CHAPTER 3 ------REQUIREMENTS AND BEST PRACTICES FOR SET-UP OF A LUNG CANCER SCREENING PROGRAM WITH PATIENT NAVIGATION

Objectives:

1) Understand the different types of LCS program organization structures and the role for patient navigation within each structure type.

2) Consider key questions and elements for helping set-up your own lung cancer screening program.

3) Explore how real-world screening programs have overcome barriers for successful lung cancer screening implementation.

Lung Cancer Screening Program Requirements

In Chapter 2 we introduced lung cancer screening as the below 5-step process for patient navigations (Figure 2-1). This same 5-step process, outlined in Figure 3-1, should also be considered when thinking about requirements and components of setting up a lung cancer screening program. It is important to remember that there is also continuous education and data tracking that takes place over the entire process.



Below are elements to consider for each step of the lung cancer screening process when setting up a new program or looking for ways to improve an existing program.

<u>Step 1: In-reach/ outreach</u>: Lung cancer screening programs should think about how they are going to find potentially eligible screening candidates and if and how they are going to advertise their program. Some items to think about to maximize in-reach and outreach for your program include:

<u>In-reach</u>: Think about whether your program will use the electronic health record to help find eligible patients. Know where cigarette smoking history is captured in your electronic health record, but also remember that this information is often inaccurate¹ and will need to be confirmed with the screening candidates. Other in-reach strategies that be used to help include potentially eligible patients include clinic lists of appointments for the day and asking clinic providers to help keep an eye out for candidates.

<u>Outreach:</u> Become familiar with resources and ways that you can let the greater healthcare organization and community know about lung cancer screening and your program. Remember that outreach provides a wonderful opportunity to educate everyone about lung cancer screening! Do you have someone in your organization you can work with the produce flyers or brochures? Does your organization host events or health fairs that you could set up a booth at? Do you have a community center you could work with to host an educational event?

<u>Step 2: Engagement and Eligibility</u>: Deciding exactly who your program should screen can be a complicated process because eligibility guidelines differ by payer source and Medicare beneficiaries require the additional components of shared decision-making and tobacco cessation for reimbursement sources. Additionally, Medicaid only covers lung cancer screening in some states and may require pre-authorization for reimbursement. To simplify the screening process for patient navigators and the overall program, your program can decide to follow the same process and eligibility guidelines for all patients that are screened.

Questions and information your program can consider for deciding whom to screen, include:

Will your program offer shared decision-making to all screening patients?

While a shared decision-making visit is a reimbursement requirement for Medicare, it is also strongly encouraged and recommended by the US Preventive Services Task Force for individuals with private insurance. To simplify the process of lung cancer screening within your organization consider if everyone will be scheduled for a shared decision-making visit.

Will your program offer a self-pay option for uninsured individuals?

Consider if your program will offer lung cancer screening for high-risk individuals that do not have insurance and whether a sliding scale for payment based on income will be used.

Will your program offer a self-pay option for high-risk individuals that do not meet recommended screening guidelines?

Consider if your program will offer lung cancer screening for high-risk individuals that meet Medicare and US Preventive Services Task Force guidelines and whether a sliding scale for payment based on income will be used.

Will your program screen individuals with Medicaid insurance?

Medicaid does not reimburse for lung cancer screening in all states. Per the American Lung Association, Medicaid covers the cost of screening for the states shaded in blue below (Figure 3-2).²

Figure 3-2. State Medicaid Coverage of Lung Cancer Screening

Medicaid Fee for Service Coverage of Lung Cancer Screening



Updated September 2020



- Is pre-authorization required for Medicaid coverage in your state?
- · Is a patient co-pay required for Medicaid coverage in your state?



Step 3: Shared Decision-Making and Tobacco Cessation: Recall that a shared decisionmaking visit and tobacco cessation (offering cessation counseling or resources for individuals that currently smoke cigarettes or positive reinforcement of abstinence for individuals that no longer smoke cigarettes) is required for Medicare reimbursement and also strongly recommended by the US Preventive Services Task Force for individuals with private insurance coverage. The purpose of the shared decisionmaking visit is to assess patient eligibility and to discuss the risks and benefits of screening. More details about these requirements are presented in Table 3-1.

