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ORIGINAL RESEARCH

Successes and challenges of implementing a lung cancer screening program in federally qualified health centers: a qualitative analysis using the Consolidated Framework for Implementation Research

Caitlin G. Allen,[1] Megan M. Cotter,[2] Robert A. Smith,[3] Lesley Watson[4]

[1]Department of Behavioral Science and Health Education, Rollins School of Public Health, Emory University, Atlanta, GA 30308, USA

[2]Population Sciences Department, American Cancer Society, Inc., Atlanta, GA 30303, USA

[3]Prevention and Early Detection Team, American Cancer Society, Inc., Atlanta, GA 30303, USA

[4]Strategy and Analytics Team, American Cancer Society Cancer Action Network, Inc., Washington, DC 20004, USA

Correspondence to: M. M. Cotter, megan.cotter@cancer.org

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ABSTRACT

In recent years, studies have shown that low-dose computed tomography (LDCT) is a safe and effective way to screen high-risk adults for lung cancer. Despite this, uptake remains low, especially in limited-resource settings. The American Cancer Society (ACS) partnered with two federally qualified health centers and accredited screening facilities on a 2 year pilot project to implement an LDCT screening program. Both sites attempted to develop a referral program and care coordination practices to move patients through the screening continuum and identify critical facilitators and barriers to implementation. Evaluators conducted key informant interviews ($N = 46$) with clinical and administrative staff, as well as regional ACS staff during annual site visits. The Consolidated Framework for Implementation Research guided our analysis of factors associated with effective implementation and improved screening outcomes. One study site established a sustainable lung screening program, while the other struggled to overcome significant implementation barriers. Increased time spent with patients, disruption to normal workflows, and Medicaid reimbursement policies presented challenges at both sites. Supportive, engaged leaders and knowledgeable champions who provided clear implementation guidance improved staff engagement and were able to train, guide, and motivate staff throughout the intervention. A slow, stepwise implementation process allowed one site's project champions to pilot test new processes and resolve issues before scaling up. This pilot study provides critical insights into the necessary resources and steps for successful lung cancer screening program implementation in underserved settings. Future efforts can build upon these findings and identify and address possible facilitators and barriers to screening program implementation.

Keywords

Implementation science, Lung cancer, Cancer screening, Evaluation, Cancer, Pulmonology

Implications

Practice: Health systems interested in implementing a low-dose computed tomography (LDCT) screening program should carefully assess their readiness for implementation (staff time, leadership support, training resources, and technology) and should consider a stepwise approach to implementation, which allows time for correcting challenges before they grow into insurmountable barriers.

Policy: Health systems should consult with private and public payers about coding, billing, and reimbursement processes to avoid potential errors and delays. Health systems in states without Medicaid expansion should anticipate significant out-of-pocket screening costs for patients.

Research: Further in-depth research is needed to uncover other potential barriers and facilitators to implementation and the sustainability of LDCT screening programs.

BACKGROUND

For many years, lung cancer has been the leading cause of cancer mortality in the USA and, until recently, disease control efforts primarily have focused on reducing cigarette smoking [1–4]. However, there is new evidence that low-dose computed tomography (LDCT) screening is associated with a reduction in the risk of lung cancer mortality among high-risk adults [2, 3, 5]. In 2014, the United States Preventive Services Task Force (USPSTF) issued LDCT as "Grade B" and recommended screening for adults aged 55–80 years, who have a 30 pack-year history, and currently smoke or have quit in the past 15 years [6]. Since 2014, further guidance has been issued to help develop high-quality screening programs [6–9]. However, LDCT uptake has been poor with only a small percentage of the eligible population reporting having received LDCT [10–12]. These low levels of screening are particularly challenging in limited-resource settings, such as federally qualified health centers (FQHCs) [11, 13, 14].

Research to understand the low uptake of LDCT has been limited and primarily focused on qualitative examinations of perceptions of cancer screening intentions among patients and providers, along

with quantitative examinations of the association between uptake and patients' sociodemographic characteristics [15–20]. Beyond individual-level factors, implementation challenges likely also affect LDCT uptake. For example, concerns have been raised about the replicability of the National Lung Screening Trial (NLST) in other settings, the complexity of the guidelines, and multilevel factors that influence implementation in health systems (e.g., lack of clinical infrastructure needed to identify patients who are eligible for LDCT) [21–23]. These challenges are especially prevalent in FQHCs and community hospital settings where 85% of all lung cancer care is provided in the USA [24]. However, there has been limited empirical study of the implementation process or barriers and facilitators to the uptake of LDCT [25].

