanic, and one identifying as mixed-race and ethnicity. Three qualitative researchers (GC, JV, and SP) conducted five observations of vaccination events held in Hispanic FBOs (n = 2), Marshallese FBOs (n = 2), and one (n = 1) church-affiliated community space. The three qualitative researchers also conducted informal interviews during events (n = 55) and invited team members at vaccination events to participate in a semistructured interview at a later date. Informal interviews consisted of short, unstructured conversations with team members concerning their experiences with vaccination events.

Following a purposive sampling approach (50), the study team recruited 17 participants reflecting diverse roles in the implementation of vaccination events, which follows standard qualitative approaches to determining sample sizes based on the scope and nature of the study (51, 52). Inclusion criteria for participation consisted of adults (≥18 years of age) who were members of the implementation team. Formal, semi-structured qualitative interviews were conducted with participants via secure video conferencing in the fall of 2021. All interviews were conducted in English, transcribed verbatim, and de-identified before analysis. Verbal consent was obtained prior to interviewing and recorded in REDCap, along with demographic information (53, 54). Most interviews lasted between 30 and 60 min, and participants were provided a \$50 incentive.

We used a semi-structured interview guide combining grand tour, open-ended questions, probe questions based on a priori CFIR categories, and topics emerging from informal interviews and observations at vaccination events to maintain consistency across formal interviews. The CFIR framework was chosen due to its comprehensive focus on implementation determinants and its frequent utilization within the IS literature. Examples of grand tour questions include, "What do you think worked well at the event(s)?", "What were some barriers or challenges to delivering the COVID-19 vaccine in a non-clinical setting?", and "What do you think could have made the event(s) more successful?" Based on the responses to the grand tour questions, additional probe questions were used based on CFIR categories and specific determinants. In addition, each participant was asked to discuss the extent to which the event(s) achieved the goal of reaching the communities of interest. All study materials

Data analysis

The co-authors conducted rapid thematic analysis following a modified framework approach (55, 56), utilizing CFIR as the a priori coding framework. Themes from each interview transcript were independently summarized by co-authors (GC, SP, JCK, and RM) using a structured coding template. The research team met regularly to consolidate the templates into one final coded template per interview, resolve discrepancies in interpretation, and assign identified barriers and facilitators to CFIR constructs. Barriers and facilitators were added to the operational definitions of constructs in the study-specific CFIR codebook. Summaries of coded data were transferred to charts with a column for each CFIR construct and a row for each participant to facilitate identification of patterns and outliers. The research team reached thematic saturation, e.g., the point at which patterns in the data were clearly identified through analysis and no new themes were identified, after analysis of 10 transcripts. Illustrative quotes were identified for each theme using a consensus approach.

Results

Seventeen participants completed qualitative interviews (Table 1). Participants were healthcare providers (n = 4), program staff (many of whom were CHWs) (n = 10), and FBO staff (n = 3). The median age of participants was 41 years, and 65% of participants were women. Participants were racially/ethnically diverse; eight participants identified their race/ethnicity as White

TABLE 1 Demographics of participants (n = 17).

	Range	Median
Age, in years	23-55	41
	Frequency	Percent (%) ^a
Primary role		
Healthcare providers ^b	4	24%
Program staff ^c	10	59%
FBO staff	3	18%
Gender		
Woman	11	65%
Man	6	35%
Self-reported race/ethnic	city	
White	8	47%
Hispanic	4	24%
Marshallese	4	24%
Asian	1	6%

^aMay not equal 100% due to rounding.

^bIncludes physicians, pharmacists, and nurses.

^cIncludes various roles including event coordination, outreach, attendee registration, etc.

TABLE 2 Emergent themes by level of relationship.

	Type of connection	Barrier	Facilitator
Organizational Level	Formal inter-organizational structures	Mismatch of policies among organizations Changing sponsors and rules at different events Need for extensive coordination among and within organizations	Regular communications Formal institutional agreements (e.g., MOU, data use agreements) Trust in partnerships among organizations
	Informal relationships among organizations	Lack of pre-existing relationships with all relevant community organizations (e.g., some churches/FBOs were difficult to engage)	Established communication channels and working relationships Familiarity/trust between individuals
Individual Level Staff roles in organization and community • Burnout among bilingual staff and staff from of focus		Burnout among bilingual staff and staff from communities of focus	Provide culturally appropriate services in language Intrinsic motivation of staff Community members trust information provided by representative staff
	Community members' familiarity with organization	Some community members and sub-populations remain difficult to reach	Community familiarity with UAMS in partnership with community organizations Community members trust services offered by/at familiar organizations

(47%), four identified as Hispanic (24%), four identified as Marshallese (24%), and one identified as Asian (6%).

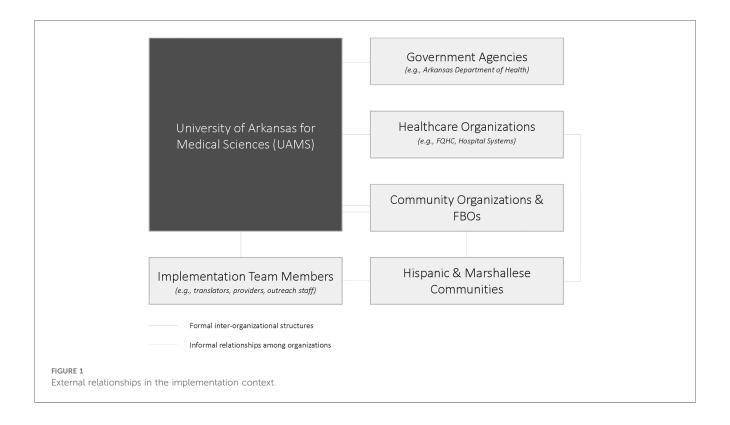
During analysis, we identified emergent themes within the a priori CFIR 1.0 category of "cosmopolitanism." Participants described both formal and informal organizational-level relationships among UAMS and team members, government agencies {e.g., Arkansas Department of Health, the Consulate of the Republic of the Marshall Islands, healthcare organizations [e.g., Federally Qualified Health Centers (FQHCs), hospital systems]}, and community organizations and FBOs. We identified themes at the organizational and individual levels for external relationships as implementation determinants (see Table 2). At the organizational level, formal interorganizational structures within the implementation environment and informal relationships among organizations emerged as implementation determinants. At the individual level, we identified themes of cultural congruence arising from the overlapping staff roles of the implementing organization with communities of focus and community members' familiarity with organization as determinants of community-COVID-19 vaccination events. Formal organizational structures included contractual agreements between organizations. Informal relationships among the implementing organization and partner organizations were developed over time through prior community-engaged collaboration (41, 47, 48). In addition, participants identified individual-level relationships, highlighting cultural congruence among community team members with dual roles in the implementing organization and as trusted members of the Hispanic or Marshallese communities. Cultural congruence, e.g., inclusion of community members as implementation team members, also facilitated community members' familiarity with the organization. The nature of external relationships, and their role as barriers and facilitators of community-based vaccination events, are described highlighting the salient formal and informal relationships.

Figure 1 presents an overview of the salient relationships within the implementation context.

Organizational level: formal interorganizational structures

The central inter-organizational structure for the intervention was a COVID-19 taskforce, described above. The community-led taskforce was organized as an extension of the community-engaged relationships among UAMS and team members, government agencies (e.g., Arkansas Department of Health), healthcare organizations (e.g., FQHC, hospital systems), community organizations and FBOs, and the Hispanic and Marshallese communities. The taskforce met monthly with an agenda focused on addressing COVID-19 disparities in the Hispanic and Marshallese communities. The taskforce was predicated on long-standing community-based relationships. Most taskforce members had established memoranda of understanding (MOU) or other formal agreements, such as data use agreements.

These formal relationships were identified by participants as facilitating implementation of the intervention in three key ways. First, the established weekly meetings of the formal partner organizations facilitated communication, serving as a forum for coordinating activities and providing input on intervention design. Second, pre-existing formal relationships (e.g., pre-existing MOU and data use agreements) among partner organizations enabled the quick start-up times for developing and deploying the vaccine events. One participant explained, "We keep getting in these projects, but it's not like we're having to shift gears or do any 180s to do that work... these projects just allow us to continue, I guess, the work that we've already been doing, and enhance on it" (program staff #1, White). Third, the long-standing formal collaborations contributed to the trust among the partners in external networks. Explained by one



participant, "We've worked with [community-based partner organizations] a lot in the past. They've always been a good partner, so it was kind of natural for us to go with them" (program staff #2, White).

Formal relationships were not uniformly discussed as facilitators, with some participants identifying barriers, such as differences in organizational policies which created operational challenges during events. For example, the categories of healthcare providers qualified to provide vaccinations varied by organization. One participant stated, "The most challenging thing about administering vaccines off-site is the regulation around it, [for UAMS supported events, the policy is] a credentialed provider [an MD, PA, or APRN] has to be on-site. Making sure that we're in compliance with all of the policies [...] was probably the most challenging thing" (healthcare provider #2, Asian).

Additionally, the collaborative nature of the events meant variability in sponsors at some events which required changes in paperwork and electronic health records systems from one event to another, along with corresponding staffing and workflow changes. A team member stated, "When we first started partnering with [the FQHC], [...] there's two consent forms they have to do, vs. the one when it's UAMS. [...] At first, we didn't have a good flow for when people came in and did the consent forms, and then got their shot and waited" (program staff #2, White). External relationships were also identified as requiring increased time and effort in communication and coordination by one participant: "I think definitely more communication between the partners [is important] so that everybody understands everybody else's roles and so when we start the event and we're

there—again, to be flexible and culturally sensitive to who's there, understanding that not everything is gonna work like clockwork" (healthcare provider #1, Marshallese).

Organizational level: informal relationships among organizations

Informal relationships across organizational boundaries were described as a primary facilitator at the organizational level and consisted of personal and professional connections among team members at the implementing organization and partner organizations (e.g., FBOs, government agencies, healthcare organizations). These informal relationships, described as developing over time, fostered collaboration across organizational boundaries during implementation of vaccination events. A leader at an FBO described how a connection between that organization's Executive Director and the Director of Health Outreach at a local hospital facilitated a vaccine clinic event. The participant stated, "We were talking to [Hospital] about that, and what all services they offered already [...] and would they be willing to be our community provider" (FBO staff #2, White). That participant concluded, "So, we just facilitated it, and made it happen.".

Other participants explained how long-standing informal relationships between organizations engendered trust and willingness to engage in implementing vaccination events. One participant noted, "It really helps already having the relationships there because we know that, 'Oh, hey, I can work with this person from [a partner organization],' and they've been a good

partner in the past; we know they're gonna show up if they say they're gonna show up" (program staff #2, White). Conversely, there was greater difficulty in engaging organizations in vaccine events when informal relationships did not already exist. Participants noted that when trying to recruit new FBOs to participate in vaccination events, "there have been several churches that said, 'We don't need 'em'" (program staff #3, Marshallese).

Individual level: staff roles in organization and community

As a result of long-term engagement with the Hispanic and Marshallese communities in Northwest Arkansas, several team members employed by UAMS are members of the Hispanic and Marshallese communities facilitating cultural congruence between the implementing organization, FBO, and the Hispanic and Marshallese communities. Participants overwhelmingly stated that cultural congruence among the implementing organization and communities of focus made it possible for team members at vaccine events to provide culturally and linguistically appropriate services. For example, one participant described culturallyappropriate messaging delivered by a trustworthy community ambassador as a facilitator for reaching the Marshallese community: "We're speaking with the Marshallese community, in Marshallese, in a way that's culturally appropriate by somebody that they trust" (healthcare provider #1, Marshallese). Team members' work in their communities was also considered a source of intrinsic motivation. One participant stated, "[Implementation team members are] part of the community that we're protecting; the same people who come and work our events. [...] So, they really take ownership [...] sometimes they're like, 'Hey, this is my church. I'm gonna be there. I'm gonna work it. I'm gonna make sure it's successful" (program staff #4, White).

Several Hispanic and Marshallese participants noted burnout resulting from their dual roles as UAMS team members and as members of the communities of focus. Participants described how this overlap in social roles became an implementation barrier as events required the involvement of bilingual team members at every stage of the process (check in, registration, consent, vaccination, waiting period, and evaluation activities). Team members with the requisite language skills worked additional and non-standard hours to accommodate vaccination events which occurred on nights and weekends and in varying locations in the region. Furthermore, some Hispanic and Marshallese staff reported serving as an unofficial point-ofcontact or source of information for members of their own community outside of their work hours. A participant described, "Cause I work with UAMS, they assume that I have the answer when they ask me things [about COVID-19 or the vaccine]" (program staff #6, Marshallese). Institutional policies related to flexible hours and paid time off were described by participants as critical to helping mitigate this barrier. One participant explained, "You get-we call it flex time. Say you worked five hours on an event on Sunday. You can then take those five hours off somewhere else in the next two weeks during your regular work time, without having to submit time through the system. That works well, except everybody's very busy, and needs their office time too" (program staff #5, Hispanic).

Individual level: community members' familiarity with organization

Participants frequently described how Hispanic and Marshallese community members in Northwest Arkansas were familiar with UAMS due to the organization's prior communitybased and community-engaged research, programs, and outreach. Participants described community members' familiarity with UAMS, and the employment of staff from their communities, as facilitating reach: "Many of the Marshallese events are being organized by Marshallese folks [staff]. They know of us, so when we approach them-I don't think anybody has turned us down yet" (healthcare provider #1, Marshallese). Long-term community engagement and outreach was described as building trust, supporting the sustainability of external relationships, and improving community buy-in with the vaccine events. As one participant narrated, "I moved here about five years ago, and I saw some of my colleagues work out in the community. [...] I was impressed with the work they were doing out in the community. So, I said to myself, well, I'm gonna apply there 'cause I wanna do work there. I wanna be among those people that are doing impact work with the community" (program staff #6, Marshallese).