Table 3-1

Eligibility Criteria	Fligibility Requirements based on Medicare Reimbursement Guidelines
Candidate Eligibility	 Age 55-77 (USPSTF recommends screening ages 50-80)* Currently smoke cigarettes or quit within past 15 years. ≥ 30 pack years (USPSTF recommends screening ≥ 20 pack years)* No signs or symptoms of lung cancer. USPSTF recommends that candidate not have co-morbid conditions that markedly limit life expectancy.
Shared Decision-Making (SDM) <i>SDM is required for</i> <i>Medicare</i> <i>reimbursement and</i> <i>strongly recommended</i> <i>by USPSTF.</i>	 Must be in-person by physician or qualified non-physician (physician's assistant, nurse practitioner, clinical nurse specialist). SDM visits have recently been allowable via telehealth options due to the COVID-19 pandemic. Use of a decision aid is required to include benefits/harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure. Counseling on importance of adherence to annual LDCT screening, impact of co-morbidities, and ability or willingness to undergo diagnosis and treatment. SDM needs to be documented in the patient's medical record and a written order is provided to the imaging facility.
Tobacco Cessation Tobacco cessation is required for Medicare reimbursement and strongly recommended by USPSTF	• Counseling on importance of maintaining smoking abstinence (if patient no longer smokes cigarettes) or smoking cessation (if patient currently smokes cigarettes), and, if appropriate, furnishing information on tobacco cessation interventions.

Shared Decision-Making: Medicare requires that the shared decision-making encounter is completed by a physician or qualified non-physician (physician assistant, nurse practitioner, or clinical nurse specialist) and should be completed with the use of a decision aid.³ If your organization will be setting up a lung cancer screening program at least one decision aid should be pre-selected that fits the flow of your clinic and preferences of the clinicians. There are many decision aids that are available for clinician use for lung cancer screening, including paper and electronic versions.

There is evidence that shared decision-making is time-consuming for clinicians and often not correctly.⁴ Proper shared decision- making is not taught in medical school, ⁵ but there are resources available for clinicians to learn how techniques to best involve lung cancer screening candidates in their decision about screening.



Find links to lung cancer screening decision aids and other helpful shared decision-making support in the resources section.



Visit the 'Checklist for Billing and Coding for Shared Decision-Making' tool to see all patient specific steps to bill for the shared decisionmaking visit.

Tobacco Cessation: Quitting smoking is the best thing a person can do to reduce their chances of developing lung cancer.⁶ Offering tobacco cessation services and resources in a vital part of lung cancer screening and is required for Medicare reimbursement. There are several types of tobacco cessation methods available (provide with resources such as a brochure, referral to a Quitline, referral to a certified tobacco treatment specialist, prescriptions for smoking cessation aids (gum, lozenge, Wellbutrin, Chantix)). Navigators should be familiar with tobacco cessation resources in their area and can help determine what kind of resources or referrals will be available for lung cancer screening participants. It is very important to remember that deciding to guit smoking is a very personal decision and if an individual decides they are not ready, the navigator or provider should not push or question their decision. Doing so may result in the patient losing trust in the provider, organization, and healthcare system.



Visit Chapter 5 to learn more about tobacco cessation in the context of lung cancer screening.



Go to the resources section to find links to nationally available tobacco cessation options.

Written order for the low dose CT procedure: After shared decision-making and a clinician has determined an individual is interested, eligible, and appropriate to screen a written order for the low-dose CT procedure must be furnished to the imaging facility. Written orders can be paper or electronic and what be sent to the imaging facility with the patient (paper), faxed, or shared electronically via the electronic health record. Ideally, written orders will contain all the information that is sourced from the ordering provider for submission to the Lung Cancer Screening Registry.

Step 4: Low-dose CT scan: When implementing a lung cancer screening program, it is important to remember that there are Medicare reimbursement criteria for the imaging center and the reading radiologist. These guidelines and recommendations, listed in Table 3-2, help standardize the lung cancer screening process and reduce risks associated with pulmonary nodule diagnosis and management.



See the 'American College of Radiology Lung Cancer Screening Registry Summary Tip Sheet' for more information about data that is collected by the ordering provider for the registry.



Go to Chapter 2 to learn more about how navigators can help with data collection for the registry and written order.

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See examples of written low-dose CT orders in the resources section.