A wide range of theories and models exist to help study barriers and facilitators to the implementation of evidence-based interventions [26–28]. The Consolidated Framework for Implementation Research (CFIR) synthesizes constructs from these theories and models to help advance the understanding of the implementation of a variety of interventions and in a wide range of settings [29]. Specifically, CFIR enables the examination of factors associated with program implementation across five domains (intervention characteristics, inner setting, outer setting, characteristics of individuals, and process) that contain 39 constructs that isolate factors that may influence the implementation of an intervention in practice [29]. While CFIR has not previously been used to study the LDCT screening program implementation, a wide range of studies have used CFIR to study cancer screening interventions in community clinics, FQHCs, and other health care settings [30–32]. Using the CFIR framework can help fill the existing gap in the understanding of multilevel factors that influence the implementation of LDCT screening programs in health systems.

To understand the implementation of LDCT screening in real-world settings, the American Cancer Society (ACS) conducted a 2 year pilot study with two FQHCs, each partnered with a local American College of Radiology (ACR) designated hospital screening facility. The Health Centers Advancing Lung Cancer Early Detection Pilot Program included the development and implementation of an LDCT referral program and care coordination practices to help move patients through the lung screening continuum [33]. ACS provided guidance, training, technical assistance, and financial support to enable the sites to implement processes to identify eligible patients, provide shared decision-making (i.e., a process in which patient and provider work together to make decisions about health care), and refer and navigate patients through screening and follow-up over the course of 2 years. The goal of the following analysis is to identify the critical facilitators and barriers to program implementation.

METHODS

Design

This evaluation was conducted as part of a pilot study that used a mixed-methods design [33]. Participant sites submitted quantitative data through quarterly progress reports throughout the pilot study. During annual site visits in 2017 and 2018, project evaluators conducted semistructured, in-depth interviews with project stakeholders. The study evaluation team was comprised of two full-time evaluators from the ACS and an independent evaluator from the Rollins School of Public Health at Emory University. The pilot study and evaluation were reviewed by the Institutional Review Board at Morehouse School of Medicine and given a nonresearch determination.

Sites and study population

This study included two sites, Site A and Site B. Each study site included an FQHC and their partner ACR-accredited screening facility, where patients could be screened with LDCT. For reporting purposes, we often use the term "site" to refer to both organizations and refer to them as one unit. Site A was located in a rural area within a state that had Medicaid expansion. Site B was in a large, urban area in a state without Medicaid expansion. Though Site A's FQHC had a Breathing Center (pulmonary rehabilitation program and a black lung clinic), neither site had established a lung cancer screening program using LDCT prior to the pilot study. Both sites received funding to support for the pilot implementation. ACS provided funds to support uninsured screening at Site B to reduce cost burden. Site A continued implementation efforts beyond the pilot project and Site B decided not to continue LDCT screening beyond the initial pilot period.

Evaluators conducted semistructured interviews in both years of the project with stakeholders, including clinicians (e.g., nurse practitioners, primary care physicians, and pulmonologists), patient navigators, and project coordinators who had both clinical and administrative responsibilities, clinic administrators, and regional ACS staff who oversaw the implementation of the pilot study. These data captured perceptions of the patient experience, but they do not reflect the thoughts or opinions of patients themselves.

Data collection

A total of 46 interviews with 33 individuals took place by telephone or during in-person site visits. Interviewers used semistructured interview guides with approximately 25 questions (see Supplementary Material). Three different interview

guides were created with tailored questions for participants from FQHCs, hospital screening facilities, and ACS staff. Topics of discussion included designing and implementing referral and screening processes, establishing and maintaining partnerships, progress on goals, and lessons learned about implementation. Examples of questions include, "How are patients navigated through the post-screening process?," "Based on your experience, what do you think is the best way to talk to patients about lung cancer screening?," and "Have you made any changes to how you track and use program data since you started the pilot?"

Grantees also submitted quarterly progress reports to ACS with quantitative data about their eligible patient population. Data points included the number of screening-eligible patients (e.g., ages 55–77, current or former smoker, and 30 pack-year history), patients assessed for eligibility, shared decision-making visits, patients referred for LDCT, appointments made, screening exams completed, screening results, diagnostic orders, and cancer diagnoses.

Data analysis

All 46 interviews were recorded with permission and transcribed verbatim using a professional transcription service. Evaluators developed a codebook comprised of 39 deductive codes based on constructs from the CFIR [29]. An additional 25 inductive, thematic codes were added to the codebook to capture topic-specific elements of LDCT screening implementation, such as smoking cessation, billing processes, and provider hesitation about screening. All three coders had previous experience applying CFIR constructs to evaluations using qualitative methods. The three evaluators applied all deductive and inductive codes to the 46 transcripts using MaxQDA 2018, a qualitative coding and analysis software. To ensure reliability, the team double-coded four transcripts and met to modify the codebook, refine code definitions, and establish intercoder agreement. After establishing agreement, the remaining 42 transcripts were analyzed and coded independently, and evaluators highlighted segments that required clarity, debate, or discussion. Coding discrepancies were reviewed and discussed until consensus was reached. In addition, basic information about sites' eligible patient population and screening referrals and completions were calculated using Microsoft Excel.