In spite of the facilitating role of familiarity with UAMS, participants identified limits to reach stemming from unmet communication needs, especially for some sub-populations who were not as easily reached, even by bilingual Hispanic and Marshallese team members. One participant specifically mentioned reaching older members of the Hispanic community as a barrier: "I have noticed that most of the elderlies [from the Hispanic community] that we get vaccinated, it's somebody else who's bringin' them. It is not them who got the information firsthand." This participant also stated that low literacy among older members of the Hispanic community was not addressed through normal outreach techniques: "We still give them the [printed flyers] but there is also the fact that usually Hispanic populations [...] our elderlies, [...] most of them don't know how to read or write" (program staff #7, Hispanic).

Discussion

This paper explored external relationships (organizational and individual) as barriers and facilitators for equitable community-based implementation of a COVID-19 vaccination intervention leveraging FBOs to reach underserved and hard-to-reach Hispanic and Marshallese communities. Engagement with FBOs to promote health equity and mitigate health disparities among Hispanic and/or Marshallese communities is described in detail

in prior publications (41, 49, 57-60). Importantly, vaccination events held in partnership with FBOs reached a higher proportion of Hispanic and Marshallese persons compared to vaccination events in secular, community contexts, and individuals vaccinated at these events were more likely to report completely trusting the COVID-19 vaccine (49). We identified themes at the organizational and individual levels for external relationships as implementation determinants. At organizational level, formal inter-organizational structures and informal relationships among organizations, which predated the development and implementation of the community-based COVID-19 vaccine events, emerged as implementation determinants. At the individual level, implementation determinants included staff roles in organization and community and community members' familiarity with organization. Participants also identified team members who belonged to the communities of focus as a facilitator for vaccination events, especially for providing culturally appropriate services in language and for leveraging cultural congruence and community members' familiarity with the implementing organization to improve reach. Participants described external relationships as critical factors in creating and maintaining trust among partner organizations and within the Hispanic Marshallese communities.

Across organizational and individual levels, our analysis highlights three critical factors among organizational and interpersonal relationships as implementation determinants. First, cultural congruence of the implementation team with target communities can be critical to implementing equitable community-engaged interventions. Our findings highlight how implementing organizations can leverage cultural congruence among implementation team members and communities of focus to facilitate outreach, build and maintain trust, and improve the reach of interventions into underserved and hard-to-reach communities. These team members served as an important intermediary between healthcare organizations, community partner organizations, and community members (14, 17, 61-64). Community representation among healthcare workers has also been reported to build trust among communities and healthcare actors (65, 66). However, these team members face unique pressures from overlapping social roles which intertwine their personal and professional lives and may result in greater levels of stress, emotional exhaustion, and burnout (67, 68), particularly during health emergencies that disproportionately impact their communities, such as the COVID-19 pandemic. Future studies of the role of organizational relationships in implementation should consider the interaction between these relationships and "characteristics of individuals" involved in implementation (4), particularly the needs, capability, and motivation of individuals with dual roles in the implementing organization and the community of focus.

Second, long-term, pre-existing relationships among organizations and individuals facilitated implementation and outcomes. Specifically, the preexisting investment in community engagement facilitated the rapid development and implementation of the vaccine events. While it is well-established

that building strong relationships is often an essential step in successful community-based interventions, building these relationships with communities requires time and focused effort, even when sufficient organizational resources are available (69, 70). Time, as a contextual variable in implementation, is not explicitly addressed by most IS frameworks, and it is often reduced to a static resource (3). Our findings suggest that the positive effects of community engagement and trust-building strengthen over time, with long-standing formal and informal relationships described most frequently as a critically-important facilitator. The role of time in strengthening community and organizational relationships contrasts with the dynamics of time in the Stages of Implementation Completion framework, where longer durations for tasks predict poor implementation. This gap highlights the lack of focus on community engagement and organizational relationship-building as ongoing processes and implementation determinants (71, 72). However, CEnR scholars, including Wallerstein and colleagues, have cited the importance of long timeframes noting that "despite enhanced focus on research and health outcomes" in community-engaged participatory projects, "the science lags behind the practice," with little evidence on the mechanisms through which engagement results in outcomes (37). The CEnR literature, especially for community-based participatory approaches, focuses more explicitly on time as a critical factor, and this body of work could be drawn upon to inform future research on communityengaged implementation (35, 73).

Finally, our findings also have implications for trust and trustworthiness as important constructs in equity-focused, community-engaged implementation. Participants explained how long-standing informal relationships among target communities and organizations involved in the intervention engendered trust in new activities or programs facilitating the involvement of hard-to-reach populations, which is broadly consistent with the community engagement literature (37, 69, 74-76). Long-term community engagement also contributed to organizational capacity for culturally-appropriate interventions, as well as the recruitment and retention of community staff whose contributions to COVID-19 vaccine events were described as essential factors in the success of the events through cultural congruence which created and reinforced trust among Hispanic and Marshallese individuals who were more comfortable with members of their own community (74, 77-79).

Recent calls for IS to focus on health equity and adopt justice-focused approaches requires an increased focus on organizational relationships and community engagement, and implementation researchers could draw on the robust CEnR literature to improve health equity (73, 77, 80, 81). Addressing structural health inequalities at the intersections of race, gender, sexual orientation, and immigration status will require a greater focus on incorporating interested communities and individuals into the development, implementation, and evaluation of interventions (27, 28, 32, 82, 27). Partnership strategies have been found to help mitigate and reduce inequities in care, promote individual empowerment, and reduce social stigma of health conditions, which further supports the results of the present study (77, 80).

Our findings suggest that if implementation researchers are to engage with communities to mitigate health disparities and promote health equity, attention needs to be paid to both formal and informal relationships among academic institutions, healthcare systems, healthcare providers and clinics, community-based organizations, and communities.

Strengths and limitations

This exploratory study was limited to Northwest Arkansas and focused on COVID-19 vaccination promotion to the Hispanic and Marshallese communities, and hence, generalizability may be limited. Further, our methods were solely qualitative in nature, which also limits generalizability of the findings. These limitations are offset by the diversity and rigor of the qualitative methods used and by the experience and expertise of the research team. As well, the relationships among organizations and the Hispanic and Marshallese communities under study were large and well-established, which provided an opportunity to investigate the potential longer-term implementation-related impacts of these relationships.

Conclusion

Achieving health equity in IS requires a greater understanding of external relationships, both at the organizational and individual levels, as implementation determinants; however, there are significant gaps in the current understanding of how these relationships affect implementation. This article makes a significant contribution to the literature through our exploration of formal and informal relationships among organizations and individuals as critical implementation determinants community-based COVID-19 vaccination events within FBOs as a way to reach underserved and hard-to-reach Hispanic and Marshallese community members. Across all levels of our analysis, we identified three critical factors for external relationships as implementation determinants. First, cultural congruence of the implementation team with communities of focus can be leveraged to facilitate outreach, build and maintain trust, and improve the reach of interventions into underserved and hard-to-reach communities. Second, long-term, pre-existing relationships allowed for rapid implementation. This study expands the current literature on time as a contextual implementation determinant, which is underdeveloped in IS, with our findings suggesting that the positive effects of community engagement and trust-building strengthen over time and facilitate subsequent outreach and interventions. Finally, this study implications understanding trust and has for trustworthiness equity-focused, community-engaged implementation, with long-term community engagement contributing to organizational capacity for culturally- and linguistically-appropriate interventions. While these concepts are understudied in IS, the literature of CEnR may be useful in informing IS. Further research is needed to clarify and understand the precise effects of external, organizational relationships on other implementation determinants.

Data availability statement

The deidentified data underlying the results presented in this study may be made available upon reasonable request from the corresponding author, PM, at pamcelfish@uams.edu.

Ethics statement

The studies involving humans were approved by the UAMS Institutional Review Board (IRB#262917). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

RM: Formal Analysis, Visualization, Writing – original draft, Writing – review & editing, Methodology. JCK: Conceptualization, Formal Analysis, Writing – original draft, Writing – review & editing, Methodology. JV: Data curation, Formal Analysis, Writing – original draft, Writing – review & editing. SP: Formal Analysis, Writing – original draft, Writing – review & editing. MS: Data curation, Formal Analysis, Writing – original draft, Writing – review & editing. SR: Formal Analysis, Writing – original draft, Writing – review & editing. EA: Writing – original draft, Writing – review & editing. APR: Writing – original draft, Writing – review & editing. ST: Writing – original draft, Writing – review & editing. GC: Conceptualization, Data curation, Formal Analysis, Writing – original draft, Writing – review & editing, Methodology.

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Conflict of interest

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

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Implementation of streamlining measures in selecting and prioritising complex cases for the cancer multidisciplinary team meeting: a mini review of the recent developments

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In January 2020, NHS England and NHS Improvement, in the United Kingdom, issued a permissive framework for streamlining cancer multidisciplinary (MDT) meetings. Streamlining is defined as a process whereby complex cases are prioritized for full discussion by an MDT in an MDT meeting (MDM), while the management of straightforward cases is expedited using Standards of Care (SoC). SoC are points in the pathway of patient management where there are recognized guidelines and clear clinical consensus on the options for management and should be regionally agreed and uniformly applied by regional Cancer Alliances. While this report marks the first major change in cancer MDT management since the Calman-Hine report in 1995, its implementation, nationally, has been slow with now nearly four years since its publication. It is argued however that streamlining is a necessary step in ensuring the viability of MDT processes, and therefore maintaining patient care in the current socioeconomic context of rising workload and cancer incidence, financial pressures, and workforce shortages. In this mini review, we offer a succinct summary of the recent developments around the implementation of the 2020 streamlining framework, including challenges and barriers to its implementation, and the potential future directions in this field, which we propose should increase utilisation of implementation science. We conclude that ensuring successful implementation of the framework and the SOC requires securing a buy-in from key stakeholders, including MDTs and hospital management teams, with clearly defined (a) management approaches that include triage (e.g. through a mini MDT meeting), (b) assessment of case complexity (something that directly feeds into the SOC), and (c) roles of the MDT lead and the members, while acknowledging that the SOC cannot be universally applied without the consideration of individual variations across teams and hospital Trusts.

KEYWORDS

cancer treatment, health care quality, standard of care, outcome assessment, shared decision making, multidisciplinary team, multidisciplinary team meeting, tumor board

1 Introduction

Multidisciplinary team (MDT) meetings are an essential part of cancer care, bringing together healthcare professionals from different disciplines (e.g., oncologists, surgeons, cancer nurse specialists, radiologists, pathologists, physicians, and in some cancers allied health professionals) to discuss patient cases, review diagnostics and develop treatment recommendations (1). However, MDT meetings can be time-consuming and resource-intensive, particularly when discussing straightforward cases that do not require true multidisciplinary input (2). This is further compounded by rising cancer incidents, staff shortages and financial pressures on healthcare (3, 4). Accordingly, there is a need to prioritize complex cases, which are those known to benefit most from a multidisciplinary approach. Indeed, focusing on complex cases has been recommended in several UK national policy documents in recent years (1, 5).

Streamlining is a process whereby complex cases are prioritized for full discussion, while the management of straightforward cases is expedited using Standards of Care (SoC; 4). SoC are points in the pathway of patient management where there are recognised guidelines and clear clinical consensus on the options for management and should be regionally agreed and uniformly applied by regional Cancer Alliances (6). By streamlining cases listed for cancer MDT review, healthcare professionals can work towards improving the efficiency and effectiveness of MDT meetings while still providing high-quality care for cancer patients (3, 7). This review will explore the implementation of the 2020 streamlining framework, emphasizing the vital role of implementation science and the importance of securing buy-in from key stakeholders.

2 The 2020 streamlining framework and its implementation

The guidance from NHS England (5) marks a departure from the NHS directives of the past 20-years (8). It suggests that not all cases require discussion and that the focus should be on complex cases. This provides cancer MDTs with a clear mandate to implement changes. The question of what constitutes a complex case, is however not so readily answered in the guidance. This question is an important one, as failure to streamline MDT processes using existing best evidence means that while the team's caseload may become more manageable, the care quality could be compromised by returning to the unwarranted variation in care that was evident before the introduction of MDTs (9, 10).

What constitutes the complexity of a cancer case for MDT discussion has been addressed scientifically and concurrently with the NHS England guidance by Soukup and colleagues, who spent 2-years undertaking an NIHR-funded mixed methods study, with input from hundreds of cancer experts, and data from hundreds of cancer MDT case discussions across the UK (11). The researchers found that each professional group within

an MDT holds a unique perspective on the question of what constitutes a complex case. Their algorithm, Measure of Case-Discussion Complexity: the MeDiC tool, includes 26 psychometrically validated indicators of complexity that represent the perspectives of all professional groups that make up an MDT. This tool allows MDTs to scientifically measure case complexity and apply this to streamlining and the selection of cases for the SoC. Subsequent research demonstrated feasibility and utility of the MeDiC tool in urology MDTs (12).

Implementing the streamlining guidance, along with structuring and organizing the MDT meeting, will require time and effort, especially if using scientific tools such as MeDiC. What resource is required, and how this is best utilized is open to debate, and the optimal strategy will likely vary from one team to another. It is hoped however, that this investment will pay dividends by allowing better utilization of these resources by focusing on complex cases, and reducing unnecessary delay for cases that meet SoC (7).

In addition, several models have been proposed to facilitate triage of cases referred to the MDT meeting, and efficient decision-making and patient management (9, 13).

The first model, referred to as the Mini MDT, constitutes a core team comprising the MDT Coordinator, MDT lead (or deputy), radiologist, and pathologist. Within this framework, all cases are subject to discussion within the Mini MDT (14). The Mini MDT collectively evaluates the results of investigations and decides whether a case should be referred for SoC management or necessitates full MDT discussion. Cases designated for SoC management have their management recommendations meticulously documented, while MDT cases undergo comprehensive deliberation during the subsequent full MDT meeting, involving the complete team.

