

# 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**

Emory University School of Public Health

**Megan M. Cotter** (✉ [megancotter2@gmail.com](mailto:megancotter2@gmail.com))

American Cancer Society <https://orcid.org/0000-0001-9268-9869>

**Robert A. Smith**

American Cancer Society

**Lesley Watson**

American Cancer Society Cancer Action Network

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## Research

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# Abstract

**Background:** The American Cancer Society (ACS) partnered with two federally qualified health centers (FQHCs) and American College of Radiology designated lung cancer screening facilities on a two-year pilot project to implement lung cancer screening. The project aimed to develop a referral program and care coordination practices to move patients through the screening continuum and identify critical facilitators and barriers to implementation.

**Methods:** Evaluators conducted key informant interviews (N=46) with navigators, clinical staff, administrators from both sites, and ACS staff during annual site visits in 2017 and 2018 to capture data on implementation barriers and facilitators. Three evaluators conducted a thematic analysis using the Consolidated Framework for Implementation Research (CFIR) and assessed factors associated with effective implementation and improved screening outcomes.

**Results:** One study site established a sustainable lung screening program, while the other encountered numerous implementation barriers which they failed to overcome. CFIR constructs highlighted critical barriers and factors associated with success and improved outcomes. *Intervention Characteristics:* Time spent with patients and disruption to normal workflows were challenges to implementation at both sites. *Outer Setting:* Both sites struggled with building patient trust and worked to gain trust by providing clear, consistent information about the screening process. One site was located in a state with Medicaid expansion that reimbursed screening but the other was not. *Inner Setting:* Engaged, supportive leaders who provided clear, consistent communication about implementation helped improve staff capacity, which was critical to building a successful program. *Individual Characteristics:* Knowledgeable, confident champions and intervention leaders were able to train, guide, and motivate staff throughout the intervention, whereas the absence of supportive leadership failed to produce staff champions and intervention leaders. *Process:* A slow, stepwise approach to implementation at one site allowed project champions to pilot-test the referral and reimbursement processes and resolve issues before scaling-up.

**Discussion:** This pilot project provides insight into critical resources and steps for successful program implementation in underserved FQHC settings. Future efforts could build upon these findings by considering self-assessment and monitoring tools that incorporate CFIR constructs to help identify and address possible facilitators and barriers to implementation of LDCT.

## Contributions To The Literature

We describe the lessons learned from implementing a lung cancer screening program in two federally qualified health centers

The project provides insight about the resources and steps needed to successfully implement lung cancer screening in underserved settings

We recommend opportunities to advance research using the Consolidated Framework for Implementation Research through development of self-assessment and monitoring tools to improve implementation success

## Background

For many years lung cancer has been the leading cause of cancer mortality in the United States, and until recently, disease control efforts primarily have focused on reducing cigarette smoking.(1-4) However, there is now 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 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 percent 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’ socio-demographic 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 multi-level 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 United States.(24) However, there has been limited empirical study of the implementation process or barriers and facilitators to uptake of LDCT.(25)

A wide range of theories and models exist to help study barriers and facilitators to implementation of evidence-based interventions.(26-28) The Consolidated Framework for Implementation Research (CFIR) synthesizes constructs from these theories and models to help advance understanding of implementation of a variety of interventions and in a wide range of settings.(29) Specifically, CFIR enables examination of factors associated with program implementation across 5 domains (intervention characteristics, inner setting, outer setting, characteristics of individuals, and process) which contain 39 constructs that isolate factors which 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 understanding of multi-level factors that influence the implementation of LDCT screening programs in health systems.

To understand implementation of LDCT screening in real-world settings, the American Cancer Society (ACS) conducted a two-year pilot study with two FQHCs which, in turn, each partnered with a local American College of Radiology (ACR) designated hospital screening facility. The Health Centers Advancing Lung Cancer Early Detection (HALE) Pilot Program included the development and implementation of a 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, and refer and navigate patients through screening and follow-up over the course of two 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 semi-structured, in-depth interviews with project stakeholders. The study evaluation team was comprised of two full-time evaluators from the American Cancer Society (MMC, LW) and an independent evaluator from Emory University (CGA) The pilot study and evaluation were reviewed by the Morehouse School of Medicine Institutional Review Board (1032106) and given a non-research determination.

### **Sites and Study Population**

This study included two sites, Site A and Site B. Each study site included a 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 semi-structured interviews in both years of the project with stakeholders including clinicians (e.g. nurse practitioners, primary care physicians, pulmonologists), patient navigators, 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 semi-structured interview guides with approximately 25 questions. 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 number of screening-eligible patients (e.g. age 55-77, current or former smoker, 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 Consolidated Framework for Implementation Research (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. 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. 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 had varied levels of success based on their implementation models and the contextual factors at play. Each site was able to adapt their 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 which have not been adapted to a particular setting are more likely to be perceived as a poor fit than those which 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 a LDCT program to staff, allowing them to gain buy-in for implementation. Further, leadership at this site was supportive of the program and communicated the advantages clearly, resulting in buy-in from staff. 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.