Results are presented by CFIR construct. Only constructs that emerged through our qualitative analysis are presented. Because both pilot sites had dramatically different contextual factors, implementation experiences, and outcomes, this comparative analysis will highlight similarities and key differences that contributed to successes and challenges at each site.

RESULTS

Overview of sites

The two pilot sites took distinct approaches to LDCT implementation and demonstrated varied levels of success based on their implementation models and the contextual factors at play. Each site was able to adapt its approach to implementation based on their specific needs. This resulted in unique approaches to implementation, determining patient eligibility for LDCT, and issuing referrals. Ultimately, Site A successfully created a sustainable screening program, while Site B struggled to overcome implementation barriers. Site A identified more screening-eligible patients (N = 364) and had an overall higher number of patients screened (N = 263; 72%) in their program. Conversely, Site B had challenges identifying patients and moving them through the referral and screening process. Across both years of the pilot study, Site B identified 128 screening-eligible patients and completed 57 screening exams (44%). Details about implementation processes are described in depth using the CFIR framework below (Table 1).

Intervention characteristics

The intervention characteristics domain examines the intervention itself (i.e., LDCT). According to CFIR, it is important to consider how interventions are perceived at study sites as interventions that have not been adapted to a particular setting are more likely to be perceived as a poor fit than those that are adapted for the site's specific setting. The most influential implementation characteristics at our pilot sites were relative advantage, complexity, and cost (Table 1).

Relative advantage

Perhaps because it was soon after lung cancer screening recommendations had been issued, and because of resource limitations, both sites struggled to see the immediate advantage of implementing LDCT screening. Site implementation leaders expressed a need for the relative advantage and importance of LDCT screening to be explicitly demonstrated and clearly articulated to staff and leadership from the beginning of the project. Although both sites recognized the difficulty in implementation, Site A leadership communicated the long-term advantages of implementing an LDCT program to staff, allowing them to gain buy-in for implementation. Furthermore, leadership at this site was supportive of the program and communicated the advantages clearly, resulting in buy-in from staff. Due to numerous competing demands at the organization, leadership at Site B struggled to communicate the advantages of lung cancer screening with LDCT to staff and leadership, resulting in ambiguity, low buy-in, and ultimately incomplete implementation.

Table 1 | Exemplar quotes from both sites by Consolidated Framework for Implementation Research (CFIR) domain and construct

CFIR Constructs	Site A	Site B
Intervention characteristics		
Relative advantage	"And there were multiple hour-long presentations on shared decision-making and I feel like it's one of those things that people – one of my life mottos is implement now, perfect later." Project Lead	"We know we're supposed to do this, but why are we supposed to do this? They felt like it was just something extra added on during the day." Director of Nursing
Complexity	"I would simplify because even my little cheat sheet... I've cut and cut and cut because if you don't keep it to a one-page or something and then a picture, it's too overwhelming." Project Coordinator	"You're having to speak with radiologists, but there's also the billing component, the registration component ... educating our staff on these patients and when they come in what paperwork is required for them. There's a lot of people that have to be at the table in order to make it seamless for that patient when they come in." Navigator
Cost	"Essentially the first year we spent troubleshooting and doing process development. ... We spent a lot of time like figuring out what insurance codes worked and how the pre-authorization process went and lots of things that were removing barriers for the physicians." Project Lead	"I would consider the time and the resources that are going to be allocated to the project because that makes a huge difference in the success of the project." CEO
Outer setting		
Patient needs and resources	"Transportation obviously is a barrier and just the cost in general for patients to travel to a center to get screened that's ACR accredited." Pulmonologist	"And they have no – no interest in quitting smoking. Okay. Keep smoking, but get screened for lung cancer because that could change your viewpoint. But I think... you can have a really great program but you have to understand the population that you're trying to reach." Director
External policies	"Well, Medicare requires that the name and date of birth, the MPI number from the physician—which physicians don't always have that on their orders—whether they're a current smoker or a former smoker, if they're former, how many years has it been since they've quit, a statement that they're asymptomatic." Lung Screening Navigator	"I think really the key was when Medicare said they would start paying for it. At that point, it really became something that people could take advantage of. I think that's really when we started being able to get substantial referrals." Screening Facility Director
Inner setting		
Networks and communication	"We meet every two weeks. We have a list of all the patients that have come back in that two-week time period. Pulmonologists, EP surgeon, the manager, me as the imagining screening navigator, the lung cancer navigator, all around the table at the same time. They go through each of those patients and look at scans together, discuss what still needs to be done next, whether it would be a three month follow up, does it look more like infection? Cancer? Or do we need to go ahead and set them up for a PET right away? They all have all that discussion around the table together." Lung Screening Navigator	"I can't tell you what it's like to receive an email to say, 'This is what we're going to implement,' and you didn't have any input on the process. Had those key players been at the table, they would have said, "That's a great idea, but here's a better way of doing it,' or 'That's just really not going to work,' or 'It's going to become overwhelming because of processes that are put in place.' It needs to trickle down to everyone and not just be a top level." Quality Improvement Officer
Implementation climate tension for change	"It was a big request from our referring doctors within the community, wanting to start a program." Hospital Nurse Manager	No examples available
Compatibility	"I always say nobody in the country has my job, and I think that's probably true, just because very few people do what I'm doing in this setting. And I thought, wow, this would be an awesome way to expand the services that we offer and care for people's pulmonary health in this area that really needs it." Project Lead	"We were going through internal challenges and kind of rebuilding the organization and recruiting more providers and trying to put processes back in place, so trying to add something to our system that didn't quite fit our priorities was going to be a challenge for us, and that proved to be true from a provider perspective." CEO