The Pre-MDT triage model (15), on the other hand, adopts a different approach. It involves a smaller triage team, consisting of the MDT Lead (or deputy) and the MDT Coordinator. For a case to be considered under this model, the radiology and pathology reports must have been reviewed and reported by a core MDT member. The pre-MDT triage team systematically reviews all cases and makes determinations regarding their categorization, either for SoC management or full MDT discussion. As with the previous model, SoC cases have their management recommendations meticulously documented and integrated into the MDT minutes, while MDT cases are subsequently subjected to comprehensive examination during the full MDT meeting, where the entire team contributes to the discussion.

A third suggested model places emphasis on active engagement from all clinicians involved in the MDT (13). The prerequisite, once again, is that radiology and pathology reports must have been reported by a core MDT member. Under this model, referring clinicians take on the responsibility of assessing whether a case warrants SoC management or necessitates full MDT discussion. The referring clinician then documents the management recommendation accordingly. Subsequently, the MDT lead reviews both the SoC and MDT lists to ensure

the appropriate categorization. Cases designated for full MDT discussion are deliberated upon in detail during the MDT meeting, involving the complete team.

These three models for MDT triage enable the allocation of appropriate resources and the identification of cases that necessitate comprehensive MDT discussion. By adhering to specific criteria and actively involving relevant team members, these models facilitate streamlined decision-making processes, ultimately ensuring the delivery of optimal patient care outcomes (16).

In this process, the role of the MDT lead holds significant importance. To ensure that the individual appointed for this role possesses the requisite experience, interest, and credibility, a competitive interview process should be considered (17). This interview process serves to assess the candidate's qualifications and suitability for the position. Furthermore, it is imperative that the role of the MDT lead is clearly defined, with a well-defined description outlining the responsibilities and expectations associated with the position (13). To ensure effective execution of the MDT, members should cover various essential activities listed in Table 1.

The roles within MDTs, as detailed in Table 1, are pivotal to the streamlining and efficiency of cancer care, yet their effective implementation necessitates adaptability to the unique environments of various teams and hospital trusts. The MDT Lead plays a crucial role in providing necessary oversight, preparation for meetings, participation in improvement efforts, implementation of streamlining strategies, and maintaining audits. This role, however, must be flexible enough to accommodate the diverse challenges and resources of different healthcare settings. For instance, in smaller trusts, the MDT Lead might engage more directly in the preparation and review of patient information, while in larger settings, their focus might shift towards strategic coordination and oversight of streamlining efforts.

Similarly, the roles of other team members, who contribute to meeting preparation and actively participate in streamlining and improvement initiatives, must be attuned to the specific dynamics of their team. In some settings, team members might

TABLE 1 Collaborative roles and responsibilities within multidisciplinary team (MDT) operations.

Role of the MDT Lead	Role of other members
- Necessary oversight: Providing guidance and coordination for MDT activities.	- Allocate appropriate time within their job plans
- Preparation for meetings: Reviewing patient information, conducting research, and collecting data for informed MDT discussions.	- Collectively agree upon their relative contributions to the preparation for these meetings
- Participation in improvement efforts: Actively contributing to enhancing MDT efficiency and effectiveness.	
- Implementation of streamlining: Identifying opportunities to optimize workflow and improve team performance.	
- Maintenance of audit: Ensuring accurate documentation of MDT decisions and monitoring outcomes.	

allocate significant time to the detailed preparation of cases due to the complexity or volume of patients, while in others, their focus might be on collective efficiency and streamlined decision-making processes. Adaptability in these roles is essential to cater to varying patient loads, resource availability, and organizational structures across different hospital trusts.

By recognizing and adapting to this variability, MDTs can ensure that their roles are not only clearly defined but also flexible and responsive to their specific healthcare environment. This adaptability is key to maintaining high standards of patient care, irrespective of the differing contexts and challenges presented by each trust.

3 Challenges, barriers, and the role of implementation science

While efforts to streamline MDT meetings are crucial, the potential disadvantages of implementing streamlining in MDT meetings needs to be considered. The specific disadvantages may vary depending on the context and implementation approach, and some to consider are listed in Table 2. It is important to

TABLE 2 The complexities and potential drawbacks of streamlining in multidisciplinary team (MDT) meetings.

1. Misapplication of Definitions of Complexity:

- Streamlining efforts may lead to mismanagement of complex cancer cases if complexity definitions are not accurately applied.	- Incorrect or misapplied definitions can overlook important nuances requiring interdisciplinary discussion.
2. Limited Time for Comprehensive	Discussion
- Streamlining intended to focus on complex cases may inadvertently reduce overall discussion time, including for complex cases.	- Complex cases may require extensive discussions for optimal decision-making.
3. Potential for Biased Decision-Ma	king
- Streamlining can introduce biases if standardized approaches prioritize certain patient aspects.	- May overlook factors like patient preferences, social circumstances, or emerging treatments, leading to biased decisions.
4. Reduced Interdisciplinary Collabo	oration
- Streamlining involving fewer disciplines can save time but limit the benefits of interdisciplinary collaboration.	- Comprehensive understanding and improved treatment planning may be compromised.
5. Incomplete Information and Data	a Gaps
- Streamlining relies on accurate, comprehensive patient data, which data gaps can compromise.	- May result in suboptimal decisions or inadequate consideration of patient needs.
6. Lack of Flexibility for Individual \	/ariations
 Streamlining's one-size-fits-all approach may overlook individual patient variations in characteristics, comorbidities, or treatment responses. 	- Impact on treatment outcomes due to lack of individualized care.

- Overcoming resistance and ensuring

team buy-in is crucial for successful

streamlining.

7. Resistance from Team Members
- Implementing streamlining measures

may face resistance from team members

who perceive it as a threat to their

professional autonomy.

carefully consider these and design streamlining strategies that strike a balance between efficiency and comprehensive patient care (18). Engaging MDT members, maintaining open lines of communication, and regularly evaluating the impact of streamlining efforts can help address these disadvantages and optimize the benefits of streamlining in cancer MDT meetings (19).

It is also important to anticipate different barriers to implementation of streamlining, such as for example challenges in selecting and prioritising complex cases (20, 21). Resistance to change is a common hurdle, as implementing streamlining measures often disrupt established routines and roles within the MDT. Additionally, necessary resources are often found to be lacking, including dedicated personnel and technology upgrades. This is improved by engaging various stakeholders, from clinicians to administrators, as disengagement from specific groups can hamper progress (22).

Challenges in the form of communication and coordination within the team can further complicate the process. Given that MDT meetings are already time-limited, time constraints can lead to rushed decision-making when introducing streamlining measures. Furthermore, an efficient streamlining process relies on access to accurate patient data, test results, and treatment guidelines (20). Barriers related to data availability, privacy concerns, or incomplete information can hinder the streamlining process. Finally, institutional culture, existing policies, and governance structures may either facilitate or hinder streamlining efforts, and legal and regulatory considerations must be navigated carefully.

4 Strategies for successful implementation

Mitigating the barriers necessitates the adoption of comprehensive strategies (21). It involves effective change-management strategies, adequate resource allocation, stakeholder engagement, and clear communication regarding the advantages of streamlining. Collaboration among MDT members, along with leadership support and commitment to adapt and learn from the implementation process, is key to overcoming these challenges and successfully streamlining cancer MDT meetings.

It is therefore important to consider optimising existing processes in MDT meetings before embarking on significant changes to the standard operating procedures (9, 23). First, a comprehensive assessment and audit of the current local circumstances is imperative, encompassing a meticulous evaluation of case volume, temporal allocation, personnel availability, and their respective contributions (24). Secondly, a revision of the clinical data available for decision-making should encompass comorbidities, social determinants, performance metrics, radiological findings, pathology reports, and patient perspectives where accessible (25). Furthermore, a judicious approach to measuring case complexity should be adopted, and the employment of a structured template or proforma is recommended (26). The team should refrain from discussing

cases that could be appropriately managed elsewhere, focusing solely on cancer cases during the MDT meeting.

To facilitate a comprehensive, holistic, and patient-centred care, the recognition and cultivation of good team dynamics, effective meeting management, and the mitigation of disruptive behaviours and distractions are important. Avoiding excessively lengthy meetings and incorporating breaks to refresh participants are also important considerations (27). Finally maintaining representative and transparent record-keeping is crucial.

Lastly, establishing SoC is critical as it requires a clear consensus regarding the most effective care management for patients (28). These standards hinge on several key factors: firstly, the condition must be categorized within the criteria for low complexity, furthermore, patients must meet the eligibility criteria with minimal comorbidities, indicating lower chances of adverse outcomes. Secondly, a robust consensus should exist regarding the optimal management strategies for the specific condition in question (22), while patients' willingness and ability to adhere to the recommended approach is considered. This approach could ensure consistent, safe, and effective management practices for low-risk conditions, ultimately optimizing patient outcomes and judiciously allocating resources.

5 Future directions and role of implementation science

Implementation science plays a pivotal role in the streamlining of MDT meetings in cancer care, bridging the gap between established guidelines and their practical application. With its focus on the methods to promote the uptake of research findings into routine healthcare practices, it offers invaluable insights for enhancing MDT meeting efficiency and effectiveness. It provides a structured framework for identifying, analyzing, and overcoming the barriers to successful implementation. By employing implementation science principles (e.g., 29-33), MDT meetings can adopt a more systematic and evidence-based approach to prioritize complex cases, optimize decision-making processes, and adapt to the unique challenges of different healthcare settings. As outlined in the recent paper (7), it equips MDMs with the necessary tools to evolve from traditional, all-encompassing discussions to a more focused and strategic model of patient case review, which is crucial in the current landscape of increasing cancer incidence and resource constraints (7).

Securing stakeholder buy-in is also a critical component in the successful implementation of streamlined MDT meeting processes. Implementation science emphasizes the need for engaging all key stakeholders—from managers to oncologists and pathologists to nurses and administrative staff—ensuring that each voice is heard in shaping the implementation. This inclusive approach not only fosters a sense of ownership among MDT members but also facilitates the identification of team-centred solutions that are sensitive to the unique dynamics and needs of each team. Moreover, implementation science provides the tools and

methodologies (e.g., 33) to tailor the streamlining strategies to fit diverse settings, acknowledging that a one-size-fits-all approach is rarely effective. By leveraging these principles, healthcare organizations can develop and implement streamlining strategies that are both effective and sustainable. These tailored strategies not only streamline the decision-making process but also enhance collaboration and communication within teams, ultimately leading to a more agile and responsive cancer care system. Through this lens, implementation science is not just a facilitator for change; it is a catalyst for creating a more dynamic, efficient, and patient-centered MDT model (7).

In addition to these direct applications, a critical aspect of implementation science in streamlining MDT meetings lies in its contribution to building and expanding a knowledge base. As MDTs adopt these streamlined approaches, the collection, analysis, and dissemination of data on their implementation and clinical effectiveness will become invaluable. This ongoing process of knowledge creation not only informs the refinement of current practices but also serves as a rich resource for other teams embarking on similar streamlining journeys. By systematically documenting successes, challenges, and lessons learned, a robust body of evidence can be generated. This evidence base is essential not only for continuous improvement within individual teams but also for advancing the overall practice of cancer care. It supports the development of best practices that can be shared and adapted across different contexts, further enhancing the capability of MDTs to provide high-quality, efficient, and patient-focused care in an everevolving healthcare landscape (7, 29-33).

6 Conclusion

The workload of MDTs is on the rise, while the effectiveness of MDT processes exhibits variability. To enhance effectiveness and efficiency, streamlining measures need to be implemented. It is crucial to concentrate the MDT meetings on complex cases, as these often require comprehensive interdisciplinary collaboration. Successfully implementing SoC necessitates directing attention towards several key factors, including areas of consensus, complexity of cases, local agreement, the operational model, and acknowledging that SoC cannot be universally applied without consideration of individual variations. Looking ahead, the integration of implementation science principles will be crucial in adapting and evolving the streamlining practices to meet the diverse needs of cancer care.

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Development of an implementation science informed "Test Evidence Transition" program to improve cancer outcomes

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Introduction: Translation of cancer research into practice takes around 15 years. Programs informed by implementation science methods and frameworks offer potential to improve cancer outcomes by addressing the implementation gap. **Methods:** We describe the development of a Test Evidence Transition (TET) program which provides funding and support to health system delivery teams and project design and evaluation partners working together to achieve three objectives: Test innovations to support optimal cancer pathways that transform clinical practice; Evidence the process, outcome, and impact of implementation; and work with strategic partners to ensure the Transition of best practice into effective and equitable adoption across UK health systems.

Results: Phase 1 launched in April 2023. Teams with the capability and motivation to implement evidence-based pathway innovations were identified and invited to submit expressions of interest. Following peer-review, teams were supported to develop full proposals with input from academics specializing in health services research, evaluation, and implementation science. Projects were selected for funding, providing an opportunity to implement and evaluate innovations with support from academic and health system partners.

Conclusions: TET aims to improve cancer outcomes by identifying and addressing local-level barriers to evidence-based practice and translating findings into consistent and equitable adoption across health systems. Phase 1 projects focus on pathway innovations in diagnosis for breast and prostate cancer. We are now launching Phase 2, focusing on colorectal cancer.

KEYWORDS

cancer, implementation science, behavioral science, evaluation, implementation research, quality improvement

1 Introduction

Cancer is one of the world's greatest challenges. In the UK, almost 1 in 2 people will get cancer in their lifetime (1). Beating cancer requires sustained and targeted work to drive scientific discovery and translate this into benefits for people affected by cancer (2). However, translation of evidence into practice is complex and challenging: a 2021 study of cancer prevention, screening, treatment, and survivorship research found time to translation averaged around 15 years. The study noted differences in the speed of implementation by race/ethnicity highlighting the role of inequitable access and use of health services in driving cancer health disparities (3). The slow and uneven adoption

of evidence into practice creates unwarranted variation in cancer care delivery and deficits in quality and safety (4).

