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Community partners identified implementation considerations prior to a randomized clinical trial for uncontrolled asthma in Federally Qualified Health Centers

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Research Article

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Abstract

Background and Purpose: Federally Qualified Health Centers (FQHC) are critically important in addressing the unmet healthcare needs of individuals impacted by poverty. We used implementation science frameworks to advance understanding of perceived and actual facilitators and barriers to a novel asthma intervention before initiating a FQHC practice-based clinical trial. *Methods:* Interviews with clinicians and administrators explored pre-implementation trial considerations. Transcripts were inductively coded using conventional content analysis. *Results:* Sixteen administrators and/or clinicians (88% female; mean age 49 ± 12.21; 44% Black race; 25% Hispanic ethnicity) from four FQHCs participated. Themes included (1) multi-level factors making successful implementation more or less likely, (2) pandemic-specific concerns with implications for current healthcare delivery challenges, and (3) unintended implementation consequences. *Conclusions:* Participants were optimistic about the likelihood of successful intervention implementation if challenges were recognized and managed. Combined with other planned assessments, this data may provide a more comprehensive evaluation of clinical trial implementation in FQHCs.

Community–academic partnerships are collaborations involving academic and practice stakeholders. Increasingly, community–academic partnerships are being formed to enhance underrepresented communities' engagement in research and to create opportunities for co-designed research that addresses the community's priorities, focusing on outcomes the community considers most relevant [1] and designed to be patient-centered and accessible. These partnerships are critical for implementation science when academic researchers may poorly understand methods for effectively adopting and implementing evidence-based practices in community settings [2–4].

Federally Qualified Health Centers (FQHCs) are essential community partners for delivering real-world interventions to reduce asthma inequities in medically underserved communities. They provide safety-net primary care to populations in the USA [5]. FQHCs provide care for 1 in 11 of the US population, including one-third of those living in poverty, 25% of racial and ethnic minorities, 20% of uninsured persons, and ~ 50% of Medicaid beneficiaries [6]. FQHCs also serve a disproportionate share of those who experience an unequal burden of chronic conditions, such as asthma (20% in FQHCs vs. 15% in the general population) [6]. When efforts are taken to build research and organizational capacity in these settings, FQHCs can engage primary care clinicians and staff and can enroll large numbers of individuals who have been historically underrepresented in biomedical research as evidenced most strikingly by the more than 10,000 participants recruited from FQHCs nationally for enrollment in the All of Us Research Program [7].

Primary care clinicians deliver up to 60% of asthma care in the US [8], and uncontrolled asthma is common in primary care settings [9] where there is less time and resources to achieve asthma control, relative to specialty care. These care challenges are even more pronounced in FQHCs where there are additional barriers such as inadequate reimbursement, high workforce attrition, high patient poverty and disease burden [5], less access to newer medications, including biologics, and other pressing social needs. Specific patient populations who receive

care at FQHCs experience significant health inequities in asthma prevalence and disease burden. For example, those living below the poverty level have higher asthma prevalence compared to those living above the poverty level [10]. The asthma disease burden is particularly high among Black patients. Black adults have higher asthma prevalence (10.9%) relative to White (7.6%) and Hispanic adults (6.4%). Asthma mortality rates are also higher among Black adults (29.7/million) compared to White adults (11.8/million) and Hispanic adults (7.8/million) [10], reflecting their greater likelihood to experience a severe asthma exacerbation [11]. These data highlight that the patients served in FQHCs would most benefit from effective interventions to address unequal disease burden.

The purpose of the present manuscript is to use implementation science frameworks to inform the design of data collection and analysis to advance understanding of perceived and actual facilitators and barriers to implementation of a novel asthma intervention in FQHCs before initiating a practice-based clinical trial at these sites. Specifically, we used both the RE-AIM (Reach-Effectiveness-Adoption-Implementation-Maintenance) Model [12–15] and the Consolidated Framework for Implementation Research (CFIR) [16,17], following conventions for operationalizing the constructs [18].