Table 1 | Continued

CFIR Constructs	Site A	Site B
Relative priority	"I feel really privileged to have this project. I think it is like being boots on the ground with the mammograms in the '70s and '80s. … And there have been large university studies on this sort of thing. This is a real world opportunity to see how this impacts people's lives that are basically living their everyday lives, rural America" Project Lead	"If it's not job-imperative that [providers] do [shared decision-making] right then, then it's going to fall to the bottom of the totem pole for them." Referral Coordinator
Goals and feedback	"Is there something you need that we're not giving you? … Are you seeing things that we could improve so that our patients don't have issue?" Project Coordinator	"I believe if we knew more about [lung screening] or why we're doing it, we'll probably be more on board to actually do it, but we just –I just was thrown into it. I didn't know anything about it." FQHC LPN
Leadership engagement	"You have to start with administrative buy-in, you have to start with physician champions that are willing to help build the program, and [our pulmonologist] has been astronomical in helping that and being on board with that. … The willingness for those physicians to recognize the need of our community and want to help, you know. That has made a big impact." Hospital Nurse Manager	"I feel like we have tried to be really understanding of [the FQHC's] process and the challenges they face, but I just don't know – since the original physician champion that was originally part of this project, once he was gone, I just don't think there was ever any real push or buy-in." Screening Facility Director
Available resources	"Using our electronic medical record does help. My MA will do the intake, and she will automatically ask them about their smoking history. It's not always accurate, but [our EHR will sometimes flag] if they're due or qualify for an LDCT." FQHC Nurse Practitioner	"Right now, we don't have the internal resources needed to be successful, based on how the project is going." Quality Improvement Officer
Access to knowledge and information	"Really understanding the referral guidelines is important. … We've made little 3x5 cards that [providers] can keep either attached to their computer very handy so they can refer to those screening guidelines whenever they're referring someone, along with the CPT codes and stuff they need to make sure that it gets billed appropriately." Pulmonologist	"Honestly, I would just go back to the training: … focus on change management from the beginning to the end. That would be my recommendation." CEO
Individual characteristics		
Individual characteristics	"There's an imaging navigator and there's a lung navigator. The imaging navigator is in charge of arranging the scans and arranging the follow-up type of things and keeping track of who needs a scan … It goes to the group with a lung navigator within that group. We email back our recommendations and the lung [cancer] navigator picks that piece up, and then she's the communication point between us and the primary doctor or referring doctor, whoever that may be." Pulmonologist	"It was the turnover with the staff, unfortunately, I believe was a major barrier, as well with this project shifting in senior leadership. … I believe it was [the referral coordinator] who kind of served in multiple roles within the clinic. If you're identifying a person as the champion for this program and you're pulling them away to do other things, then the program isn't getting the time and attention that it needs." Outcomes Coordinator
Process		
Planning	"We took a lot of time on the front end to plan the process steps and the flow. And we tweaked it as we've gone along, but we didn't go live until we got all our ducks in a row." Imaging Manager	"I think that may have been one part that was left out of the training, because I think a lot of the staff felt like … are we trained? So how do we really do it? Like how could it look?" Primary Care Physician
Reflecting and evaluating	"We meet every other week and discuss our issues, monthly, every other week, you know … and asking questions, are these patients getting referred or where they're getting referred." Nurse Manager	"We did [meet] but we don't anymore. … I do know that [the navigator] has spoken to the coordinator frequently… So there's been communication… but not a standing meeting." Outcomes Coordinator