There are multiple factors underlying this "implementation gap". For example, Mitchell and Chambers (5) highlight that efficacy studies do not usually provide information about barriers and enablers of implementation or the effects of individual and organizational context on intervention efficacy; efficacy studies are also not generally designed to manualize an intervention for use in routine practice, confirm the nature and extent of intervention adaptation that is permissible while preserving efficacy, or address sustainability of the intervention in delivery settings. Researchers further highlight that Quality Improvement (QI) initiatives are often used to increase uptake of Evidence Based Interventions (EBIs) but these tend to be local in focus and not designed to enable consideration of the generalizability of findings or understanding of the mechanisms underlying practice change, while reports on the impact of QI often provide limited detail on the strategies used or extent of user engagement (5, 6). Introducing innovations into care delivery settings, both within the cancer context and more widely is often opportunistic rather than systematically planned and may be based on untested assumptions (e.g., relating to the effectiveness and acceptability of the innovation, the skills and resources needed to deliver it safely and effectively and fit with the wider care pathway) (5, 7, 8). Such problems may be compounded by a lack of capacity for research and innovation among those in frontline healthcare roles, with high demands of clinical services and no protected time for research cited as frequent barriers (9).

Service innovation projects also tend to pay insufficient attention to the organizational, financial, and human resources needed to scale-up innovations beyond the local level. Consequently, managers responsible for roll out at regional or national level are faced with the challenge of implementing the innovation with few resources in health systems that may be characterized by weak capabilities and multiple pressing priorities (10).

2 The role of implementation science

The gap between identification of evidence-based innovations and translation into practice has led to development of the field of implementation science (also referred to as dissemination science improvement science, and implementation research), which Eccles and Mittman (11) define as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care" (p1). With interdisciplinary underpinnings, implementation science involves a theory-driven approach that explicitly examines the link between an intervention and an outcome and seeks to explain why the intervention worked or failed in a particular setting, as well as considering the influence of context on health care professional and organizational behaviors (5, 12).

In addition to facilitating the implementation of a specific intervention, the systematic approach underpinning implementation science research can lead to creation of generalizable knowledge surrounding methods for the sustainable implementation of interventions across studies and settings (12). This includes understanding the most effective techniques to improve the dissemination of evidence; incorporate new discoveries into clinical care delivery (preserving intervention fidelity and sustainability) and intervene on the determinants of successful and failed clinical implementation (5). Implementation science theories, models and frameworks are used to inform evaluation of barriers and facilitators, identify stakeholders, guide the selection of implementation strategies, and anticipate and implementation failures. They also provide a framework to measure the effectiveness of implementation and identify factors that should be considered to achieve sustainability (5). There is increasing recognition that implementation science has a vital role to play in transforming the delivery of evidence-based cancer care, addressing persistent disparities and driving improvements in patient outcomes (5, 12). The growing global burden of cancer (13) points to a need to accelerate these efforts, including targeted initiatives to fund and support the development, refinement and application of implementation science methods and approaches (6, 14, 15).

3 The test evidence transition program

Test Evidence Transition (TET) is a multi-phase program of commissioned activity delivered by Cancer Research UK (CRUK), the world's leading independent cancer charity dedicated to saving lives through research, influence, and information. TET was developed to support CRUK's strategic "Translate" objective, which focuses on addressing the implementation gap by working "with health systems to make sure that best practice is rolled out consistently, effectively and equitably across health systems to benefit everyone" (p20) (2). In line with this objective, the program aims to:

- *Test* service innovations to support the delivery of optimal cancer pathways at a local level.
- Evidence the process, outcomes, and impact of implementation at a local level, focusing on identified metrics that will drive adoption; and
- Work with strategic partners to enable the effective and equitable
 Transition of identified best practice into mainstream practice
 across the health system.

TET builds on the former Accelerate, Co-ordinate, Evaluate (ACE) Program which was developed in collaboration between CRUK, Macmillan Cancer Support and NHS England to meet an identified need for published evidence on the impact of service innovations in real world contexts (16). A "Wave 1" cohort of 60 projects added to the evidence base for known innovations in the priority areas of lung and colorectal cancer pathways, patients presenting with vague symptoms, and uptake of bowel screening. The "Wave 2" cohort of five pilot projects provided proof of concept evidence for novel rapid diagnostic pathways for patients presenting with *nonspecific but concerning symptoms* indicative of possible cancer, a more precise term that evolved iteratively during the "Wave 1" cohort from vague symptoms (17).

A Realist Evaluation of projects supported in Wave 1 found that the most important enabling conditions ("contexts") identified were the prevailing organizational culture (history of service improvement at this scale, with a proactive approach to developing services and change management) and commitment to quality improvement. Being part of a high profile, national initiative was also important. The mechanisms that emerged as enabling implementation included good quality project management, clinical leadership and engagement communication within and between partner organizations. The extent to which these were present, as well as the extent to which service improvements were normalized, or incorporated into the working practice of user and providers varied across projects (18). Interviews with project teams also revealed that having a network of committed people was vital for both initiating and sustaining change, while understanding stakeholders' emotional responses to change helped mitigate emergent challenges (19). This multiplicity of intermediate conditions, acknowledged in the ACE Theory of Change model (20), while depicting the complexity of change, also enabled ACE to influence through a variety of routes in pursuit of its strategic goal, sustaining health systems innovation.

TET aims to build on the successes of the ACE program by ensuring these elements are in place at the planning stage, applying implementation science models, frameworks, and approaches to identify barriers and facilitators of implementation, promote the systematic uptake of evidence-based innovations and create the conditions necessary for effective and equitable scale up across health systems. Key program elements are described below. Table 1 links these to implementation science strategies as defined by Expert Recommendations for Implementing Change (ERIC) initiative (21) ERIC has been highlighted as a useful resource for embedding implementation science in cancer improvement initiatives (5).

3.1 Multidisciplinary leadership

TET is led by CRUK's Social and Behavioral Research Team in close collaboration with teams across the Evidence and Implementation Department, ensuring that the program design is informed by a detailed understanding of the cancer research and care landscape, underpinned by data and evidence and supported by strong stakeholder relationships (including health systems leaders, academic experts, clinicians, patients and public). This multidisciplinary leadership team is responsible for the program design, including the identification of implementation strategies relevant to TET objectives and their translation into practical application in the organizational context (e.g., considering fit with wider strategic objectives and resources available).

3.2 Team selection

Health systems delivery teams with the capability and motivation to implement and scale an innovation are invited to

apply for funding and support. Applicants are asked to describe the team's ability and experience in delivering, mobilizing, implementing, and spreading a service innovation. Applications must also demonstrate appropriate stakeholder engagement and involvement (including patients and the public), understanding of relevant governance frameworks, consideration of potential risks to project delivery and how these may be addressed. These criteria are intended to ensure that the enabling conditions identified from the former ACE program (18, 19) are in place from the start. Consistent with the program objectives, applications must also demonstrate consideration of health inequalities. Applications are subjected to peer review and funding panel discussion prior to selecting successful teams.

3.3 Active commissioner model

The program adopts an "active commissioner" model, in which projects selected for funding receive ongoing support throughout the process of designing, implementing, evaluating, and scaling innovations. This includes support from the TET program team and stakeholders (described above), as well as project design and evaluation partners—experts in relevant research and evaluation methodologies funded by CRUK to support the project teams and wider program. The program team also has expertise in methodologies relevant to TET, including health services research, evaluation, behavioral science, implementation science, quantitative and qualitative methods.

CRUK supports the delivery of projects using management approaches including an initiation meeting, project initiation document, regular monitoring and progress reports, a communications and dissemination plan, comprehensive critical appraisal and coproduction of project outputs including quality assurance and sign-off. Strategic oversight and monitoring of risks and progress are provided via regular steering group meetings at both the project and program level.

3.4 Program phasing

In line with the program objectives, TET focuses on innovations which are already proven to be effective, with an existing evidence base, that need to be implemented more effectively and equitably. Each phase of the program has a specific focus (e.g., geographical region, cancer type), identified as a key priority for CRUK, ensuring resources are directed toward activities with the greatest potential to improve cancer outcomes.

Phase 1 projects launched in April 2023, with a focus on the UK's devolved nations. This phase of the program provides funding and support to three teams in Scotland and Wales implementing and evaluating innovations to improve the timelier diagnosis of breast and prostate cancer. Table 2 provides an overview of the three Phase 1 projects.

Further detail in relation to the two projects in Scotland is provided in the recently published protocol paper (28). Phase 2

TABLE 1 TET program strategies and practical application.

TET objectives	Barriers identified	Strategy ^a	Practical application
Test service innovations to support the delivery of	Lack of capacity for service innovation	Identify and prepare champions	TS
optimal cancer pathways at a local level.		Assess for readiness and identify barriers and facilitators	TS
		Obtain formal commitments	TS
		Access new funding	TS
		Recruit, designate, and train for leadership	TS
	Lack of organisational support for service innovation	Involve executive boards	ML
		Inform local opinion leaders	ACM
	Lack of access to methodological expertise/high quality	Work with educational institutions	ML
	project management	Develop academic partnerships	DTR
		Develop and implement tools for quality monitoring	DTR
	Lack of support for navigating the challenges involved	Build a coalition	ACM
	in implementation, evaluation and scale-up/Lack of	Centralize technical assistance	ACM
	access to high quality project management	Facilitation	ACM
		Provide ongoing consultation	ACM
		Use advisory boards and workgroups	ACM
Evidence the process, outcomes, and impact of	Insufficient evidence on impact in real world contexts	Use data experts	ML
implementation at a local level, focusing on identified metrics that will drive adoption		Audit and provide feedback	ACM
	Insufficient evidence on acceptability of innovations/ extent of user engagement	Involve patients/consumers and family members	ML
	Insufficient evidence on skills and resources needed to deliver innovations safely and effectively	Use an implementation advisor	CD
	Insufficient evidence on how and to what extent innovations can be adapted while preserving efficacy	Purposely reexamine the implementation	CD
		Promote adaptability	CD
		Tailor strategies	CD
Work with strategic partners to enable the effective and	Implementation efforts may not be designed to inform adoption beyond the local level	Create a learning collaborative	ACM
equitable Transition of identified best practice into		Capture and share local knowledge	ACM
mainstream practice across the health system.		Stage implementation scale up	PP
		Organize clinician implementation team meetings	PP
		Promote network weaving	PP
		Visit other sites	PP
	Implementation efforts may not be designed to manualise innovations for use in routine practice	Develop a formal implementation blueprint	SS
		Develop an implementation glossary	SS
		Develop and implement tools for quality monitoring	SS
		Develop educational materials	SS
		Distribute educational materials	SS
	I .	Use mass media	SS

^aStrategies are drawn from the Expert Recommendations for Implementing Change (ERIC) (21). Please refer to the original source for full concept definitions.
TS, Team Selection; ML, Multidisciplinary Leadership; ACM, Active Commissioner Model; DTR, Development of Tools and Resources; PP, Program Phasing; CD, Co-design; SS, Support for Scale-up.

will have a UK-wide focus, supporting teams to implement and evaluate innovations with the potential to improve timely detection and diagnosis of colorectal cancer.

Projects receive funding and support for a period of 18 months to two years. This phased approach allows for learnings from each phase to inform the design of subsequent phases, while overlap between the funded projects allows for cluster meetings, bringing teams together to share learnings. Program phasing is also intended to facilitate analysis of data and insights across the funded projects, drawing out considerations relevant to specific contexts, populations, and innovations.

3.5 Co-design

An early learning from Phase 1 was that health systems delivery teams with the capability and motivation to implement service innovations do not necessarily have established relationships with academics specializing in research and evaluation methodologies, which presents a barrier to developing funding applications. For Phase 2, we therefore adopted a different approach. Health systems delivery teams may apply without identifying academic collaborators or proposing a detailed methodology. Once health systems delivery teams are selected for funding, projects will then be

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TABLE 2 Summary of phase 1 projects.

Organizations	Project title	Aim	Design	Implementation science model/Framework/Approach
NHS Forth Valley, Scotland;	Implementing fast-track access from primary	To introduce, evaluate and assess the scalability of a	A mixed methods approach, collecting and analyzing	Design is guided by the Evidence
University of Stirling and the	care to a breast assessment clinic for patients	change in pathway in NHS Forth Valley to allow fast-	qualitative and quantitative data. A hybrid effectiveness-	Integration Triangle (EIT) (24) and the
National Centre for Sustainable	presenting with a breast lump: an evaluation	track access to assessment clinics for symptomatic	implementation design (22) will allow for the identification	evaluation uses Theory of Change
Delivery; NHS Scotland. UK.*	and scalability assessment.	patients with a breast lump to support earlier breast	of potential improvement within a complex system. A	(ToC) (25).
		cancer diagnosis	naturalistic case study design will be used to explore	
			context and process (23).	
NHS Fife, Scotland; University of	Improving the suspected prostate cancer	To develop, implement and evaluate an Advanced	As above.	As above.
Stirling; the National Centre for	diagnosis pathway: a hybrid effectiveness	Clinical Nurse Specialist-led prostate cancer		
Sustainable Delivery; NHS Scotland.	implementation evaluation of an advanced	diagnostic model in NHS Fife, to improve the process		
UK.a	clinical nurse specialist-led model in Fife.	from referral to diagnosis up until decision to treat		
Hywel Dda University Health Board,	Development of a Model Prostate Cancer	To develop, pilot and evaluate the Model Prostate	A mixed methods approach, collecting and analyzing	A Realist Evaluation (RE) approach (26)
Wales; Swansea University; the Wales	Diagnostic Pathway	Cancer Diagnostic Pathway within the service, to	qualitative and quantitative data. The design incorporates a	has been adopted. Plan plan-do-study-
Cancer Network, NHS Wales. UK.		shorten time from referral to diagnosis (and	whole systems co-produced approach including	act cycles will be used (27).
		potentially time to definitive treatment).	implementation review, qualitative interviews, continuous	
			data review and an economic model to estimate the cost	
			and consequences of the novel pathway compared to the	
			usual standard pathway.	

^aPlease refer to the published protocol paper for further detail on the two projects in Scotland (28).

co-designed with input from the project design and evaluation partners, TET program team and wider stakeholders.