Methods

Overview

We used qualitative descriptive approaches grounded in naturalistic inquiry [19] to guide our data collection and analytic approaches in exploring this study's implementation metrics of interest. The qualitative data were collected as part of a pre-implementation assessment of local FQHCs who were approached to participate in an upcoming multi-site group-randomized clinical trial (RCT) of a shared decision-making (SDM) intervention to enhance asthma outcomes among Black adults with uncontrolled asthma. The RE-AIM [12–15] and CFIR [16,17] frameworks allowed us to learn about the facilitators and barriers to trial implementation before roll-out and planned delivery of intervention components. We used the guidelines in the Standards for Reporting Qualitative Research checklist (Supplement Table 1) to foster comprehensive reporting of the qualitative data collected in the pre-trial phase [20].

Site selection

We identified four FQHCs in New York City and New Jersey serving a predominantly Black adult population with asthma to learn clinicians' and administrators' perspectives of pre-trial implementation indicators, including anticipated barriers and facilitators to the planned multi-site RCT. Participating sites either expressed an interest in trial participation or were eligible for participation. Potential sites were members of the Clinical Directors Network's (CDN) extensive practice-based research network (PBRN), our community–academic liaison for this project. CDN is a not-for-profit clinician membership organization, PBRN, and clinician training organization, founded to provide peer-initiated activities for clinicians practicing in low-income, minority, and other underserved communities. CDN's overall goal is to translate clinical research into clinical practice for the enhancement of health equity and improvement of public health.

Asthma intervention

The Brief Evaluation of Asthma Therapy (BrEAThe) intervention trains clinicians to deliver a four-step 9-minute SDM intervention using motivational interviewing techniques focused on asthma self-management integrated into an office visit for uncontrolled asthma. Training required 2 hours of instruction. Office visits are audio recorded and scored for fidelity by an adjudicator masked to assignment. Feedback is then provided within 48 hours of the office visit via an email to the clinician. The BrEAThe intervention has undergone feasibility testing and has been shown to be efficacious in improving asthma control for three months post-intervention in a population of Black adults with uncontrolled asthma [21,22]. In this group-randomized efficacy-implementation trial, we plan to compare asthma control among Black adults receiving the active or dose-matched attention control condition in a 12-month longitudinal study. Clinicians will be randomized to deliver either a brief SDM (i.e., 9 minutes) intervention using motivational interviewing (active) or a 9-minute healthy exercise/eating discussion (control condition) at a single office visit [21,22]. A web-based application ('app') will be used in the trial to prompt the clinician through the scripted steps of the active and control interventions and visits will be audio recorded to allow assessment of fidelity. Study staff from the Clinical Directors Network (CDN) will support the project by screening patients from primary care clinician panels for uncontrolled asthma, enrolling those interested, and collecting all data.

Interview guide development

We followed best practices for the development of an interview guide [23], consulting with an implementation science expert (RS) to draft an initial guide informed by constructs from the RE-AIM and CFIR frameworks [24]. RE-AIM provides guidance in tracking dissemination and implementation outcomes, and CFIR helps identify and explain multi-level contextual factors that influence successful implementation. Internal piloting of the guide allowed for item refinement and order. The guide was iteratively refined in that what was learned from earlier interviews informed later interviews. The interview guide integrates constructs from the RE-AIM framework (Reach [patient engagement], Effectiveness [impact on outcomes], Adoption [provider acceptance], Implementation [organizational and workflow integration], and Maintenance [sustainability over time]) to assess the likelihood of successful adoption and implementation. Additionally, facilitators and barriers to implementation are mapped to the CFIR dimensions ensuring a structured evaluation of implementation factors (Intervention Characteristics [usefulness, feasibility], Inner Setting [organizational climate, leadership support], Outer Setting [broader healthcare challenges], Characteristics of Individuals [provider perceptions], and Implementation Process [facilitators, barriers, and long-term success factors]) (see Table 1).