Complexity

Similar to relative advantage, both sites felt that the LDCT program was highly complex and would be difficult to implement. Specifically, there were a high number of intervention steps that disrupted normal workflows and felt burdensome to staff. Sites dealt with this complexity differently. Site A actively sought to reduce complexity by creating workflows that would address the challenges (e.g., creating a referral template), which they pilot tested and perfected prior to full implementation. In addition, having multiple intervention leaders who knew the plan and served as resources to staff helped reduce strain and lessened the perceived complexity. Site B's approach involved numerous steps and handoffs, which unintentionally built more complexity into the referral process. For example, at one point during the pilot, the process was as follows: The referral coordinator would examine the records of patients due for an appointment the upcoming week and send a list of potentially eligible patients to nurses and medical assistants. The nurses or medical assistants would ask the patient screening questions (e.g., smoking status and symptoms) during their appointment and make a note for the physician to have a shared decision-making conversation with patients who were eligible. If the physician determined screening was appropriate, they would give the patient a paper referral form to take to a scheduling assistant at the front desk who would book an appointment for them. This long process required actions from five people, including the patient. If an error occurred at any of these handoff points, such as a patient losing their paper referral form or the physician not having time to finish the shared decision-making conversation, the process would fail and the patient would leave without an appointment.

Cost

Cost includes financial and resource investments required to implement and sustain an intervention. Pilot study funds were perceived by site leadership as sufficient for implementation. Because Site B was located in a state without Medicaid expansion, they used grant funds to pay for screening uninsured and underinsured patients. Site A did not need to do so because their state had expanded Medicaid and, thus, had few uninsured patients. The primary cost-related concerns for LDCT screening was time and staff resources. Site B did not have access to an electronic health record (EHR) system and, thus, implemented a time-intensive approach that involved tracking referral forms manually. They also opted to spend pilot study funds on hiring new staff dedicated to the intervention, which was high cost and unsustainable after pilot funds were depleted. These one or two staff absorbed much of the extra work involved in the intervention, which further resulted in the perceived high cost of time and staff resources. Site A invested in strategic planning and staff training about the intervention beyond the initial training ACS provided, which were high-cost but also high-impact activities that reached more staff and produced a sustainable, higher-impact intervention. Training and engaging all staff also resulted in the burden of time being distributed more evenly.

Outer setting

According to CFIR, the outer setting domain examines external influences on an intervention, such as the economic, political, and social contexts within which the organization operates. These may include how the organization is networked with other organizations, peer pressure from similar organizations, and large-scale policies that impact implementation. In the current study, patient needs and resources (e.g., transportation) and external policies (e.g., Medicaid expansion or nonexpansion) influenced implementation at both sites (Table 1).

Patient needs and resources

Both sites identified patient trust as an ongoing challenge in their patient population, especially among adults at high risk of lung cancer. Building trust among current smokers was difficult because they were often fatigued by smoking cessation conversations, which are an aspect of the LDCT intervention. Low health literacy is common in this population, posing challenges to understanding insurance coverage, and the information presented in shared decision-making conversations, resulting in opportunities for patient hesitancy, misunderstanding, and subsequently misinterpretations of screening exam results. Thus, both sites faced greater than average challenges to providing clear, understandable information about the screening process in a manner that gained trust.

External policies

Both sites were aware of the Centers for Medicare & Medicaid Services (CMS) policy related to reimbursement for LDCT screening before beginning the pilot study; however, there were differences in coverage policies that impacted both sites. Site A was located in a state with Medicaid expansion that reimbursed LDCT screening. However, implementation leaders discovered that Medicaid and some private insurers would not reimburse follow-up tests done within 12 months of the initial screening, despite ACR guidelines recommending follow-up 6 months after a Lung-RADS 3 finding. Because of this, FQHC and ACS staff at this site continuously engaged with insurance and reimbursement experts to resolve errors, adding more burden to the process but ensuring that patients would not receive costly out-of-pocket bills. Site B was in a state without Medicaid expansion, so they did not

face reimbursement challenges; instead, they faced the challenge of identifying funds to pay for LDCT screening and recommended follow-up tests, especially when pilot funds were depleted. Site B had low screening and follow-up rates; therefore, there were few participants to share information about if or how reimbursement policies affected follow-up or intervention implementation.

Inner setting

The inner setting involves characteristics of the organization and the context in which the intervention is being delivered. In this project, the inner setting included the FQHC and LDCT screening partner. Three primary factors of the inner setting that impacted implementation outcomes included: networks and communication within the organization, implementation climate or capacity to change, and the organization's readiness to implement the LDCT program (Table 1).

Networks and communication

Networks and communication differed considerably between the sites. From the beginning, Site A engaged stakeholders who could capture an array of perspectives for implementing an LDCT program successfully from frontline office staff to the radiology suite. Communication was facilitated through direct calls between implementation leaders on personal lines and regular meetings, including multiple representatives from both organizations and ACS. Although it was sometimes unclear which partner should be accountable for emerging issues, when problems arose, partners worked together to resolve them quickly. In contrast, Site B experienced poor communication between the FQHC and screening facility, as well as between leadership and clinical staff. Leadership from the FQHC and screening facility were not engaged in regular communication about the intervention with each other or with their respective employees, only engaging when a problem arose. This resulted in chronic misunderstandings about the screening process, unclear goals and division of responsibility, and ultimately frayed relationships that ended the project. Poor communication between FQHC leadership and screening center staff also resulted in disengaged employees and staff not feeling empowered to provide feedback about the program. Furthermore, the referral process required many steps to communicate basic information between the FQHC and screening site about patients, often on paper forms that were passed between multiple people in order to schedule screening and follow-up appointments.