### Complexity.

Similar to relative advantage, both sites felt 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, 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 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 and external policies 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 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 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 a 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. Further, 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 pre-existing 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 over-screening 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 hesitations 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 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 were 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 electronic health records (EHR). 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 this resource was highly valuable to the overall success of the program. Site B's, however, had human resources to support this project were insufficient, as 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 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 PCMH status.

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 it left them feeling unprepared for implementation. They suggested 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 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 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 use of the intervention. CFIR examines four sub-processes 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 about 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 multi-level 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 personnel and other resources are available. Prior literature has assessed 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 multi-level determinants that should be considered in the implementation planning stage.<sup>(40)</sup> 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 are 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 implementation in two unique settings, while both high lung cancer incidence settings and partnerships between FQHC and an accredited screening facility, 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. Thus, our project data includes only stakeholders' and providers' perceptions of the patient experience but do not reflect the thoughts of patients themselves.

## 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.

## Abbreviations

**ACS:** American Cancer Society

**FQHC:** Federally Qualified Health Center

**CFIR:** Consolidated Framework for Implementation Research

**LDCT:** Low Dose Computed Tomography

**ACR:** American College of Radiology

**HALE:** The Health Centers Advancing Lung Cancer Early Detection

## **Declarations**

### **Ethics Approval:**

The pilot study and evaluation were reviewed by the Morehouse School of Medicine Institutional Review Board (1032106) and given a non-research determination.

### **Consent for Publication:**

All authors have completed a review of the article and approve it for publication.

### **Availability of Data and Materials:**

Qualitative data are available upon request from the corresponding author.

### **Competing Interest:**

None to Note

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### **Author Contributions:**

LW and MC conceived and designed the analysis of this study; LW and MC collected data; CGA and MC performed the analysis; CGA and MC wrote the paper; LW and RS reviewed the paper and made updates. All authors reviewed the final submission.

### **Acknowledgements:**

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# Tables

Table 1

## CFIR Domains and Definitions

Domain and Definition	Site A	Site B	Similarities and Differences
<b>Intervention Characteristic</b>			
<p><b>Relative Advantage:</b> Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution (N=17)</p>	<p>"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</p>	<p>"When [leadership] came to me... that was pretty much the discussion. 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</p>	<ul style="list-style-type: none"> <li>· Relative advantage needs to be explicitly demonstrated and clearly articulated to staff from the beginning</li> <li>· Both sites recognized how difficult it was to implement, but Site A was able to see the bigger picture and long-term advantage of implementation</li> </ul>
<p><b>Complexity:</b> Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement (N=59)</p>	<p>"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." Breathing Center Assistant</p>	<p>"But on the [hospital] side, you're having to speak with radiologists, but there's also the billing component, the registration component, bringing in the registration team, the new consults, educating our staff on these patients and when they come in what paperwork is required for them. Like I said, billing and all that. 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</p>	<ul style="list-style-type: none"> <li>· Both sites felt overburdened prior to beginning the program</li> <li>· Approach to dealing with complexity was different by site</li> <li>· Site A actively sought to reduce complexity through creating auto-referrals and one order sheet; knew it was a complex process, so they studied and pilot tested to help simplify</li> <li>· Site B had many steps and handoffs in the process; unintentionally built more complexity into their system without thinking through ways to simplify</li> </ul>
<p><b>Cost:</b> Cost of the intervention and cost associated with implementing that intervention,</p>	<p>"Essentially the first year we spent troubleshooting and doing process development. And I think that's the point at which we talked, and I noticed when I got the site</p>	<p>"I would consider the time and the resources that are going to be allocated to the project because that makes</p>	<ul style="list-style-type: none"> <li>· Although same funding amount, resource allocation influenced perceived financial and other costs (e.g., Site B</li> </ul>

<p>including investment, supply, and opportunity costs (N=47)</p>	<p>report that it was kind of like they really need to expand on their sites and like all of that was kind of part of the long-range plan. But for the first year 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</p>	<p>a huge difference in the success of the project.” CEO</p>	<p>engaged in many high cost activities like high staff turnover, tracking by hand, filling out forms</p> <ul style="list-style-type: none"> <li>· Site A had high cost of planning and training, which were absorbed later with success)</li> </ul>
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**Outer Setting**