The co-design process is intended to ensure:

- A robust methodology, informed by relevant frameworks (e.g., implementation science, behavioral science, health services research, service improvement and evaluation)
- A realistic and deliverable project design, informed by an understanding of the health service delivery context and factors influencing evaluability (e.g., availability of data and resources)
- Collection and analysis of qualitative and quantitative (including economic) data required to evidence the implementation process and outcomes and build a case for Transition.
- Appropriate patient, public and stakeholder involvement in the co-design process and throughout (including local and national stakeholders relevant to Transition)
- Robust research governance and project management processes (e.g., supporting teams to submit projects for ethical review, monitor project timelines, milestones, and key deliverables, identify risks and mitigations)
- Close collaboration with CRUK's Test Evidence Transition program team throughout, including regular communication (e.g., emails, virtual/face-to-face meetings), attendance and reporting to steering group meetings (e.g., updates on activities/timelines, risks/mitigations) and co-authoring reports, publications, and presentations.

Project design and evaluation partners will continue to work closely with health systems delivery teams throughout the implementation and evaluation period. Approaches may be adapted to address barriers and leverage facilitators identified as the projects progress.

3.6 Development of tools and resources

In addition, we have commissioned a team of academics to cocreate a suite of resources that will assist health systems delivery teams in planning, taking forward and scaling up innovation and evaluation projects. These will include, for example, guidance on developing logic models and monitoring and evaluation frameworks, involving patients and the public and engaging effectively with stakeholders. These resources will be developed with input from the health systems delivery teams, project design and evaluation partners, TET program team and wider stakeholders, including patient and public involvement.

3.7 Support for scale-up

A central objective of the TET program is the transition of innovations beyond their site of origin, so that these can be successfully adopted and sustainably scaled across the healthcare system, outlining the routes to scale and the wider-system conditions required for transformative spread. In addition to

outputs outlined above, projects (and analysis of program level data) will also deliver:

- Evaluation protocols allowing for innovations to be reproduced at other sites, including assessing fidelity and identifying adaptations required.
- High-quality case-studies with evidence of how and why the innovation has worked at a local level which informs sustained change; detailing the impact of the service innovation compared to the current patient pathway and any resulting impact on improving cancer outcomes; the impact of the innovation on cancer services and how health systems may need to be adapted to deliver more system-wide benefits.
- A detailed assessment of the sustainability of each innovation, supporting the development of a program scalability and transition plan.
- A cost-effectiveness and affordability analysis for each innovation, incorporating any identified direct cost-savings and an assessment of the health economic impact.
- Wider financial analysis capable of producing an influential business case, including cost of transition for commissioners and health system leaders.
- A demonstration of how the innovation ensures equitable access to improve both patient experience and measurable cancer outcomes.
- A demonstration of how acceptable the innovation is to patients and their support networks, and to healthcare professionals, and how these groups are involved in the design, implementation, and ongoing monitoring.
- Implementation handbook including "cheat sheet" identifying barriers and enablers to change which are non-site specific.
- Any necessary training and service planning guides.

Active engagement with local and national level stakeholders throughout the program phases is essential for creating the conditions for scale-up (10, 18).

4 Conclusions

The purpose of this paper is to illustrate how implementation science has been incorporated into the design and delivery of a program of commissioned activity which aims to address the slow and uneven adoption of evidence-based practice in cancer care. This program has been developed in the context of recognition among the healthcare community of the significant global burden of cancer and urgent need to address cancer inequalities (13) as well as recognition by researchers and research funders that targeted work is needed to address the implementation gap in cancer care, harnessing methods and approaches from the field of implementation science (5, 6, 12, 14, 15).

TET harnesses implementation science in several ways: by integrating evidence-based implementation strategies into the program design; requiring funded projects to adopt implementation science models, frameworks, and approaches; and involving experts in implementation science throughout the process of peer-review, team selection, co-design, ongoing

monitoring and critical appraisal, development of tools and resources (to assist health systems delivery teams in planning, taking forward and scaling up innovation and evaluation projects), and co-production of project outputs (to disseminate findings and permit transition of innovations beyond their site of origin). TET goes beyond the remit of traditional research funding programs by adopting an "active commissioner model" in which funded teams are supported to navigate the complex challenges involved in implementation, evaluation and scale-up, drawing on input from CRUK's multidisciplinary leadership team and wider stakeholders. Program phasing is designed to enable shared learning between teams, as well as analysis of data and insights across projects, drawing out considerations relevant to specific contexts, populations, and innovations.

A limitation of this program is that we are only able to select health system delivery teams with the capability and motivation to take forward innovation projects, which means that we will not capture insights from teams that are either unable or unwilling to engage in this type of program. This is a decision we considered carefully when designing the program selection criteria, as these teams are arguably in even greater need of support. However, lack of motivation and capability to engage in research and innovation in the context of the UK National Health Service often stem from a combination of high demands of clinical service provision and lack of protected time; these are systemic problems, which lie beyond the influence of this program and require a system-based approach involving all components of the research ecosystem (policy, funding, training, academia, healthcare organizations, government bodies) (9, 29). We also considered that such pressures may be exacerbated by adding further unrealistic demands to already overburdened teams—as such, selection criteria were determined by ethical and practical considerations as well as theoretical.

We will continue to report on progress and outcomes as this program moves forward. Insights from funded projects will also be disseminated by project teams, including submissions to peer-reviewed journals. Ongoing engagement with the academic and healthcare communities will be important for ensuring that the program remains grounded in rigorous evidence and findings feedback to inform both healthcare improvement efforts and the wider implementation science literature.

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

KH: Writing – review & editing, Project administration, Methodology, Funding acquisition, Conceptualization. AF: Writing – original draft, Project administration, Methodology, Conceptualization. NM: Writing – review & editing, Methodology, Conceptualization.

BK: Writing – review & editing, Project administration, Methodology, Funding acquisition, Conceptualization. CS: Writing – review & editing, Project administration. LW: Writing – review & editing, Project administration.

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Conflict of interest

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

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"We all see things through a different lens based on our life experiences": co-production of a web-based implementation toolkit with stakeholders across the health and social care system

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Background: Implementing new innovations across the health and social care system is complex, involving many factors that in recent years have been compounded by Covid-19. While a plethora of implementation tools and frameworks are available, there are limitations in terms of their design and accessibility. Co-production is a valuable mechanism for developing tools that have utility and accessibility for those tasked with using them in health and social care organisations and there is growing acknowledgement of increasing the role of co-production in implementation science. This paper provides novel insight into co-production practices and relevance to implementation science by reporting findings from a study to co-produce a web-based implementation toolkit (WIT) that is accessible, usable and designed to support adaptive implementation across health and social care systems. Key themes relating to the process of co-production are outlined and the value of using co-production in implementation processes are discussed.

Methods: A web-based survey (n = 36) was conducted with a range of stakeholders across health and social care. Findings identified a need for WIT. Survey respondents were invited to express interest in becoming part of a coproduction group and to take part in three online interactive workshops to co-produce WIT. Workshops took place with the group (n = 12) and focused on key developmental stages of WIT.

Results: Online co-production workshops were integral to the development and refinement of WIT. Benefits of using this process identified three interrelated themes: (i) Co-designing key features of the toolkit, (ii) Co-producing a toolkit with utility for users across health and social care settings, (iii) Co-producing a toolkit to support the implementation journey. Our approach of undertaking co-production as a dialogic process enabled generation of these themes. To illuminate discussion of these themes we draw upon iterative co-development of the "active ingredients" of key components (e.g., interactive Implementation Wheel) and functions (e.g., interactive "pop-up" definitions of keyword) and features (e.g., case studies) of WIT.

Abbreviations

PPI, patient and public involvement; WIT, web-based implementation toolkit; QT, qualitative theme; AHSN, Academic Health Science Network; HIN, Health Innovation Network; NIHR ARC Wessex, National Institute for Health and Care Research Applied Research Collaboration Wessex.

Conclusion: Using a co-production approach with a range of end-users across health and social care systems, highlights the benefits of understanding implementation processes for users in these settings. User-centred design and processes for ensuring accessibility readily support the translation of implementation into rapidly changing health and social care systems to benefit outcomes for patients, their families, carers, service users and practitioners.

KEYWORDS

co-production, implementation, toolkit, web-based, stakeholder, innovation, health care, social care

Introduction

Implementing new innovations or changes to practice across health and social care systems is complex. It requires consideration of a variety of adaptive, multifactorial changes, which have been compounded by Covid-19 (1-7). For example, a qualitative case study approach examined implementation activity by staff employed by Academic Health Science Networks (AHSNs). There are fifteen AHSNs across England who provide the main innovation component of NHS England (5, 6) [now structured as Health innovation Networks (HINs)]. A series of focus groups was conducted with senior and operational staff from across the AHSNs. Participants reported the rapid implementation of innovations, brought about by a number of Covid-19 associated factors. This included changes in NHS governance processes enacted at local and national levels resulting in new processes to enable agile and responsive decision-making alongside an increasing acceptance of risk to manage implementation challenges and an adherence to social distancing regulations which were introduced with minimal notification. Furthermore, a shift to online modalities of working, were reported to improve efficiency of AHSNs, reducing time needed for engagement as well as enhancing inclusivity through reaching a more diverse range of people than would have been possible in person (5).

The rapid implementation of innovations in the context of Covid-19, has highlighted the need for developing implementation tools that are responsive and have utility and accessibility for those tasked with using them in health and social care systems. While numerous implementation tools and frameworks are available (8, 9), limitations can be identified in terms of design, accessibility, and being targeted to specific users (10–15).

There is growing acknowledgement of the role of co-production in implementation science and research and how involvement of users can help to ensure implementation tools and frameworks are accessible, agile and responsive to the needs of those tasked with introducing new innovations or changes to practice in health and social care (16). Involving end-users in co-development is more likely to lead to successful adoption of interventions and changes in practice that bring about improvements in experiences of service users, their families and carers (17, 18).

The concept of co-production has been widely and flexibly used across health and social care research (19). Co-production can be defined as bringing together experts by experience, by

occupation and researchers to work together, sharing power and responsibility in an equitable partnership (20). While coproduction approaches vary, they share the position that those affected by the research have knowledge and expertise equal to the researchers, making them integral to design and deliver it. In addition, co-production approaches foster two-way learning between researchers and experts by experience and occupation, and can increase experts' sense of self-confidence, empowerment and evidence-based knowledge (21).

Despite increasing recognition of the value of co-production in implementation, there has been limited understanding of the methods involved in applying co-production in practice (22). To address this, we provide methodological insight into co-production in practice through describing the development of a web-based implementation toolkit (WIT) (23).

We approach co-production as a dialogic process, involving activities to elicit reflection, discussion and refinement. Methodological insight is illuminated by examples depicting iterative co-development of the "active ingredients" meaning the key components, functions and features, of WIT through three online co-production workshops. These components include co-development of an interactive Implementation Wheel, as well as refinement of an existing Implementation Checklist. Co-development further informed key functions of the toolkit including interactive "pop-up" definitions of keywords, drop-down question and answer style interactive menus and key features including embedded examples of implementation and case studies designed to assist implementation in practice. Opportunities and challenges in online co-production are reported.

An Implementation Checklist was initially designed and developed in 2020 by the National Institute for Health and Care Research Applied Research Collaboration Wessex (NIHR ARC Wessex) Implementation Team to help ARC Wessex researchers think about implementation considerations from the outset of their projects. The Checklist was informed by the Medical Research Council Framework for Developing and Evaluating Complex Interventions (24), and the empirically based knowledge and experiences of implementation of the Implementation Team. It was also informed by feedback and consultation with NIHR ARC Wessex research teams and regionally with other ARC Wessex Network members.

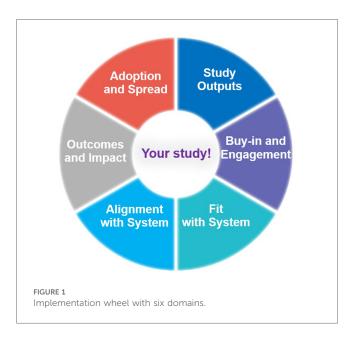
The Implementation Checklist comprises of six domains (Table 1), with corresponding statements to prompt the user into considering various factors to support decision-making about

TABLE 1 Six implementation domains with definitions.

Domain	Definition
Project outputs	This domain encourages considering the deliverables or what is to be produced as a result of a project
Buy-in and engagement	This domain focuses upon who needs to be engaged as part of the implementation process, what routes to engagement to use and how engagement will be maintained during implementation
Fit with health and social care systems	This domain concentrates on how implementation of a project output(s) fit with the changing needs of health and social care systems and local, regional and national directives and policy
Alignment with health and social care priorities	This domain focuses upon how implementation of project outputs(s) aligns with the changing needs of health and social care priorities in local, regional and national directives and policy
Outcomes and impact	This domain enables consideration of the outcomes and impact of a project output(s) for patients, service users, health and social care professionals, third sector organisation professionals and health and social care systems
Adoption and spread	This domain encourages consideration of factors that may influence the uptake of the project output within the original context in which it is to be introduced and to other organisations

implementation. It asks users to indicate whether they agree/disagree with statements and to provide evidence to support their response detailing how these areas are being addressed. Use of the Checklist was encouraged at the inception and throughout a project to support users on their implementation journey and address any challenges which may arise. It was initially developed for use by a variety of stakeholders including: clinical and non-clinical academics, researchers, clinicians, public contributors and managers. Early feedback from users suggested the Checklist prompted thinking about identifying implementation considerations for individual projects, but the format was "clunky" and time-consuming to complete suggesting improvements were required to ensure usability, accessibility and utility.

In 2021, the ARC Wessex Implementation Team delivered a series of four bite-sized webinars aimed at ARC trainees and implementation champions. One session explored "Factors affecting Implementation," based on the six domains of the Implementation Checklist. To present the Implementation Checklist visually and address the existing identified challenges including usability, accessibility and utility, the Implementation Checklist was redesigned, so all six domains could be visualised in a wheel format in one diagram (Figure 1), with component segments representing each domain. The webinar session was well received and confirmed a need to develop tools that are user-friendly and easily applied by researchers. Discussions with colleagues in other ARCs showed that similar challenges were identified with existing implementation materials, in terms of a need for usable and accessible tools. The Implementation Wheel was presented and used as a visual prompt and a core component in a workshop activity at an ARC Wessex Stakeholder Event in 2022. Feedback from the event indicated that participants from across health and social care considered the wheel to be helpful and usable.