Implementation climate

Implementation climate encompasses the ability to change the interest or receptivity of implementation among participants. According to CFIR, a variety of factors influenced the implementation climate in the two settings, including tension about change, compatibility, relative priority, and the organization's ability to set goals and provide feedback. After recognizing the relative advantage of implementing LDCT, Site A had a strong interest and desire to implement a lung cancer screening program prior to the pilot project. This preexisting tension for change facilitated buy-in among referring providers and motivated them to succeed.

The lung cancer screening program aligned well with the patient-centered missions and values of both organizations. There were some providers at both sites who were somewhat familiar with lung screening literature, such as the NLST, and were initially hesitant about overscreening patients or the potential for false positives. Implementation leaders at Site A successfully addressed provider hesitancy through training and sharing their own patient success stories. At Site B, leadership never addressed provider hesitancies and instead allowed individual providers to opt out of the referral program if they had concerns.

At Site B, the pilot study opportunity came at a time when the FQHC was facing many competing priorities and did not have the human or financial resources to implement a new, highly complex screening and referral program. FQHC leadership were more invested in attaining patient-centered medical home accreditation and addressing high staff turnover, making the LDCT screening intervention a low priority. Not only was prioritization an issue at the leadership level but it also trickled down to patient encounters. The FQHC was understaffed, and providers often reported that they did not have time to conduct shared decision-making or discuss lung cancer screening during patient encounters. As part of the intervention, providers received daily reminder emails with names of screening-eligible patients, meant to keep the intervention top-of-mind; however, this sometimes overwhelmed providers who felt short on time and wanted to prioritize patients' primary concerns. Although Site B agreed to participate in the pilot study, it was ultimately unable to devote the time, attention, or resources needed to make the program a success. Site A faced fewer competing demands and made the LDCT intervention a high priority, allowing them to devote resources to developing and executing the slow, stepwise implementation process that ultimately led to their success.

Regular, formal education and training at Site A enabled them to clearly communicate the purpose and importance of the program and provided an opportunity to share feedback and ideas for improvement. Clinical staff at Site B did not feel that the goals of the program were well communicated, resulting in low motivation, and staff felt unable to provide feedback about the implementation process.

Readiness for implementation

Both sites differed in their readiness to implement a lung cancer screening program. Readiness for implementation was heavily influenced by their level of leadership engagement, available resources, and access to knowledge and information.

Leadership engagement was critically influential in facilitating implementation. Site A obtained buy-in from key staff and leadership from the beginning of the pilot study and maintained engagement throughout, especially if issues emerged. Engaged, motivated leaders and an enthusiastic project champion resulted in better readiness for implementation. Alternatively, leadership at Site B's FQHC struggled to engage leadership due to competing priorities at the organizational level, resulting in poor planning, low prioritization, and misunderstandings about project details, such as goals and objectives. The original clinic leadership, including the pilot study champion, left the organization shortly after beginning the intervention and was replaced by new staff who did not prioritize the pilot study. This new leadership was largely disengaged until major issues arose, leading to miscommunication and missed opportunities to address issues before they grew too big to handle.

Sites differed in the resources available for this project, particularly human resources and customizable EHRs. Site A had substantial resources available to facilitate implementation. The FQHC and screening facility were both able to dedicate staff time from clinicians, navigators, and other staff to ensure project success. Additionally, their EHR was easy to customize and required only a simple step to capture screening eligibility data, including a pack-year history calculator; staff felt that this resource was highly valuable to the overall success of the program. The FQHC at Site B, however, had insufficient resources to support this project. They lacked support, time, and enthusiasm for implementing a new lung screening referral process. Major staff and leadership turnover, especially in key leadership positions, meant that staff were overwhelmed and the intervention became a low priority. The FQHC was also in the midst of other resource-intensive priority activities during the pilot: implementing a new EHR system and applying for patient-centered medical home accreditation.

Finally, sites had similar access to knowledge and information to help prepare them for implementation. During the capacity-building phase that took place prior to beginning implementation, ACS subject matter experts provided both sites with high-level presentations about the evidence supporting the benefit of LDCT screening for lung cancer and evidence for practice interventions associated with higher rates of adherence with screening. Participants from both sites expressed dissatisfaction with the training sessions, expressing concerns that the training did not meet their specific needs because it was too high level, did not explain the relative importance and long-term benefits of LDCT screening programs, and left them feeling unprepared for implementation. They suggested that future trainings focus less on national studies and instead use local data and patient examples, when possible, to make training more relevant and offer practical implementation guidance, including change management principles. Participants from Site A also felt disconnected from ACS subject matter experts and shared that they would have felt more comfortable learning from local experts who knew the area and way of life.