Population studied and recruitment

We used purposive sampling to identify clinicians responsible for a caseload of adults with asthma or administrators responsible for chronic disease management initiatives at their respective FQHC. All who were approached agreed to be interviewed. Participants received the consent form in advance, and study staff reviewed it with participants, answering any questions pertaining to the purpose of study procedures, prior to obtaining verbal informed consent. Basic sociodemographic data, that is, sex, age, race, ethnicity, role,

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Table 1. Interview guide informed by the RE-AIM and CFIR frameworks

Model	Factors	Questions and probes
Factors influencing the success of new interventions		
RE-AIM	- Adoption - Maintenance	In your practice, what has made new interventions/programs or innovations successful in the past? **Probes**: What factors contributed to success for providers, patients, and leadership/administrators?
CFIR	- Intervention characteristics - Inner setting	
Challenges in implementing the new intervention		
RE-AIM	- Implementation	We will now be testing this intervention in a larger group-randomized trial. Tell me what you think are some real/important issues or challenges that providers would have in delivering this intervention/program. **Probes**: What things could be done to address them?
CFIR	- Inner setting - Characteristics of individuals - Process	
Provider and staff perceptions of new care delivery interventions		
RE-AIM	- Adoption - Implementation	How do the providers and staff here receive information about or respond to new care delivery interventions/programs? **Probes**: What about a new program do providers usually approve of/reject? Are there certain features or characteristics that might make them challenging to deliver? What about the process of roll-out of a new program do providers approve of/reject? What makes for a successful program? How is "success" defined from the perspective of providers in your practice? Or successful implementation of a program? What gets in the way of providers delivering a new program (e.g., workload, not integrated in the clinical workflow, competing demands, lack of skill/knowledge, lack of organizational resources or support?) What do you think will support providers in routinely delivering the program (e.g., leadership support? EHR or system prompts? Shifting provider norms in the practice? Patient demand?). – anything about financial incentives or incentives in general?
CFIR	- Inner setting - Process	
Organizational climate and readiness for implementation		
RE-AIM	- Implementation - Maintenance	Specific to the organizational climate/work culture of this FQHC, what may get in the way of delivering the program? **Probes**: What do you think will facilitate it? What role does leadership play in the roll-out of new programs? How do you think the different issues facing FQHCs right now will affect roll-out? (probe about COVID) How ready is your organization to routinely deliver the program? Are there any existing policies/practices that might get in the way of widespread adoption or use of the program?
CFIR	- Inner setting - Outer setting	
Patient-level challenges in program adoption		
RE-AIM	- Reach - Effectiveness	Knowing your patient population, what do you think are possible issues the roll-out may face? **Probes**: What will facilitate delivering this program to patients? Are there certain sub-groups of patients that might be more challenging to reach with this program and why?
CFIR	- Patient needs and resources	
Feasibility and appropriateness of BrEAThe in clinical practice		
RE-AIM	- Effectiveness - Implementation	How do you see BrEAThe being used in your practice? **Probes**: How do you feel about the program? What makes it easy/not easy to use? What makes it appropriate/not appropriate for the patients that you see here? What makes it a good fit or not with your current organizational setting/practice?
CFIR	- Intervention characteristics - Compatibility	
RE-AIM	- Effectiveness - Implementation	Can you envision any negative effects or unintended consequences of implementing BrEAThe in your practice? If yes, who would they impact (e.g., patients, providers)?
CFIR	- Process	

RE-AIM = Reach-Effectiveness-Adoption-Implementation-Maintenance; CFIR = Consolidated Framework for Implementation Research; BrEAThe = Brief Evaluation of Asthma Therapy.

and discipline, were collected after consent and prior to the start of the interview. All data were stored on a HIPAA-compliant server behind a password protected firewall accessible only to the study team. The study was approved by the Western Institutional Review Board, Inc. (tracking ID # 20211166). Interviews were conducted between November 2021 and March 2022.

Data collection

An experienced qualitative expert (MG) and trained interviewer (SK) together conducted individual semi-structured interviews. All interviews were conducted on a HIPAA-compliant virtual platform; only audio recordings were retained. Once a verbatim transcript had been created, audio recordings were deleted. All participants were provided with a $50 gift card for their time.

Qualitative analysis

Transcripts were transcribed and inductively coded by an interdisciplinary team (MG [nurse scientist], SS [research associate], KD [public health master's student], JMB [psychologist]) using conventional content analysis to build an iterative

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codebook that directed subsequent analysis. In this process, the coding team first read transcripts independently to identify codes, that is, concise representations of core concepts discussed by participants [25]. Coding conflicts were resolved through group consensus. Codes representing similar aspects of a concept were grouped to form categories or subthemes. Lastly, overarching themes that cut across the interviews were identified. A saturation table was constructed to track code identification chronologically. When no new codes were identified in later interviews, data collection ended as the sample was determined to be large enough to provide comprehensive data. NVIVO 12 (Lumivero, Denver, CO) was used to manage data. Multiple approaches were used to reduce the risk of bias in collecting and analyzing the qualitative data. These included, but were not limited to, peer debriefing to enhance the credibility of analysis, a codebook to foster code application consistency, and interprofessional coding teams to increase the likelihood of unbiased interpretations [26].