<p><b>Patient needs and resources:</b> The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization (N=157)</p>	<p>“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</p> <p>“The culture of [this state] is a challenge, too, and to change or at least enlighten these people that have been smoking since the age of seven—changing that culture of ‘everybody smokes in my family’ to ‘gosh, I’m going to have cancer and I’m going to die...’ to just try to emphasize how important [quitting] is.” Pulmonologist</p>	<p>“We have some interesting dynamics in [this city] in general just by nature of the impoverished state in which our patient population lives. We have patients who don't want ‘cancer center’ coming up on their caller ID because they live with a daughter or someone and they're like, ‘Why are you going to a cancer center? You didn't tell me you had cancer!’ You know, freak out the whole family because you're getting calls from a cancer center.” Quality Improvement Officer</p> <p>“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 it's, you know, you can have a really great program but you have to understand the population that you're</p>	<ul style="list-style-type: none"> <li>· Both sites identified patient trust as a challenge</li> <li>· Transportation was a barrier at both sites</li> <li>· Smoking cessation was a challenging conversation at both sites; did not want to push patients away</li> <li>· Low levels of literacy at both sites and opportunity for patient misunderstanding and misinterpretation of results</li> </ul>
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		trying to reach.” Director	
<p><b>External Policies:</b> Broad constructs that encompass external strategies to spread interventions, including policy and regulations, external mandates, recommendations and guidelines, pay-for-performance, collaborative, and public or benchmark reporting (N=68)</p>	<p>“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</p>	<p>“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. And we do get them from outside the clinic from some of our [partner] physician practices, as well as some people just self-refer.” Screening Facility Director</p>	<ul style="list-style-type: none"> <li>Both are aware that CMS policies and reimbursement exist; recognizing that reimbursement triggered/initiated focus on lung cancer screening even before the intervention</li> </ul>
<b>Inner Setting</b>			
<p><b>Networks and Communication:</b> The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization (N=347)</p>	<p>“We’ve really developed the relationships over the last couple years, and I would venture to say [the FQHC] would be willing to call any of us at any time, and as well as us to them.” Hospital Nursing Manager</p> <p>“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</p>	<p>“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</p>	<ul style="list-style-type: none"> <li>Site B hospital leadership was not very engaged in FQHC communication and only engaged when needed (as problems arise); many steps to communicate basic information (papers get passed between multiple people before the patient has appointment)</li> <li>Site B key players like the hospital navigator did not feel like they had a say in whether or not to participate. The team at FQHC felt like the implementation process/decisions were dictated to them and they didn’t have say in how/what happened.</li> <li>When problems arose at Site A, they worked together to resolve them without blame.</li> </ul>

- Site B had very tense relationships.
- Site A had many people at routine meetings and representation from both the FQHC and the screening partner.

**Implementation Climate:** The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which that intervention will be supported within the organization (N=234); note sub-themes included

***Tension for Change***

“So that group kind of got together with our scheduling program and started the program because it was a big request from our referring doctors within the community, wanting to start a program.” Hospital Nurse Manager

***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

***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. This is a super cool opportunity. And there have been large university studies on this sort of thing. And I feel like one flaw to our research system is that almost all of the research is done in ivory towers. This is a real world opportunity to see how this impacts

***Tension for Change***

No examples available

***Compatibility***

“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

***Relative Priority***

“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... So that's one of the biggest barriers that I have really, as far as my role in the project. ...If I were clinical, I would probably spend two days a week at [one site] screening patients, not spend two days a week at [another site]

***Tension for Change***

- Pre-existing interest in lung screening prior to beginning the grant in Site A

***Compatibility***

- At both sites, lung screening referral programs were aligned with mission and patient centered; it was a good moral fit
- Site B was bad timing for implementation of a new, complex referral program (too many competing priorities)
- Site A had good timing for implementation. The screening facility was already beginning a screening program and no other major competing priorities

***Relative Priority***

- Site A prioritized ACR accreditation at a second screening site so they could reach more patients (forefront of lung screening)
- Site B had too many competing priorities and to many

people's lives that are basically living their everyday lives, rural America. Rural America doesn't get a lot of research love, for sure. I don't want to let the opportunity to follow this group of patients and their data go. I care very much about the patients but I feel like if this is going to be scalable, and a large portion of the country lives in rural settings, it's really important to figure out what happens." Project Lead

**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? ... That kind of thing. You walk through 'What do your regular patients do?' and then, 'How is it going to change after you do an LDCT through the program?'" Breathing Center Assistant

screening patients, and I come back here one day a week and consolidate them all on a list and keep it moving. That would be ideal, but it didn't work out that way." Referral Coordinator

**Goals and Feedback**

"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

other things to do during patient encounters

- Both sites created process to help gain/maintain buy-in and prioritization of screening program

- (approach to helping providers prioritize) Site A had a clear process in place to prioritize (implementation leaders worked out issue prior to rolling out to providers in order to improve buy-in)