Recognising the potential collective value and utility of the Implementation Checklist, Wheel and Webinars to support a variety of users in their implementation journey, we applied and were awarded funding from the NHS England National Insights Prioritisation Programme (NIPP), to co-produce an implementation toolkit.

This paper reports on findings from a study to co-produce WIT- a Web-based Implementation Toolkit designed to be accessible, usable and to support adaptive implementation across health and social care systems. The study aimed to (i) identify awareness and understanding of implementation toolkits and frameworks by clinical and non-clinical academics, researchers, clinicians, patient and public involvement (PPI) contributors, managers, and third sector organisation representatives in regional networks as well as (ii) establish a co-production group to co-develop the "active ingredients" of WIT comprising representatives from the above groups and (iii) finalise the prototype WIT and its constituent components for testing and evaluation in real world settings. Patient and public involvement (PPI) was essential and integral to these aims so as to ensure development of an accessible and appropriate toolkit so that those who are in receipt of the results of new innovations and interventions are involved throughout the process. Additionally, from the breadth of diverse experience PPI contributors bring and through challenging of any pre-assumptions brought by professionals (Table 2).

Methods

Design

There were two key stages in the co-production of WIT. First, following feedback from the stakeholder event to further establish the need for WIT, we undertook a web-based survey conducted

TABLE 2 Application of GRIPP 2 reporting checklist (short) (25).

Section and topic	Section and topic	ltem	Reported on page number
1	Aim	The aim of PPI in the study was to (1) ensure development of an accessible and appropriate toolkit that has relevance for diverse end-users (2) challenge professional language and assumed knowledge and (3) achieve an inclusive and transparent process.	
2	Methods	A PPI network was approached, and participants invited to take part in an online survey who had an interest in implementation across health and social care settings. PPI representatives were included in the survey to ensure representation and inclusion throughout the whole research process. Interested participants were then invited to take part in online co-production workshops to develop the toolkit.	
3	Study results	PPI represented 29% of roles in the survey and 29% of roles in the workshop. PPI involvement illuminated key features to be considered and developed including design and accessibility, applicability and general development of the toolkit. PPI ensured clarity and consideration of different interpretations of terminology. They enhanced the toolkit through bringing experience from implementation offering suggestions for improvements by providing examples.	
4	Discussion and conclusions	PPI participants remained focussed on the key aims of the toolkit and played a key role in ensuring other group members did not become distracted or go off at a tangent that risked diverting from the task in hand. PPI members also brought a different lens to enhancing usability by challenging assumptions and taken-for-granted meanings associated with specialist terminology. The importance of considering how PPI are recruited and able to participate including their access to resources such as the internet is essential. The research team facilitated workshops to ensure inclusivity and provided different options to participate including verbal and written at the time of workshops and in between via email.	
5	Reflections/critical perspective	PPI brought a breadth of diverse knowledge and experience to the research process and the toolkit development. PPI involvement was highly valued, and their input was recognised and acknowledged by ensuring they were reimbursed for their time and having the opportunity to be included in dissemination activities, such as co-authoring papers.	

with a range of stakeholders (aim i). Second, upon establishing this need, co-producing the "active ingredients" of WIT and a prototype through three online interactive workshops (aims ii and iii).

Co-production process

Sharing data alongside the study aims, informed the focus of the workshops. These included considerations of the three key themes including, design and accessibility, applicability of the toolkit for a wide range of users and supporting users in their implementation journey, which were incorporated within the three workshops. Each workshop focused on key developmental stages of WIT. Before each workshop, a programme was sent by email to the group. Details of the programme are provided in Table 3. This included details of the focus of the workshop as well as some questions/considerations to be discussed at the workshop.

A dialogic approach involving a combination of activities was used to elicit participant reflection and discussion including MS PowerPoint® to depict visual discussion points and design images, open discussions, as well as using the Zoom chat function (Table 3). Co-production group members were also invited to review and share feedback on the evolving WIT content and design features in-between workshops via email.

Data collection

Web-based survey: establishing the need for WIT

In order to gain understanding of respondents' awareness, understanding and needs regarding implementation and identify awareness and understanding of implementation toolkits and frameworks a web-based survey using MS Forms® was shared via administrators across two NIHR Infrastructure mailing lists

including (i) a public involvement network, (ii) a network comprising clinical and non-clinical academics, researchers, managers and third sector organisation representatives. The email accompanying the survey, was addressed to those with an interest in implementation or tasked with implementation in a health and social care setting. Through the public involvement network, patient and public involvement (PPI) representatives were invited to take part in the survey to share their implementation experiences and ensure representation and inclusion throughout the whole research process (Table 2).

At the end of the survey, these self-selecting respondents were asked to indicate if they were interested in becoming a member of a co-production group which involved participating in three online interactive workshops to co-produce WIT. Potential respondents were informed that each workshop would take no more than two hours and that a briefing document and materials relating to each one would be circulated by email at least one and a half weeks in advance of each session.

Online co-production workshops: co-producing the web-based implementation toolkit

Over eight months, three two-hour online workshops with the co-production group (n = 12) were held via Zoom and facilitated by the research team using a dialogic approach. Participants were encouraged to keep their camera on though this was not mandatory but had been found by the facilitators to aid discussion in previous online workshops.

Sample

A total of thirty-six respondents completed the survey. Of the thirty-six respondents, roles included Academic (39%); PPI

TABLE 3 Structure of workshop sessions.

Workshop	Focus
Pre-workshop 1	Research team emailed a copy of the original Implementation Checklist to the co-production group and requested them to feedback their overa
	perceptions at Workshop 1
1	Welcome, introductions and aims
	• Introductions
	 Background including why we are undertaking the project Agree terms of reference for the group
	Overview of Project aims
	Presentation of survey results-what you told us
	Introducing the ARC implementation checklist and wheel
	What works well?
	What doesn't work so well? Let a strict the stric
	• Is there anything, missing? What do you need from an online Implementation Toolkit?
	What is an online Implementation Toolkit?
	What implementation topics would be useful to address:
	How can public contributors inform implementation?
	• What does a toolkit need to include to help you know how to implement?
	What would be useful in terms of design?
	What would be useful in terms of access? Closing remarks/questions and Data of part workshop.
Datarram supulsahan	Closing remarks/questions and Date of next workshop
Between workshop 1 and 2	 Research team emailed co-production group to ask them to consider any examples of implementation which had worked well/not worked well workshop 2
2	Welcome, Overview and Focus of Workshop 2
	Introduction and aim of Implementation Toolkit Project
	Introduction and aim of Implementation Toolkit Project
	Aim of the workshops and how we will work together
	Summary of main discussion points from Workshop 1
	Definitions How does the Implementation Tability add value?
	 How does the Implementation Toolkit add value? How will the Implementation Toolkit work?
	How will the Implementation Toolkit be easily accessible?
	Implementation Checklist
	Specific areas which we would welcome your feedback on today
	Feedback Session 1: Implementation Wheel Update and discussion
	What do you think of the proposals for how the Implementation Wheel will be used in the toolkit? And the proposals for how the life and the proposals for how the law and the law an
	 Are there any other areas that it would be useful to have links to on the home page? Feedback Session 2: Sharing examples of implementation in practice to help develop case studies for the Implementation Toolkit
	Please share an example of where implementation:
	Has worked well in practice
	Has not worked well in practice
	Next steps, closing remarks/questions
Between workshop	Co-produced feedback from Workshops 1 and 2 about the "active ingredients" of WIT, i.e., the key components (e.g., Interactive Implementation
2 and 3	Wheel and refinement of an Implementation Checklist), functions (e.g., "pop-up" definitions of keywords, drop-down question and answer sty
	interactive menus) and features (e.g., embedded examples of implementation and case studies), were shared with the web designer ahead of Workshop 3.
	The web designer implemented the feedback into the operationalisation of the prototype toolkit. The prototype toolkit was shared by the research
	team with the co-production group both ahead of and during Workshop 3, within which participants had the opportunity to feedback.
3	Welcome, Overview and Focus of Workshop 3
	Introduction and aim of Implementation Toolkit Project
	Welcome and overview of the Implementation Toolkit Project
	Overview of the session Output
	Summary of main discussion and development areas since Workshop 2 • Development of Web-based Implementation Toolkit
	-home page
	• -domain pages
	-case studies/examples
	Accessibility considerations
	Specific areas which we would welcome your feedback on today
	Sharing of WIT prototype (during Workshop 3) Ecodhoek Session, Web beard Implementation Toolkits Design, content and applicability
	Feedback Session: Web-based Implementation Toolkit: Design, content and applicability • What do you think of the Web-based Implementation Toolkit?
	What do you think of the web-based implementation Toolkit: Landing page
	Domain page
	 Do you have any thoughts at this stage how you may use the Implementation Toolkit?
	• Is there anything missing?
	Next steps, closing remarks/questions
	Potential interest in involvement in co-production paper
Post-workshops	

representatives (29%); Clinical Academic (11%); Clinician (8%); Programme Management (5%); Charity (5%); Research and Engineering (3%), with representation across university (47%) primary care (9%); secondary care (16%); patient and public involvement (24%); third sector (4%). Of the thirty-six survey respondents, fourteen participants consented to take part in the online co-production workshops, of which two could not attend due to other commitments at the time of the workshops. Twelve participants formed the co-production group, roles included Academic (43%); PPI representatives (29%); Programme Management (7%); Charity (14%); Research and Engineering (7%) with representation across university (43%), secondary care (14%), third sector (14%) and PPI (29%). Each participant took part in at least two workshops. PPI participants were vital to the study to challenge assumptions, which informed both toolkit design and content and helped to ensure its accessibility to diverse end-users.

Data analysis

Analysis of web-based survey

Open ended survey responses were analysed using the constant comparative method (26). Themes are described in turn. For quantitative data, data analysis involving descriptive statistics which summarised the characteristics of the data was conducted using MS Excel®.

Analysis of online co-production workshops

The three members of the research team all attended and facilitated the workshops and two of the researchers took notes during each of the workshops to ensure inclusion of key points. Workshops were audio recorded (with consent) and transcribed by a professional transcriber. In all workshops, researchers

relayed key discussion points back to the group to ensure they had understood what participants had said correctly. Summary points of key discussions from the previous workshop were communicated at the start of Workshops 2 and 3 (Table 3). Participants were provided with an opportunity to feedback further comments via email between workshops. This enabled participants to have several opportunities to reflect and provide feedback for refining of the toolkit.

The research team held data analysis meetings following each workshop in which key areas for the development of the toolkit were agreed. To improve the rigour of the analysis and trustworthiness, triangulation of data was performed whereby all researchers independently analysed transcripts with the notes and came together in the analysis meetings to discuss and arrive at a consensus. A thematic approach (27) was used to guide analysis of transcriptions which were used in conjunction with the notes using MS Word. This involved six core stages; (1) Familiarisation, (2) Identification of coding categories, (3) Grouping codes into themes, (4) Reviewing themes, (5) Naming and refining themes and (6) Presenting the findings. Data workshops were held within the research team to discuss findings and interpretation of responses. Core themes are presented in Table 4.

Results

Web-based survey

Qualitative analysis

The web-based survey analysed participants responses to five open-ended questions about what would be helpful to consider when developing a web-based implementation resource, what would encourage/discourage use of a web-based implementation

TABLE 4 Key qualitative themes from the web-based survey and online co-production workshops.

Top ther	three qualitative nes	Open-ended survey questions (<i>n</i> = 5)	Total no of items (<i>n</i> = 146)	Total no of respondents (n = 36)
QT1	Design and accessibility	What would encourage you to use a web-based online implementation resource? What would discourage you to use a web-based online implementation resource? In developing a web-based online resource to support implementation what would be helpful to consider? Please tell us anything else you think is important to consider when developing the web-based online implementation resource	60 (41%)	31 (86%)
QT2	Applicability for a wide range of users	 In developing a web-based online resource to support implementation what would be helpful to consider? What would encourage you to use a web-based online implementation resource? What would discourage you to use a web-based online implementation resource? List up to three ways a web-based online implementation resource may help you Please tell us anything else you think is important to consider when developing the web-based online implementation resource 	32 (22%)	25 (69%)
QT3	Supporting the implementation journey	 What would encourage you to use a web-based online implementation resource? What would discourage you to use a web-based online implementation resource? In developing a web-based online resource to support implementation what would be helpful to consider? Please tell us anything else you think is important to consider when developing a web-based resource, such as a website? List up to three ways a web-based online implementation resource may help you 	24 (16%)	20 (56%)

resource, listing up to three ways a web-based implementation resource may help and any other considerations in developing a web-based implementation resource.

Analysis of qualitative responses from the survey revealed three principal themes; (i) design and accessibility; (ii) applicability for a wide range of users; (iii) supporting the implementation journey (Table 5). Themes are described in turn and illustrated through free text extracts. The extracts are labelled according to the participant's role and setting.

Design and accessibility

Design and accessibility, including being freely available in the public domain, were reported by respondents as key factors that would encourage use of WIT. An engaging visual design with a clear and uncluttered layout, effective use of colour schemes, simple language with definitions of relevant terminology appropriately placed, as well as signposting to relevant sections, were given as examples to support accessibility and ease of use:

It would have to be accessible, engaging and enable me to find what I need very easily. The language used within the website to describe the options available would have to match the language I use to describe the topics. It would need to be reasonably simple. (PPI representative and Charity lead, Third sector)

It's often good to have an easy read format, and to be succinct, but it can be helpful to have more info[rmation] embedded (maybe by drilling through the top layer page so as not to clutter the first page) for those users who want or need to find out more. Infographics can sometimes be helpful to convey meaning without using a lot of words. Consideration of colour schemes for those with visual impairment and not having things too cluttered for those who can become over stimulated. Keeping terminology suitable for the readership making sure terms are defined somewhere if they are needed... If a website needs to be used by a wide audience, it helps not to have assumed knowledge for using it, but for it to be easy to

TABLE 5 Top three qualitative themes from the web-based survey.