Results

Sixteen key stakeholders participated: eight administrators, six clinicians, and two individuals in clinician and administrator roles. The 10 clinician/clinician-administrators included 4 physicians, 3 nurse practitioners, 2 nurses, and 1 physician assistant. Table 2 provides the demographic characteristics of the participants. Interviews averaged 36 minutes in length (range 24–49 minutes). All but one category demonstrated saturation by interview 13 (see Supplemental Table 2).

Table 2. Demographics and roles of the interviewed stakeholders

	Clinician $N = 6$	Administrator $N = 8$	Both (clinician and Administrator) $N = 2$
	n (%)	n (%)	n (%)
Sex, female	6 (100%)	6 (75%)	2 (100%)
Race			
Black	3 (50%)	4 (50%)	
White	2 (33%)	4 (50%)	2 (100%)
No response	1 (17%)		
Ethnicity			
Hispanic/Latino/a	2 (33%)	2 (25%)	2 (25%)
	Mean ± SD (range)	**Mean ± SD (range)**	**Mean ± SD (range)**
Age, year	48.2 ± 7.82 (39–60)	49.9 ± 14.9 (23–60)	57 ± 11 (46–68)

Themes

Three overarching themes related to implementation of the proposed RCT in the FQHC were identified. Each of these themes corresponded to key dimensions of RE-AIM and CFIR: multi-level factors influencing implementation (aligned with RE-AIM Adoption and Implementation; CFIR Inner Setting, Outer Setting, and Characteristics of Individuals), pandemic-specific concerns (aligned with RE-AIM Implementation and Maintenance; CFIR Outer Setting), and unintended consequences of implementation (aligned with RE-AIM Effectiveness; CFIR Process and Characteristics of Individuals). Supporting exemplars are noted in the text below and/or in Table 3.

Multi-level factors that can impact implementation

In this theme, participants identified barriers and facilitators that would make it more or less likely that the RCT and/or intervention components would be successfully implemented in the FQHCs.

Patient-level factors (RE-AIM reach; CFIR patient needs and resources). Participants identified patient-related barriers and facilitators that could impact RCT success. Existing trust between clinicians and patients was seen as a facilitator to recruitment and engagement. One administrator (Site 2) said, "*Most of them [clinicians] are women of color, which is the majority of our patients, so that's easier to build trust.*"

However, behavioral and socioeconomic challenges were seen as key barriers: "*The biggest barrier is having them [patients] be interested in how to take care of themselves*," said another administrator (Site 4). Other anticipated obstacles to patient participation included high rates of multiple chronic conditions, substance use disorders, poverty, unstable housing, and low educational attainment.

Clinician-level factors (RE-AIM adoption; CFIR characteristics of individuals and inner setting). While lack of clinician time to participate in research during clinical hours was seen as the primary obstacle to RCT implementation, this was balanced by the desire to learn new interventions, particularly if it was seen as benefiting patients. One administrator said, "*The providers are always willing and wanting to participate in anything that's going to better the health of their patients*" (Site 4, Administrator).

Administrative considerations (RE-AIM implementation; CFIR inner setting). Buy-in across all levels of FQHC staff, from clerical to leadership, was critical to the successful roll-out of research at FQHCs. Some centers had dedicated research champions who were seen as ensuring successful trial implementation. For other administrators, research endeavors were seen as necessary to attract new patients. "*It's going to be additional patients for the clinic, so our numbers are gonna' go up,*" said one administrator (Site 4). Equally appealing was the possibility that the intervention could effectively enhance disease control, thus decreasing the number of unplanned urgent visits.