Table 3-2

Eligibility Criteria	Eligibility Requirements based on Medicare Reimbursement Guidelines.
Screening facility eligibility	Accredited advanced diagnostic imaging center with training and experience in low-dose CT (LDCT) screening.
	• Use of LDCT with ≤3.0 mGy for standard size patients.
	• Use of standardized reporting with criteria for lung nodule identification and classification (e.g., Lung-RADs).
	Submission of data on all LDCT screening to a CMS-approved registry.
Radiologist eligibility	Current certification with American Board of Radiology (or equivalent).
	 Training in diagnostic radiology and radiation safety.
	• Supervision and interpretation of ≥300 chest CT scans in prior 3 years.
	Participation in CME as required by ACR.
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It is imperative to foster and maintain a good relationship with the imaging facility. Radiology centers are an integral part of the screening process and have a lot of requirements to follow to be reimbursed for completion of the CT scan and read. In addition to having to be accredited by ACR to perform the scan they must also submit data to the Lung Cancer Screening Registry for Medicare requirements. Elements collected by the Lung Cancer Screening Registry include both required and optional elements, with many of the required elements included in the written order. It is very important to work with the imaging facility to make the overall screening process work as best as possible.

A key element of working with a screening facility is to have a business agreement or Memorandum of Understanding (MOU) in place so that both parties know what is expected and required during the lung cancer screening process. Patient navigators may be able to help set-up these agreements. One of the biggest pieces of the process is the data that moves back and forth between the patient, the ordering provider, and the imaging facility. In addition to the written order that must be sent to the imaging facility, the results of the CT scan must also be sent back to the ordering provider and the patient. The flow of this information is an imperative piece to include in an MOU.

With all of this data moving back and forth it is a good idea for navigators to get to know who they are working with at imaging facilities or at other care facilities. Reach out to any imaging facilities you want to build a business relationship with for lung cancer screening referrals. This approach builds a sense of trust making it easier to solve problems in a straightforward and effective manner since everyone is working toward a common goal.

Step 5: Follow-up and Reporting: Once the low-dose CT procedure is complete, the results will be returned to the ordering provider. Next steps for each patient will depend on the CT results, recommended follow-up, and patient and provider preference. Lung cancer screening programs need a way to track next steps for their patients and know when referrals and reminders need to be made. Patient navigators can help think about the best way for their organization to track patients for follow-up. Consider if you have a tracking system from other cancer screening types (mammography, colonoscopy) that can be modified for lung cancer screening. Do you have a way to track patients via spreadsheet or in the electronic health record? Is a specific lung cancer screening software from an outside vendor feasible for your organization?

Another aspect of patient follow-up to consider is whether you need to set-up business relationships with pulmonary nodule management programs or multidisciplinary lung cancer tumor boards. These programs have expertise in lung nodule management and diagnosis, which is important if a lung cancer screening finds a nodule that is worrisome for cancer. Navigators should be aware of where their organization will refer screening patients that need follow-up on a lung cancer screening CT result.





Use the 'American College of Radiology Accredited Screening Center Detail Template' tool to help find lung cancer screening facilities in your area and items you should know about each screening facility.



Use the 'Imaging Partner Memorandum of Understanding Template' tool to build business relationships with imaging facilities in your area!

Visit Chapter 2 to learn more about the patient information and results that flows between the ordering provider and the imaging or screening facility. Use the 'Pulmonary Nodule Management & Multidisciplinary Tumor Board Referral Partner Detail Template' tool to think about considerations for referrals for pulmonary nodule management.

Link to the 'Lung Cancer Screening Evaluation Metrics' tool for a list of suggested evaluation metrics. Those highlighted in yellow are the minimum recommended elements.

Visit Chapter 2 to learn more about data collection and evaluation metrics.

Screening programs should also collect evaluation metrics to help understand the screened patient population, to verify that all aspects of the screening process are happening, and to check the outcomes of your program. Keeping track of these metrics will help pinpoint areas in your program that may need improvement and help the overall process and success of the screening program. Alternatively, good performance on guality metrics can maintain support of the screening program with personnel, providers, and administration. When setting up a lung cancer screening program consideration should be given to how, who, and what evaluation metrics will be collected. How often will data be summarized and shared with program personnel and administration?

Types of Lung Cancer Screening Program Structure

Lung cancer screening programs usually fit within one of three general categories: centralized, decentralized, or a hybrid structure.⁷ The structure of the program will depend on available resources, the type of institution and practice, and the skills and interests of the individual providers.⁷

Centralized programs:7

In a centralized lung cancer screening program, all activities are conducted by the program. This includes recruiting eligible patients, conducting shared decision-making, discussing and assisting with tobacco cessation counseling, scheduling the LDCT, reporting results to the patient and ordering provider, scheduling follow-ups, and tracking all evaluation metrics and outcome data. This model requires significant resources including a dedicated LCS coordinator, clinical leadership, and an integrated multidisciplinary program team. The screening process for program with a centralized structure is shown in figure 3-3.