Web-based survey themes		Co-production workshops themes with examples of WIT "active ingredients" produced	
QT1	Design and accessibility	Co-designing key components of the toolkit Example: Implementation Wheel component Refinement of the Implementation Checklist	
QT2	Applicability for a wide range of users	Co-producing a toolkit with utility for users across health and social care settings Example: Pop up definition function Drop down question and answer function	
QT3	Supporting the implementation journey	Co-producing a toolkit to support the implementation journey Example: Case studies feature Examples of implementation feature	

navigate past the basics for those who don't need the basics. (PPI representative)

Applicability for a wide range of users

An implementation toolkit that has applicability and relevance to a variety of users was considered important by respondents. Suggestions of how relevance could be achieved included giving evidence-based examples relating to different implementation challenges and solutions to "bring them to life." Other suggestions involved providing a telescopic-style approach to information provision; an overview of key issues and areas for the user to browse, with an option to "deep dive" further information if needed, and flexibility to use the toolkit in accordance with individual and shared needs with colleagues and wider networks in different settings. Public contributors brought a different lens to enhancing usability by challenging assumptions and taken-for-granted meanings associated with specialist terminology and added insights which otherwise may have gone unnoticed:

We all see things through a different lens based on our life experiences and education. Public contributors bring a fresh perspective to areas being considered. They are not as familiar with areas being looked at, less familiar with the jargon often involved, so can ask the obvious questions which others [may] miss. They can help understanding about how those outside the projects can view subjects being considered. (PPI representative)

Some areas of quick content with [the] option to dive more deeply where needed (Programme Manager, Secondary care)

Easy to navigate and flow to the format. Content should be evidence informed and include examples to bring it to life. (Charity Researcher, Third sector)

Supporting the implementation journey

Respondents reported the value of an implementation toolkit to enable utility to navigate and chart their implementation journey, providing guidance from initial stages of preparation, across different levels of implementation (e.g., strategic or clinical levels) through to potential challenges and how to address them. Similarly, the provision of a holistic one-stop place for all implementation considerations, whilst simultaneously enabling flexibility to focus on specific areas, was recognised as important:

I'm hoping you will develop something that guides people through the process, thinking about how they need to prepare for and conduct the implementation to address key barriers that can come up with working with each stakeholder (e.g., those at high strategic level within organisations like the NHS, those within clinical roles on the ground who would be closer to implementation)... things that would be helpful. (Academic Researcher, University)

There are so many ways to implement research outputs, it would be great to have something that can draw this into one place... It could be used as part of education and knowledge for people who start within our team. It can be used to share with researchers who should consider implementation as part of grant applications to give them an idea of how they can plan for implementing their research. (Charity Researcher, Third sector)

If it was easy to use and flexible to local/project needs. If it gave hints to tackle tricky implementation pitfalls. If it was a tool that I could use to demonstrate progress on implementation or describe barriers to a wide range of stakeholders [in an] understandable way that could then be addressed in a logical and systematic way. If the tool could help demonstrate the impact of good implementation processes which might feel cumbersome or irrelevant to stakeholders. (Programme Manager, Secondary care)

Quantitative analysis

In addition to the qualitative thematic findings, over half of respondents reported having "some knowledge" of implementation (53%); some reporting "a little" (30%). Only 11% stated they had "quite a lot" of knowledge and 1% "very much".

Online co-production workshops

Qualitative analysis

We approach co-production as a dialogic process, involving activities to elicit reflection, discussion and refinement. Methodological insight is illuminated by examples depicting iterative co-development of the "active ingredients".

Undertaking co-production as a dialogic process involving reflection, discussion and refinement (Table 3), enabled generation of three key themes: (i) Co-designing key features of the toolkit; (ii) Co-producing a toolkit with utility for users across health and social care settings; (iii) Co-producing a toolkit to support the implementation journey (Table 4). To illustrate discussion of the themes, we draw upon iterative co-development of the "active ingredients" of the key components (e.g., interactive Implementation Wheel) and functions (e.g., interactive "pop-up" definitions of keywords) and features (e.g., case studies). Interwoven is reference to the process of discussions, reflections and refinement involved in this co-production throughout and between workshops. Themes are described in turn and illustrated through verbatim extracts. The extracts are labelled according to the type of participant.

Co-designing key features of the toolkit

The use of design including style, images, diagrams and colour schemes featured strongly in discussions surrounding accessibility and were most evident in the co-development of the core component and end-product of the Implementation Wheel during the workshops. Through the co-development process and as will be demonstrated through reference to the process of

discussions, reflection and refinements, the Implementation Wheel co-developed from a visual image depicting holistic oversight of the six domains in Workshop 1, through to an interactive online tool by Workshop 3, with functionality to navigate across WIT as a whole. The other core components of the Implementation Checklist and Implementation Webinars were also discussed though they did not feature as consistently and prominently as the wheel in discussions relating to this theme.

Ahead of Workshop 1, a copy of the original Implementation Checklist was circulated to the co-production group who were asked to feedback their overall perceptions on the day. Providing an opportunity for participants to share their views and suggestions provided confirmation to the researchers of the comprehensiveness of the checklist in enabling implementation considerations to be comprehended. Similar to feedback on the early formulation of the checklist discussed earlier, workshop participants commented on accessibility and usability, and suggested amendments including reductions to the amount of text and simplifying language. Their input was essential for ensuring the appropriateness, utility and usability of the toolkit for a diverse range of stakeholders across health and social care.

Using MS PowerPoint®, the Implementation Wheel was introduced in a visual format in Workshop 1 (Figure 1) and coproduction group members were asked to feedback their overall perceptions of the wheel. The design of the wheel and representation of the six implementation domains as colour coded segments (Figure 1), was positively received, with suggestions to develop the interactive capacity of domain segments as "clickable", to enable holistic oversight of all domains with the opportunity to select specific domain(s) in accordance with implementation needs. Additionally, to increase usability options, it was also suggested that the implementation domains could be designed in a colour matched menu bar, should users prefer a more traditional route of selecting domain(s). These co-design suggestions therefore contributed importantly to the re-design and overall accessibility of the wheel from something static and one-dimensional to interactive and multi-purposeful:

It [the implementation wheel] shows that actually all six parts of the implementation wheel are— are hugely important. That actually, you need elements of all of them in order that the implementation is going to happen and kind of bring rewards. (Programme Manager, Secondary care, Workshop 1)

I found it really helpful to have the domains represented visually because— especially with the colours because I tend to remember things with colours. So, it just helped me to remember what the six domains were and if they corresponded with the colours in the Word document [Implementation Checklist], I would find that really helpful. (Academic Enterprise Researcher, University, Workshop 1)

At the beginning of Workshop 2, the research team presented a summary of key discussion points from Workshop 1, suggested areas of development and subsequent actions undertaken.

Feeding back to the group offered a further opportunity for clarification. With reference to design, this primarily focused upon developments to the Implementation Wheel. An updated visual representation of the wheel with instruction of interactive operability, including clickable domains, which enabled navigation to relevant domain pages was shared (Figure 2). This received positive feedback, and led to discussions as to where the wheel would best be situated in the toolkit. The consensus was that it should feature on the home page, with smaller interactive versions being available on each domain page. With this interactive capacity, the wheel was recognised not only as a key tool to support users in their implementation journey but also a navigation tool allowing users to move iteratively and flexibly across the toolkit to suit their needs:

I really like the idea of having this [Implementation wheel] on the homepage and having the clickable sections to go in and read more about each part. (Academic Researcher, University, Workshop 2)

it would be great if you could hover over these things that maybe a little definition kind of just popped up because it could be that, you know, people may feel a bit more competent in those initial stages of the wheel but actually, what they're not so sure on is kind of the outcome and the impact and the adoption (...), they can kind of dip in and out of it rather than seeing it as a whole thing that they have to work through. It might just make it a bit more accessible in that context. (Academic Researcher, University, Workshop 2)

Following the second workshop, the research team worked with the web designer to implement the amendments from the co-production group which were fundamental to the final design. Ahead of the third workshop, an interactive prototype of the home page (including the Implementation Wheel) and several of the domain pages were shared with the group who were asked to review and feedback comments on the prototype during the final workshop. For consistency and to address suggestions from Workshop 1, the research team also developed the design and format of the Implementation Checklist to match the colours of the wheel, reduce text where possible, develop considerations for users across social care and the third sector, as well as produce two versions in an editable Adobe pdf and MS Word® format to enhance utility of WIT. Domain names were also slightly amended to be more consistent with those in the Implementation Checklist. To enhance readability and contrast, colours were also enhanced by the web-designer (Figure 3).

At the final workshop, the key design developments made to the wheel described above (Figure 3), were agreed by members with additional suggestions offered:

it looks very appealing and— and straightforward and you've succeeded really well in— in making it really nice and simple...it works well to have the wheel and then the tabs across the top (PPI representative, Workshop 3)

Thanks for the summary. You guys have been really busy, and I really like the look of the website. It's very usable...so, basically, there's three components. There's your implementation wheel, your implementation checklist and bitesize implementation webinars (Academic Researcher, University, Workshop 3)

Implementation Wheel

 Propose to situate on the home page accompanied with an introduction to the online Implementation Toolkit

Interactive

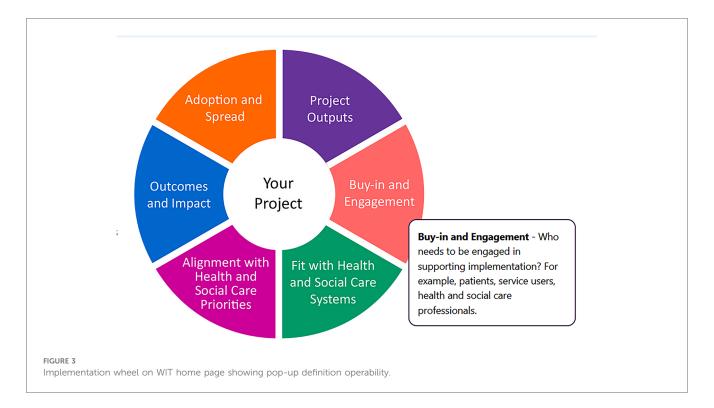
- Click on a segment/domain and a domain page will appear
- Each domain page will contain an introduction to the domain with key considerations about what and how to implement
- Navigate to other segments/domain without having to return to home page
- · Alternative accessibility in a menu format



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FIGURE 2

MS PowerPoint slide depicting interactive operability of the implementation wheel.



it looks a good piece of work. It's responsive. I've actually gone onto the website both online [to] use and the laptop but also...I went on my i-Phone and it's responsive. It... it looks and feels, you know... very creative (PPI representative, Researcher and Engineer, Secondary care, Workshop 3)

Co-producing a toolkit with utility for users across health and social care settings

A key outcome of co-producing was ensuring a focus on utility for users across health and social care settings, which featured as a key focal point across the workshops. As workshops progressed, co-production discussions evolved from early considerations around the purpose, intended users and name of the toolkit to more specific conversations about how to make the toolkit relevant and usable by different audiences. Suggestions resulted in amendments to toolkit functions including a drop-down interactive question and answer style of implementation considerations for each domain page as well as "pop-up" definitions of keywords to support accessibility to a wide range of users across health and social care systems.

Participants identified language as integral to enhancing the usability of the implementation toolkit. Early discussions in Workshop 1, focused upon nomenclature of the toolkit and whether it was a tool, toolkit or a resource, were viewed as important for different users and how it would be used. The word tool was identified as singular, as one component, whilst the word resource was viewed as a repository of information. The word toolkit was agreed to be most appropriate because it is plural term comprising of constituent parts (i.e., implementation wheel, implementation checklist and implementation webinars).

I suppose, for me— obviously, online— well, that's obvious, something online but it's— for me, a toolkit is something that's useful. It makes your life easier, something you can use to achieve what you're trying to achieve. So, the same way as a toolbox has, you know, spanners and wrenches and things that you— you can use to achieve, you know, whatever you're trying to achieve. A toolkit would be much the same. So, I want something that's flexible, that had all the tools that I needed in one place (PPI representative and Charity lead, Third sector, Workshop 1)

I think, the— the toolkit implies that it has— has a range of tools, a range of things that I could go away and use to consider to help answer the question that I'm looking to answer, and we've kind of eluded in this conversation the kind of range from tools of use, all the way through to self-assessment and it— there's— there's a kind of a grey scale of broadness in there as well (Programme Manager, Secondary care, Workshop 1)

I think, resource would mean to me something where I'm going to find out information... And, for me, the toolkit is this multifaceted thing with all the different bits in it and a tool, I would probably expect to be coming across one thing. So, that's how I would differentiate my interpretation of those words (PPI representative, Workshop 1)

The question of intended end-users for the toolkit was also discussed. Ensuring a toolkit with relevance and utility to a range of users in health and social care settings was supported whilst there was recognition of complexity in the need to balance

between providing a toolkit with value for all alongside guidance for specific users.

I think, different areas will have their own challenges and barriers, or successes, when it comes to implementation so, I think, that— you know, rather than looking at kind of how we could solve everything... what exists already that could support people (Charity Researcher, Third sector, Workshop 1)

consider who the audience is for this ... if you try and be everything to everybody, you might not get to a point that's useful for anybody (Programme Manager, Secondary care, Workshop 1)

At Workshop 2, the research team presented a summary of substantive discussion points from the previous workshop, including recognition that the implementation toolkit should comprise the: Implementation Wheel, Implementation Checklist and Implementation Webinars. Regarding how the toolkit would work or be used, it was recognised that having a toolkit that was flexible and agile was essential to usability, to facilitate navigation of the complexities and uncertainties of implementation including changes to timelines, resource provision and relations between individuals and contexts.