Organizational-level factors (RE-AIM implementation and maintenance; CFIR inner setting and outer setting). Characteristics of the FQHC practice model that were perceived as enabling RCT implementation included a focus on serving the community and on quality improvement. One clinician said, "*We're very quality assurance [oriented]. We really do a lot of best practice models, and we are always giving statistics*" (Site 1). However, heavy clinician workloads may impede RCT implementation, leading to clinician burnout and attrition. "*It's very hard sometimes. You have to see a certain number of patients; double-booked. It's a lot. A big turnover, sometimes. Right now, we're settled [i.e., not experiencing staff turnover]. I don't know how long it's gonna' last,*" reported one clinician (Site 1).

Shared decision-making (SDM) intervention considerations (RE-AIM effectiveness; CFIR intervention characteristics). Upon learning about the intervention components and required training for interventionists to deliver the active or control interventions, participants reflected on components of the intervention that

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Table 3. Additional exemplar quotes

Theme	Subtheme	Code	Subcodes	Exemplar
Multi-level factors that can impact implementation	Patient-level factors	Patient-level factors that may impede implementation	Poverty	*"I work in an area where patients, they struggle. And in my experience, they miss appointments because they didn't have money to take the bus to get to the appointment."* Site 1, Clinician
			Housing instability	*"Patients who live in shelter/transitional housing being unable to fully engage in a telehealth visit due to external environment."* Site 1, Clinician
			Educational barriers	*" . . . there's a large portion that unfortunately are uneducated . . . so when you try to educate them about something that they never heard of . . . it's a little bit hard for them to understand i. And you gotta kind of be on top of them more often so you could make sure they follow instructions."* Site 1, Clinician
		Patient-level factors that may enhance implementation	Trust	"*I think the thing that is most successful is that, again, the patients having a trusting relationship with their provider . . . I can almost guarantee if I suggest it they will do it, you know, because they have such a trusting relationship with me."* Site 3, Clinician
			Motivated by success	*"People wanna' hear 'I'm doing well.' You know, we hear so much about our illnesses, but we don't celebrate the wins when they do accomplish things."* Site 2, Administrator
	Clinician-level factors	Clinician-level factors that may impede implementation	Time	"*I think that most of them wouldn't want to [do the RCT] . . . they're all young new grads . . . with small children . . . I don't know if they wanna' put in the time or extra."* Site 1, Clinician
		Clinician-level factors that foster implementation	Motivated to learn and do better	*"We have a lot of residents that are working and doing primary care there that are very motivated just to learn, in general."* Site 1, Clinician/Administrator
	Administrative considerations	Administrative considerations that may foster implementation	Buy-in is required	"*Of course, you have to have buy-in from staff and upper management."* Site 3, Administrator
			Focus on research	*"We have a director of research, and we are moving in that direction where, you know, we're participating in studies and we're having research at the center.""* Site 3, Administrator
			Win–win	*" . . . if the . . . intervention is working the way it should, we should actually be decreasing the number of visits. So that's a win for everyone."* Site 2, Clinician
	Organizational-level factors	Organizational-level factors that may impede implementation	Scheduling demands and attrition	*"Scheduling; double booked. They are mandated to see [the] patient if they're less than 30 minutes late to an appointment. And there are too many patients on their schedule – puts them behind all day."* Site 1, Clinician
		Organizational-level factors that may foster implementation	Quality assurance-oriented	*"They're [clinicians] willing to take the tools to improve those patient outcomes . . . so opportunities like this to have someone else come in and give them that tool is great."* Site 2, Clinician/Administrator
			Mission focused	*"So it was a struggle at the beginning but we really, really have evolutioned (sic) into something . . . We really do a lot for the community and that's what I really love."* Site 1, Clinician
	Considerations for a shared decision-making intervention	Components of the intervention or training that may impede implementation	Seen as an added burden	*"I think phrasing it in a way that it's not extra work. 'It's a refinement of work that we're already doing' would be a good approach."* Site 2, Clinician/Administrator
			Training	*"The initial training . . . we might need to break up into two separate hours"* Site 2, Clinician/Administrator
		Components of the intervention or training that may foster implementation	It's evidence based	*"An evidence base . . . intervention . . . there will be some level of improvement."* Site 4, Clinician/Administrator
			Brief intervention	*"I think nine minutes for that intervention allows them time to deal with the other aspects of that visit."* Site 1, Clinician/Administrator
			Motivational interviewing is a transferrable skill	*"It will certainly benefit the providers at our part of this study in learning, you know, motivational interviewing . . . that's sort of new and hopefully it will carry over to other areas."* Site 1, Clinician/Administrator
			Tailored intervention	*"Tailored patient education and culturally based patient education is very important because one thing I realized is you cannot . . . one doesn't fit all"* Site 2, Clinician