Individual characteristics

The individual characteristics domain examines details about individuals involved with intervention implementation (e.g., knowledge and beliefs about the intervention). In our pilot, roles within the organization were important influencers for intervention success (Table 1).

Both sites appointed an intervention leader to serve as a bridge for communication and coordination between the FQHC and screening facility. At Site A, the intervention leader was a respiratory therapist and, at Site B, a screening facility navigator and a referral coordinator from the FQHC shared coordination responsibilities. Project staff articulated the importance of appointing implementation leaders and working together across roles to make sure patients do not fall through the cracks. At both sites, the intervention required a variety of dedicated staff, including nurses, physicians, navigators, and others to answer patient questions, issue referrals, and deliver appropriate screening and follow-up. At Site A, there were clearly delineated roles and expectations for all staff. Many clinical staff at Site B shared that they did not clearly understand their roles or expectations, which caused confusion about who was responsible for the patient throughout the referral and screening processes and led to referrals for several ineligible patients.

Process

The process domain captures the various steps to achieve both individual- and organizational-level uses of the intervention. CFIR examines four subprocesses included in the intervention process: planning, engaging, executing, and reflecting. The planning and reflecting processes emerged as most critical for implementation success at the pilot sites (Table 1).

Planning

Planning includes the degree to which the implementation method is developed before implementation. Both sites received high-level training about the

intervention and lung cancer screening from ACS during the capacity-building phase but after training sites differed in how they engaged in planning for execution. Both sites completed process mapping prior to implementation. Site A engaged in process mapping and pilot testing of processes and clearly defined roles before rolling out to all physicians, which facilitated successful implementation. At Site B, staff and leadership were less engaged in process mapping and the planning process was less clear and intentional, with few opportunities for initial planning among the staff. Both sites articulated the importance of careful planning and process mapping prior to implementation to facilitate success.

Reflecting and evaluating

The pace of implementation at each site created various opportunities for reflection and evaluation. Site A used a slow, stepwise approach to implementation, which allowed project champions to pilot test the referral and reimbursement processes and resolve issues before scaling up and expanding. This site viewed process improvement as an ongoing and essential part of the program. Clinical staff had regular opportunities to provide feedback for improvement during partner meetings; this kept staff engaged and captured issues before they grew into bigger problems. Site B focused on rapid implementation, which did not allow time for identifying and addressing emerging issues, and there was no routine meeting or other manner for staff to submit program improvement ideas. This approach left little opportunity to reflect on implementation progress and engage in process improvements.

DISCUSSION

The evaluation of this pilot project provides insight into critical resources and steps that promote successful LDCT screening program implementation for high-risk adults in FQHCs. Using the CFIR framework to analyze qualitative data and synthesize study findings helped us compare and contrast the two pilot sites to identify facilitators and barriers to successful implementation.

Staff and leadership at both sites acknowledged that implementing LDCT screening for lung cancer is a highly complex process that requires substantial upfront planning and investment among leadership and staff, as well as ongoing communication to help troubleshoot challenges that arise throughout the implementation process. Given this high level of investment required, sites developing LDCT screening in the future should consider their readiness to implement prior to committing to LDCT screening. This process involves determining if there are potential multilevel barriers to success and the organization's ability to overcome them prior to beginning the project. Organizations could consider undertaking a thorough capacity and readiness assessment to ensure that personnel and other resources are available. Prior literature has assessed the readiness of primary care clinics to implement LDCT programs, finding that only 10% of respondents had lung cancer screening available in their practice [21]. Similar to our findings, this study also suggested high levels of uncertainty about LDCT, including the need for guidance about implementation and concerns about how screening programs would be integrated into EHRs. As suggested by our evaluation, identifying and addressing these practical needs is an important step prior to beginning implementation.

While there is currently no existing readiness assessment specifically designed for LDCT programs, other assessment tools exist and could be adapted for use among sites considering LDCT. For example, the Diabetes Care Coordination Readiness Assessment is designed to measure primary care clinic readiness to coordinate care for adult patients with diabetes [34]. The tool considers five domains: organizational capacity, care coordination, clinical management, quality improvement, and infrastructure when assessing for implementation readiness. A wide range of other readiness assessment tools exist and could be adapted, including the Practice Transformation Readiness Assessment and Quality Improvement Capacity Assessment [35, 36]. Others have used CFIR to assess readiness for implementation, suggesting that readiness is often captured by two CFIR domains: inner setting (e.g., readiness for implementation, implementation climate, networks, and communication) and characteristics of individuals [37]. Specifically, for LDCT, an assessment could include identifying competing priorities, concurrent activities, ongoing or upcoming systems challenges, and system readiness. If there is reluctance or hesitation about implementing or if an organization feels unprepared for LDCT implementation, then it would be important to consider these challenges and ensure full buy-in to the program before beginning.