It was suggested having keywords with "hover options," enabling definitions to appear when "hovering" over the term, whilst not disrupting the flow of the sentence would enhance usability. User-centred language was also cited as key, with introductory sections on the main page and domain pages with direct user-centred language e.g., "you", "outputs", so that the user immediately perceived the website of relevance to them, regardless of their reason for accessing or occupational role. While another was to ensure that language was not limited to specific sectors (e.g., academia), so as not to exclude people from other professions, contexts or settings. In addition, codevelopment of a drop-down interactive question and answer style implementation considerations for each domain should be included, which users could opt to use dependent on their awareness of implementation and need:

It would just be interesting to think about the introduction to the online toolkit like basically, an initial explanation of who this is for... I guess, something just to reassure people that they're in the right place and how this can help. Something quite brief and snappy that would just sort of encourage you to look a bit. (Academic Researcher, University, Workshop 2)

It would be great if you could hover over these things that maybe a little definition kind of just popped up because what they're not so sure on is kind of the outcome and the impact and the adoption... they can kind of dip in and out of it rather than seeing it as a whole thing that they have to work through ... I think, to use examples, you know, — have been taken through would be a lovely way to illustrate how— illustrate how it could be used in practice. (Academic Researcher, University, Workshop 2)

Following Workshop 2, the research team worked with the web designer to operationalise suggestions including the incorporation of user-centred language, "pop-up" definitions of keywords (Figure 4), and interactive drop-down question and answer style implementation considerations relating to each domain (Figure 5):

An interactive prototype of the home page and several domain pages were shared with the co-production group ahead of Workshop 3. Here there was agreement that the changes made worked well. In particular the interactive drop-down question and answer style implementation considerations (Figure 5), enabling a flexible "as needed" approach to information:

I think, when we're all time short and we're all skim-reading., I'm on the: "fit with health and social care systems" and I'm reading down the list of white coloured boxes that—they can be expanded and I really do like that you can expand each of those. (PPI representative and Researcher and Engineer, Secondary care, Workshop 3)

I really like the two pages that have been done on the: "fit for systems" and: "outputs"— outputs and impacts. I found it really helpful as some of you—I think, the drop-down questions just really helped bring it to life and make it feel more achievable to fill-out the checklist (Academic Researcher, University, Workshop 3)

Co-producing a toolkit to support the implementation journey

The group agreed that a key function of the toolkit was to support users on their implementation journey. Early discussions focused upon the need for an agile toolkit to enable this and suggested providing examples of implementation challenges. For example, creation of additional work for those involved in implementation or not having time or resources to support implementation. Discussions led to examples that were coproduced and included challenges and solutions operationalised

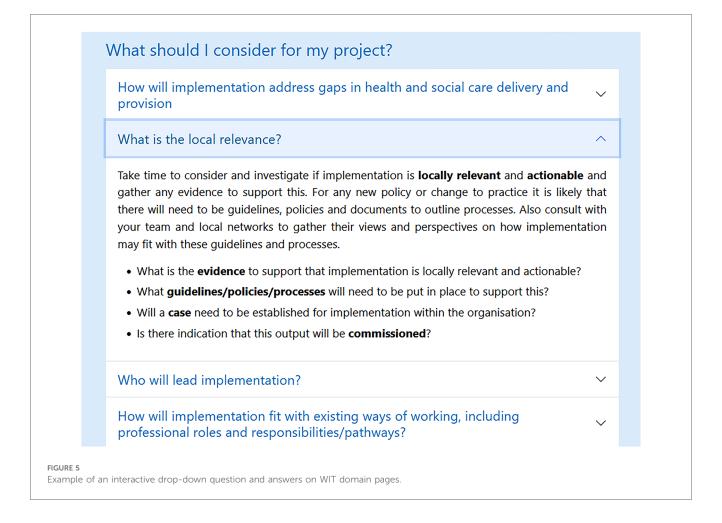
Why use WIT?

co-produced

Co-production refers to a way of working together, often with service users, to reach a collective output.

 WIT was co-produced through interactive workshops with health and social care professionals, third sector organisation professionals, academics and members of the public.

FIGURE 4
Pop-up definition of keyword function.



within the "question and answer" style drop-down menus on the domain pages.

The need for an agile toolkit was recognised early in the coproduction process, as a way for users to flexibly navigate the complexities and uncertainties of implementation including changes to timelines, resource provision and relations between individuals and contexts. Group members offered examples of these across different health and social care contexts:

To help guide me at all the different stages at which I might be thinking about implementation and it might be that that gets split into different parts of the process....I guess, I would want it to highlight to me solutions to the kinds of common problems that we face at the stage— the stage of implementation... And there are bound to be other sort of common problems that people are facing that your expertise could help guide— give guidance on and perhaps sort of examples of how other people have done it. Sort of stories, modelling, how other projects did things might be useful. (Academic Researcher, University, Workshop 1)

So, you almost create a journey, don't you, through that kind of implementation for that research and those involved in that. (Charity Researcher, Third sector, Workshop 1)

The co-production process enabled examples of challenges and solutions to be shared during workshops which enhanced discussions about adoption and sustainability of the toolkit following its development. For example, proposals put forward included involving users and beneficiaries in the planning for the study to maintain longer-term impact, considering relevant evidence needed to persuade stakeholders, and resource considerations beyond the life cycle of the project. The group also reiterated the importance of flexibility in addressing these, to accommodate potential challenges:

So, any implementation of any project is not linear, it comes and goes, there's different waves, there's different points in time, there's things that are in your control and out of your control. So, I think, having implementation plans that are flexible and then can adjust and accommodate all those different things throughout your implementation period, is actually really important (Programme Manager, Secondary care, Workshop 2)

So, I say that in terms of timing and priorities within organisations so, you know, from a—so, a sector perspective as we enter a new strategy, we've got strategic priorities out—which might fall outside of those or they may not be relevant no more so, therefore it may be really great, we may have all the intention to kind of implement that but actually, we can't

because it's not part of our strategic direction or way that we want to go. So, I think, there's that consideration of kind of things that kind of— we can't control and actually, it's more meaningful that we don't try and shoehorn something (laughing) into a space and it be used meaningfully. (Charity Researcher, Third sector, Workshop 2)

Following the workshop, the research team worked with the web designer to incorporate these examples within the interactive "question and answer" style drop-down options (Figure 5), and case studies to depict navigation of these considerations in projects across health and social care. These examples and case studies were included as part of the prototype implementation toolkit shared ahead of Workshop 3. Due to their embedded nature within the context of relevant implementation questions and answers, the examples, were felt to have more utility than the case studies which were longer and in narrative form. Instead, the case studies were considered a useful endorsement of how to use the toolkit to support a specific project:

I favoured having examples so that when you click-on your drop-down and you're looking at the thing, to actually have a few examples... That's really valuable (PPI representative, Workshop 3)

having the specific examples within each drop-down is actually really helpful because then you're looking at it— you've got an example at the same time as you're reading the definition. (Academic Researcher, University, Workshop 3)

I guess, the case studies are almost...more of an endorsement of like the tool and so they could almost be like collated- it's almost evidence, isn't it? (Academic Researcher, University, Workshop 3)

Discussion

In this paper, we have reported findings from a study to co-produce a web-based implementation toolkit (WIT) to facilitate adaptive implementation across health and social care systems and have shown the value of a co-production approach to toolkit development. The co-production group, involved a diverse range of end-users across different settings who through participating in a series of online workshops which provided space for reflection, discussion and refinement, worked in partnership with researchers to co-develop an accessible and usable toolkit to support the implementation of changes to practice or innovations in health and social care systems. The benefits of co-production enabled support for the translation of implementation into health and social care systems to improve outcomes for a variety of people. The value of co-production is demonstrated through three core themes:

- Enhancing accessibility and usability through design
- Relevance of implementation for a variety of users across health and social care settings

 Supporting adaptive implementation in accordance with user needs

Enhancing accessibility and usability through design

Including those involved in implementation or, in the case of PPI representatives, as service users through co-production ensured style, images, diagrams and colours that are important to end users were included in a way that increased the accessibility and usability of WIT. Drawing upon the example of the Implementation Wheel, a core component of WIT, we demonstrate how involving stakeholders in shared decision-making informed co-development of the wheel from a visual static image through to an interactive online tool, with further functionality to navigate across WIT as a whole. The value of co-production processes with a variety of stakeholders to increase the accessibility and usability of toolkit uptake, strongly resonates with other research advocating iterative co-production methods to develop interventions with stakeholders (28–30).

Co-production of WIT through online workshops incorporating iterative cycles of consultation, reflection and feedback addresses the call for more qualitative and pragmatic approaches within both implementation science co-production work (22). It extends opportunities for exploration of complex concepts and inclusion of a variety of stakeholder views (31). For example, the co-development of a hover "popup" definition function of key implementation terminology across WIT suggested by the group, increases the inclusivity of WIT for people who may have otherwise been unfamiliar with the terminology, concepts or relevance to practice. The PPI representatives in the group were invaluable in this respect by challenging any assumptions of knowledge those more familiar with implementation had and challenging use of terminology that was not transparent for all.

Relevance of implementation for a variety of users across health and social care settings

Co-production with stakeholders across health and social care systems, serves to increase awareness of the value of implementation for users across these systems. In our study it promoted interdisciplinary knowledge exchange and learning, raising awareness of considerations specific to different perspectives and contexts (32). Participants continually brought to the fore the importance of considering the relevance of WIT to the end user. For example, through initial discussions around the value of WIT and consensus to describe WIT as a "toolkit" rather than as a tool or resource, to later discussions, surrounding practical challenges and enablers participants had encountered in their experience of implementation across health and social care systems, which were embedded in interactive drop-down "question and answer" style menus on the domain pages.

The co-production group worked well together and showed mutual respect in terms of listening, acknowledging and supporting different views and perspectives during the WIT development process which helped to support this collaborative approach. In this sense, WIT is an example of successful coproduction. Though the group was diverse in terms of roles and representation, consensus was achieved and where differences of opinion these were resolved satisfactorily for the group. However, research suggests that our experience is not necessarily the norm, and has highlighted potential barriers of competing priorities and interdisciplinary conflict between stakeholders across different fields when working together (27, 28). We suggest that the collaborative environment established in the co-production workshops, may also have been underpinned by a reiteration of the overall shared purpose of the project at the beginning of each workshop and the importance of co-producing a toolkit that had utility and value for a variety of users throughout the workshops. Also, the key role played by PPI participation, which ensured the group remained focussed on the key aims and were not distracted or diverted when other issues or professional agendas could have diverted the focus of the group.

Supporting adaptive implementation in accordance with user needs

Adopting a co-production approach to the development of WIT, whereby stakeholders from a range of roles with differing implementation experience and knowledge, across health and social care systems, enabled rich and meaningful data to be generated that informed the development of an agile and flexible toolkit, to guide users on their implementation journey. The sharing of their own experiences of implementing complex interventions in health and/or social care, or as a recipient of the intervention demonstrated the complexity of implementation, and the relational dynamics between individuals, local contexts and wider health and social care systems and implementation challenges and enablers, which were included as examples and case studies in the toolkit. In doing so, as co-designers of the toolkit, through their contributions, participants encouraged holistic oversight of these interactions and "normalised" implementation challenges, supporting encouraging users in navigating adaptive and complex situations, such as those compounded by Covid-19 (1-5, 33).

Online co-production processes as a mechanism for encouraging collaboration

Reflecting upon the co-production processes involved in the online workshops, also contributes to informing co-productive practices, and an opportunity to consider what works well and what does not (22). In our experience online co-production workshops, with activities to elicit reflection, discussion and refinement offered opportunities for enhanced co-production and inclusivity. Firstly, online workshops, did not involve the Covid-19 infection risks associated with travelling to or attending

in-person workshops. Secondly, through virtual participation, they negated time, travel and related expenditure considerations more generally (34, 35); enabling a cross-section of stakeholders from a wider geography to participate at shorter notice (36). The "chat" function on Zoom was useful because it gave an alternative opportunity for people to contribute without having to verbalise their comments and also enabled inclusion of those who were less confident to speak less in a group. The "raise a hand" function helped with turn taking, giving an opportunity for participants to signal their intention to speak to the facilitators. Both these functions provided additional options for participation thereby enhancing inclusivity. This resonates with other work which highlights the benefits of online modalities in terms of representation, inclusivity and accessibility, whilst acknowledging potential limitations, including information technology literacy and accessibility, including internet access and observing body language cues (36).

It is worth noting that participation in online co-production workshops requires a number of accessibility and usability considerations which may not be available to all. For example, in this study, PPI representatives were recruited from established public and patient involvement networks where participation in online and in-person research workshops may be more familiar and therefore may not be representative of PPI contributors who had not been recruited from these sources. PPI representatives also had good and reliable internet access, and ensuring adequate costings in the funding budget for PPI enabled patient and public contributors to be fully reimbursed for their participation in workshops and as co-authors on publications. The opportunity to build language translation functionalities into WIT may further improve accessibility and may lead to increased engagement.

Conclusion

Co-production provides unique opportunities for interdisciplinary knowledge exchange and learning, increasing awareness of implementation considerations and its importance in translation of outputs into practice. By embedding stakeholder experiences of implementation within WIT, it highlights the complex relational dynamics between users and health and social care systems to provide a flexible and agile toolkit to support users on their implementation journey. Co-production of WIT with a variety of end-users across health and social care enhances the utility, accessibility and appropriateness of WIT and the translation of implementation across these settings to benefit outcomes for a variety of people.

Data availability statement

The data and materials are not available for open access, due to restrictions governed by the ethical agreement approved by the University of Southampton. Requests to access the datasets should be directed to c.f.brooks@soton.ac.uk.

Ethics statement

The study was approved via the Faculty Research Ethics Committee at the University of Southampton (Ethics/ERGO number: 68868). The studies were conducted in accordance with institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

CFB: Conceptualization, Formal Analysis, Methodology, Writing – original draft, Writing – review & editing. SL: Conceptualization, Formal Analysis, Methodology, Writing – review & editing. DK: Conceptualization, Writing – review & editing. SLJ: Writing – review & editing. MM: Conceptualization, Formal Analysis, Methodology, Writing – review & editing.

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Conflict of interest

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

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