(*Continued*)

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Table 3. (*Continued*)

Theme	Subtheme	Code	Subcodes	Exemplar
			Guidelines are "terrible"	*"I think it'll be great. You know, I actually looked earlier, and we have the clinical practice guidelines for asthma and they're terrible."* Site 2, Clinician/Administrator
			Incentives	"*And just to be blunt and honest, these people want incentives."* Site 4, Administrator
			Training	*"I think that providers need to talk and come to some solutions themselves. They need to talk about it. You know, they're in silos a lot of times . . . and they don't talk about 'Well, this is what I'm dealing with patients' . . . I think that's [training] good."* Site 2, Clinician
			Deliver in tandem with health educators	*"I think health coaches play a big role with helping providers get the message across to controlling and to doing those reminders about asthma and medication." Site 2, Clinician*
Implementation considerations during COVID-19 pandemic	Impact of COVID-19 on trial implementation	How COVID-19 may impede implementation	Staff illness	*"So, from the providers to the Administrators to everybody, everybody is taking a lot. And secondly, because of COVID . . . people are falling ill. So yeah, we providers are get[ting]sick. Administrators are getting sick. So, it's just a lot of pressure on us to deliver the basic services that we can deliver. So that is the climate now."* Site 3, Administrator
			Losing staff	*"It's hard to compete financially because, you know, with all these Covid vaccinations and testing centers and even a lot of the hospitals needing staff, they're pulling staff and offering them agency rates far beyond what we can compensate."* Site 2, Clinician/Administrator
		How COVID-19 may foster implementation	Telehealth makes it easier	*"We could certainly implement the [trial], you know, by tele-video appointment. I don't see any issue there that it would directly impact how to implement it."* Site 2, Administrator
			Office space allows in-person visits	*"The community room's large enough for social distancing, so, you know, all of those workflows and infection control measures are in place and second nature to us and most of our patients and staff. So, you know, as long as you're following the guidelines while you're here, which I . . . they're easy to follow . . . I don't see it being an issue."* Site 2, Clinician/Administrator
			Patients are more interested	*"Covid pandemic . . . well, it may just make people more interested in controlling their asthma, that's all. Because you have better control, less risk."* Site 1, Clinician
Unintended consequences of implementation	How the intervention may have unexpected impact	How the intervention may have unintended negative impact	May increase anxiety about asthma control	*"Introducing the idea that a patient's asthma is uncontrolled w/n the climate of COVID can prompt heightened anxiety"* Site 1, Clinician
			Risk of longer visits or neglecting other things because focus is on asthma	*"It just depends on what the patient is presenting with, right? So if you have other things going on . . . But if it's just simply for treatment of asthma, uncontrolled asthma . . . So they come in and let's say they're having problems where their lights are threatened to be turned off and there are social issues there that could potentially have the visit a little longer because then the patient wants to talk about what's important to them, you know?."* Site 3, Clinician

would impede or foster implementation. Two impediments were (1) length of the training (2 hours for the active SDM intervention) and (2) the potential perceived risk that a clinician randomized to serve as an interventionist might see integrating the 9-minute research intervention into an office visit as an added burden. This was countered by strong support for the intervention components, that is, SDM and motivational interviewing, which were characterized as brief, evidence-based, and tailored. In addition, motivational interviewing training was perceived as beneficial to the clinicians' continuing educational needs and was viewed as a valuable skill that would apply to patient populations beyond those with uncontrolled asthma. Further, current asthma guidelines were described as "terrible" (Site 2, Clinician/Administrator), and the SDM (active) intervention was seen as a way of overcoming limitations of current asthma guidelines. The plan to offer patient remuneration at each data collection point was considered respectful of patient's time and perceived as potentially helpful in overcoming some of the individual-level barriers identified.