After buy-in was established, we found that having at least one champion who is enthusiastic and knowledgeable about the project can help provide guidance throughout the initial planning and implementation process. The value of a program champion has consistently been demonstrated in the literature [38]. Ideally, given the complexity of LDCT screening, it would be best to have both administrative leadership and a physician champion. We found that these champions should be involved in the day-to-day implementation and monitoring of the program. Specifically, this includes an individual who is dedicated to communication between the FQHC or primary care site and screening facility. Other studies have similarly found that two champions can help with implementation success—a project champion who leads change

efforts specific to the implementation of a program and an organizational change champion who focuses on higher-level issues, such as mobilizing resources and linking the project vision with the vision of the broader organization [39].

Developing a successful program also requires careful planning. In our pilot study, implementation was more effective when using a bottom-up approach with frontline staff who were responsible for implementation rather than a top-down approach. This approach helped gain buy-in and input when rolling out implementation to providers, whereas administrative leadership overseeing and directing the implementation process without frontline staff input resulted in missed opportunities and miscommunication. These observations are especially true in the context of LDCT screening, which is relatively new and unknown for staff and providers alike.

While we used CFIR as an evaluation framework applied retrospectively, it would also be possible to use CFIR and other frameworks as an implementation planning framework. For example, combining CFIR with the Theoretical Domains Framework (TDR) could help identify multilevel determinants that should be considered in the implementation planning stage [40]. The process of planning and using a stepwise approach to implementation with built-in opportunities for evaluation allows for regular updates and modifications to the process as needed. As we found in our pilot study, this stepwise method of implementation and scale-up is not necessarily a quick process, but careful planning using an implementation framework could help anticipate and mitigate challenges.

Our study is not without limitations. We provide a qualitative overview of LDCT program implementation in two unique settings; while both sites had high lung cancer incidence and aimed to develop partnerships between FQHCs and accredited screening facilities, there were many practical differences between the sites that were not revealed until implementation began. Although we interviewed a wide range of staff across sites and at multiple time points, our findings cannot be widely generalized. Relatedly, these sites had high levels of support from ACS staff and ample funding, which likely does not reflect the implementation experience at other sites. In addition, we retrospectively applied CFIR as a framework for qualitative interview analysis. Our initial interview guide did not specifically consider CFIR constructs; however, future studies could incorporate elements of CFIR throughout the planning of the program, development of the evaluation, and qualitative and quantitative measures of implementation success. Finally, we did not interview patients as part of our evaluation. Given the exploratory nature of this pilot study and limited resources, we opted to focus on capturing the experiences of health professionals involved in implementation. Thus, our project data includes only stakeholders' and providers' perceptions of the patient experience but do not reflect the thoughts of patients themselves. Future studies should engage patients to further explore patient-level barriers and facilitators.

CONCLUSIONS

Screening patients for lung cancer using LDCT has been shown to improve health outcomes for high-risk adults but, without commitment, readiness, and resources, the road to successful program implementation can be a long one. Our pilot study identified a variety of facilitators and barriers to program implementation and provided two starkly contrasting examples of how implementing and managing screening programs can be complex, time consuming, and resource intensive. However, with thoughtful planning and execution, open communication, and motivated staff, health systems can ultimately build a path to lung cancer screening for their patients and reduce lung cancer deaths.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Translational Behavioral Medicine* online.

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Compliance with Ethical Standards

Conflicts of Interest: M.M.C., R.A.S., and L.W. are employed by the ACS and ACS CAN, which receive grants from private and corporate foundations, including foundations associated with companies in the health sector, for research and initiatives outside of the submitted work. The authors are not funded by any of these grants, and their salary is solely funded through ACS and ACS CAN funds. C.G.A. declares that she has no conflicts of interest.

Author Contributions: M.M.C. and L.W. collected all project data. C.G.A., M.M.C., and L.W. coded and analyzed the data. C.G.A. and M.M.C. wrote the manuscript with input from R.A.S. and L.W. R.A.S. served as the study's primary investigator, provided input on analysis, and contributed subject matter expertise to manuscript writing.

Ethical Approval: This study did not contain any studies with human participants performed by any of the authors. The pilot study and evaluation were reviewed by the Morehouse School of Medicine Institutional Review Board (1032106) and given a nonresearch determination. This article does not contain any studies with animals performed by any of the authors.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Reporting Guidelines: Because our analysis used an implementation science framework, we chose the Standards for Reporting Implementation Studies (StaRI) Standard as our reporting guideline because it is one of the most commonly used among qualitative and implementation science research.

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