- Site B process involved referral coordinators sending out daily reminder emails with names of eligible patients so the program would be top of mind for provider

**Goals and Feedback**

- Site A had no mention of inter-clinic or other competitors

- In Site B clinical staff at FQHC did not feel like goals were communicated to them and they didn't understand goals

**Readiness for Implementation:**

Tangible and immediate indicators of organizational commitment to its decision to implement an intervention, including leadership engagement, available resources, and access to

**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. If you don't have that, it's going to be very difficult, and it's like that with anything, not just lung. But the willingness for those physicians to

**Leadership Engagement**

"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

**Leadership Engagement**

- Site A FQHC and screening facility both thought carefully about who to involve in initial discussion to make sure the project got started on a good foot; they felt it was important for staff on all levels to be involved, to make sure everyone knew their job

information and knowledge (N=354); note: sub themes included

recognize the need of our community and want to help, you know. That has made a big impact.”  
Hospital Nurse Manager

real push or buy-in.”  
Screening Facility Director

- Site B was not engaged in process mapping and planning process

### ***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 generate in our quality measures tab, if they’re due or qualify for an LDCT.”  
FQHC Nurse Practitioner

### ***Available Resources***

“Right now, we don’t have the internal resources needed to be successful, based on how the project is going.” Quality Improvement Officer

- Site B leadership were unaware of details of project, out of the loop unless big issues arose; change of leadership meant uninterested and unaware of goals and purpose

### ***Access to Knowledge and Information***

“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

- Site A screening facilities had key buy-in and leadership from revered pulmonologist who helped make program successful

### ***Access to Knowledge and Information***

“Early on, we got a lot of referrals from people that just didn’t understand the criteria. They were sending symptomatic patients with weight loss and all kinds of other stuff and we were finding ‘Lung-RADS 18’ on the scans... So really understanding the referral guidelines is important. And to that effect, what we’ve done is we’ve made little 3 x 5 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

### ***Available Resources***

- Site B had limited buy in from staff necessary to complete project

- Site B FQHC felt they benefited from having a navigator, outreach coordinator, and QI team; major disadvantage was heavy staff turnover, especially in key stakeholders and leadership positions

- Site A involved support staff like imaging specialist, navigators, nurses across care continuum to make sure process was working smoothly

- Site A had customizable EMR to collect data

- Navigators played an important role at both sites

### ***Access to Knowledge and Information***

- Site B FQHC thought initial trainings by ACS were helpful, but they wanted to information about change management
- Site A felt initial trainings were high-level and shouldn't be taught by higher-ups from ACS, they should be taught by FQHC staff and local lung cancer specialists to gain buy-in
- Site A FQHC created provider prompts to remind doctors of eligibility criteria

### **Individual Characteristics**

#### **Role (N=388)**

"There are two navigators. There's an imaging navigator and then 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 when and all of that administrative mess that you need a very organized person for because she's the one that gets those initial results. She's the one that sends out and ... 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

- Both sites appointed someone to serve as a bridge between FQHC and screening facility
- At Site A project coordinator/respiratory therapist from FQHC was bridge; in Site B navigator and FQHC referral coordinator were bridges
- Important to work together across roles to make sure patient does not fall through the gaps; this involved a mixture of navigators, imaging specialists, nurses
- At both sites, dedicated staff were appointed to make sure patients had their questions answered, received correct care and follow-up, didn't miss appointments;

			<p>also had dedicated staff for training providers on how to provide correct care to patients</p> <ul style="list-style-type: none"> <li>· Neither site had written or defined roles;</li> <li>· Site A had clear roles and expectations (though not for leadership)</li> <li>· Site B no one had clear roles or expectations</li> </ul>
<b>Process</b>			
<p><b>Planning:</b> Degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods (N=135)</p>	<p>“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</p>	<p>“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, so how do we do it? Like are we trained? So how do we really do it? Like how could it look?” Primary Care Physician</p>	<ul style="list-style-type: none"> <li>· Site A used process maps and thinking through options for implementation prior to implementation can help facilitate likelihood of success</li> <li>· In Site B, the turnover rate at the site resulted in interference with planning</li> </ul>
<p><b>Reflecting and Evaluating:</b> Quantitative and qualitative feedback about the progress and quality of implementation accompanies with regular personal and team debriefing about progress and experience (N=109)</p>	<p>“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 and different things.” Nurse Manager</p>	<p>“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 since [ACS] has facilitated the meeting.” Outcomes Coordinator</p>	<ul style="list-style-type: none"> <li>· Site A had opportunities available to reflect and evaluate, with a formal approach to this process; saw it as an essential part of the program</li> <li>· Site B did not have built in opportunities to reflect and evaluate</li> </ul>

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [AllenCotter2020StariChecklist.docx](#)