Implementation considerations during the COVID-19 pandemic with implications for current healthcare delivery challenges

In this second theme, clinicians and administrators highlighted factors specific to the pandemic that would serve as facilitators or barriers to conducting the trial in the context of COVID-19,

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mapping to RE-AIM Implementation and Maintenance and CFIR Outer setting. Importantly, these factors are relevant to ongoing changes in health care delivery, for example, telehealth options after the pandemic.

Barriers to implementation. Interviews were conducted during the pandemic and reflected concerns common in the clinical care setting: frequent COVID-19 cases among staff and mandated isolation periods left FQHCs chronically understaffed. Staff burnout and the loss of staff to more lucrative offers from nearby hospital systems amplified understaffing challenges then and now.

Facilitators to implementation. Participants perceived several pandemic-specific factors as making it more likely that the intervention could be successfully implemented after the pandemic. For example, increased remuneration for telehealth increased providers' interest in and use of telehealth. Despite the connectivity issues that were commonly experienced by low-income communities in New York during the pandemic [27], one administrator noted, *"to my amazement, a lot of the patients do like telehealth, you know, 'cause they don't have to come in*" (Site 4). Additional enabling factors included the availability of large clinical spaces that could be used for research since telehealth has replaced many in-person office visits. Additionally, the increased attention on the potential adverse effects of COVID-19 infections among those with asthma in the media was seen as making it more likely that patients would be interested in enrolling in studies to improve asthma control.

Unintended consequences of implementation

Participants identified potential unintended consequences of the intervention in this final theme (related to RE-AIM Effectiveness; CFIR Process and Characteristics of Individuals). Two potentially adverse outcomes were identified: the risk of increasing patients' anxiety about asthma control during a time of already heightened anxiety about asthma and COVID-19, as well as the risk that longer office visits would be necessary as many patients have multiple chronic conditions, not only uncontrolled asthma. However, all participants were optimistic about the likelihood of successful implementation if challenges were recognized and managed.

Discussion

Although each clinical setting will have its own unique barriers and facilitators that need to be understood, this paper contributes to understanding the factors that may influence implementation in the context of FQHCs, for example, high clinician attrition, demanding appointment schedules, an essential but understudied implementation setting for addressing inequities [28]. This step is essential in ensuring a safe and effective implementation of the asthma control RCT, as done in previous practice-based FQHC studies [29–31]. In this qualitative assessment of pre-trial implementation factors, clinicians and administrators identified three broad themes related to implementation of the proposed asthma control RCT in their FQHC that would increase or reduce the likelihood for success of the BrEAThe trial: (1) multi-level factors (including patient-level factors, clinician-level factors, administrative considerations, organizational-level factors, and intervention components); (2) pandemic-specific concerns with implications for implementation feasibility in the current health-care delivery environment; and (3) the potential for unintended consequences of implementing the intervention. These findings align with implementation science frameworks, specifically the RE-AIM framework, which assesses Reach, Effectiveness, Adoption, Implementation, and Maintenance, and the CFIR framework, which examines inner and outer setting factors, individual characteristics, intervention characteristics, and process elements.

This study highlights facilitators and barriers affecting RCT implementation at different levels, aligning with RE-AIM (Adoption, Implementation, Maintenance) and CFIR (Inner Setting, Characteristics of Individuals, and Intervention Characteristics). Many of the variables our participants identified as likely to increase or reduce successful trial implementation have been reported previously as they relate to communities that are underrepresented in biomedical research generally [7,32], and FQHCs specifically [33,34]. For example, trusting relationships between patients and providers and a commitment to the community are at the core of the care that FQHCs deliver; these features of patient-centered care are known to foster research participation by groups who are underrepresented in biomedical research [32]. However, these enabling factors would likely be offset by the constraints of working in resource-scarce environments [35] and the demands that impacted work engagement and burnout during the pandemic [34] which have consequences for impeding research engagement.

Interestingly, the FQHC clinician and administrator participants interviewed during COVID-19 did not see the pandemic as a barrier to research but rather as an unparalleled opportunity for conducting clinical research then and now. While this was not true for many academic research enterprises [36,37], clinical research conducted in the community was impacted to a lesser extent because technology allowed for the online delivery of interventions and remote data collection, aspects of telehealth that address the ongoing need for alternative health care delivery post-pandemic. In addition, subjects' fear of contracting the virus during travel or long waits at research settings were mitigated when home visits or local community facilities could be used as places to conduct research or collect data [36].

Our participants also perceived that their patients with asthma were experiencing more anxiety during the pandemic. During this time, there was a great deal of concern that COVID-19 infection might lead to more serious adverse outcomes for those with chronic respiratory conditions. This was cited as the reason for increased levels of anxiety observed among those with asthma, relative to those without asthma [38,39]. Our participants believed that they could channel this anxiety into greater participant enrollment even after the pandemic. While anxiety has been shown to increase information-seeking behaviors [40] this may not translate to clinical trial participation, particularly in FQHCs [7]. For example, to successfully recruit for the All of Us Research Program, Inokuchi and colleagues had to establish performance management and operations improvement metrics, build data analytics and decision support systems, and facilitate research capacity through education and skill development. Despite our participants' optimism about recruiting for an asthma trial during the pandemic, social isolation mandates and fear of virus transmission likely led to higher anxiety, which has been linked to reduced rates of enrollment in and higher withdrawal rates from clinical trials during COVID-19 [33,36,41]. Notably, one of our participants identified the risk of unduly increasing patient anxiety about asthma control in the backdrop of the pandemic as an unintentional consequence of the trial.

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Only one other participant identified a potential unintentional consequence of trial implementation: the risk of neglecting other medical or social needs if a primary care visit focused on asthma control. While the financial health of FQHCs has improved with Medicaid expansion [42], small operating margins and increasing enrollment of uninsured patients place intense financial demands on clinicians to see as many patients as possible in a day; 15-minute bookings and frequent double bookings were commonly reported in our participating FQHCs. Further complicating financial performance demands are multiple unmet clinical and social determinants of health needs. FQHCs serve demographics facing high rates of chronic conditions, disease outcome disparities, and social inequities [6,43]. This makes chronic disease management particularly challenging in settings like FQHCs with limited human and financial resources [7]. It is not surprising, then, that one participant identified that a potential unintentional consequence of the planned intervention was either a longer visit or a visit that focused on uncontrolled asthma at the expense of other pressing medical needs. This is a challenge facing implementation trials, where unintended consequences could include reduced access to care for vulnerable populations [44]. Shortening the allotted time for an office visit has clinical implications and affects patient and provider satisfaction [45–47]. Alternatively, other participants identified improved asthma control as lessening their workload because unscheduled urgent visits would be reduced.

Limitations

Because interviews took place over five months at the time of heightened anxiety about a surge in COVID-19 infections from the omicron and delta variants, relaxed eligibility requirements for vaccines and boosters, and shortened isolation periods, and because earlier COVID-19 infections had particularly impacted the New York–New Jersey areas, the views expressed may have been unusually pronounced, transient and not representative of FQHC staff or administrators outside the region. In addition, the study faced challenges commonly associated with small qualitative research. For instance, findings are derived from a relatively small sample limited to four northeastern urban FQHCs, which may not fully capture the diversity of experiences across broader populations and geographic areas. Also, participants willing to engage in interviews may differ systematically from those who decline, potentially skewing the results toward individuals with stronger opinions or specific experiences. There is also a risk that staff perception of patient barriers could misrepresent the end-user perspective since patients were not interviewed. Despite efforts to maintain neutrality, the presence of an interviewer and the phrasing of questions may inadvertently shape participant responses. The findings are also influenced by the specific social, cultural, and institutional settings in which the study was conducted, making them less transferable to different healthcare systems or geographic locations. Lastly, there was also the risk that interest in participating in the upcoming trial may have led some staff to self-censure their answer to interview questions, leading to socially desirable responses.

Conclusions

In summary, findings from this study highlight the potential benefits of conducting assessments of perceived and actual barriers and facilitators prior to implementing a practice-based clinical trial. While COVID-19 provided a unique context for clinical trial roll-out, post-pandemic implications related to staffing levels and burnout were applicable to current health care delivery challenges. These data may provide crucial pre-trial implementation metrics that, when combined with other planned assessments, may provide a more comprehensive assessment of clinical trial implementation in FQHCs. By focusing on the needs and outcomes that matter most to the community, this type of community- and implementation science-informed research may encourage more community–academic partnerships that can increase research engagement by underrepresented populations of clinicians, staff, and patients.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/cts.2025.10204.

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