Figure 3-3. Lung Cancer Screening Process for a Centralized Program Structure

Decentralized programs: 7

In a decentralized program, the program only performs the LDCT and interpretation. The primary care (ordering) provider is responsible for all other aspects of the screening process, as shown in Figure 3-4.

Figure 3-4. Lung Cancer Screening Process for a Decentralized Program Structure



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Hybrid programs: 7

Hybrid lung cancer screening programs use aspects of both centralized and decentralized programs. The most common type of hybrid program has decentralized CT ordering, meaning primary care providers identify interested and eligible candidates and refer them to a specialty clinic that centralize the remaining screening process (shared decision-making, tobacco cessation, referral for CT scan, and all follow-up). This set-up is shown in Figure 3-5.



Proposed Steps for Setting up Your Lung Cancer Screening Program

Setting up a lung cancer screening program, from conceptualization to implementation, can be a complicated process that requires multilevel support and resources. Below are some suggested steps and questions to think about for set-up of a lung cancer screening program. These steps are based on suggested clinical practice guidelines for implementation from the *American Thoracic Society* and the *American College of Chest Physicians* and are organized into three phases: planning, implementation, and maintenance.⁸

Complete a self-assessment using the 'Lung Cancer Screening Readiness Survey for Primary Care' tool to assess which phase of set-up your program or organization best fits with.





✓ If ratings on the self-assessment were mostly scores of 0 or 1 - yourprogram is in the <u>planning phase</u> of program set-up.

 \checkmark If ratings on the self-assessment were mostly scores of 2 or 3 – your program is in the <u>implementation</u> <u>phase</u> of program set-up.

✓ If ratings on the self-assessment were mostly scores of 4 or 5 – your program is in the <u>maintenance phase</u> of program set-up.



Go to the Resources section to find suggested shared decision-making and training resources available for providers.

Program Planning

• Establish your leadership team, including a clinical champion and a multidisciplinary steering committee, if applicable. Multidisciplinary steering committees are common in centralized screening programs with recommended involvement from pulmonary, primary care, radiology, thoracic surgery, interventional radiology, and medical and radiology oncology.⁸ This leadership team will act as liaisons within the healthcare organization and community to promote and champion the screening program.⁸

• Determine what type of screening program structure (centralized/ decentralized/ hybrid) works best for your organization and available resources.

• Engage primary care⁸ and find imaging and referral partners to set-up workflows and business relationships, helping to mitigate problems from the onset. This engagement may require providing educational opportunities and setting up business agreements or a Memorandum of Understanding.

• Develop a business plan, workplan and/ or workflow to leverage support of administration and other departments to establish a sustainable screening program.

Consider the following questions for how your lung cancer screening program will operate and how best to engage personnel and resources:

✓ Which patients will you screen? Does Medicaid cover the cost or screening in your state? Will your program offer a self-pay option for ineligible or uninsured individuals?

✓ How will you find eligible patients? (Electronic medical record / clinic lists/ etc.)

✓How and by whom will eligibility be confirmed?

- ✓Will shared decision-making be required for all screening participants?
- ✓ Who will perform shared decision-making? (PCPs/ mid-level provider)
- ✓ How will it be determined a person is appropriate and interested in being screened?

✓How will tobacco cessation be performed? What resources will be offered?

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\checkmark How will the written order and patient information be shared with the radiology dept/ facility?

- ✓How will results of the low dose CT be shared with the patient and provider?
- ✓Who will follow-up on screen detected anomalies and incidental findings?
- ✓Who will be responsible for management of screen detected anomalies and incidental findings?
- ✓Who will be responsible for patient tracking and data collection?
- Program costs to consider when planning a lung cancer screening program.⁸

✓ Personnel/ human effort for shared decision-making, tobacco cessation, to provide a point of contact for other clinicians, and to maintain contact with the patient throughout the screening process to confirm eligibility and ensure appropriate and timely follow-up.

✓ Equipment costs, such as the low dose CT scanner.

 \checkmark Information technology costs to develop and maintain a database of patients for follow-up and program metrics and integration of this database with the electronic medical record, if applicable.

 \checkmark Marketing costs associated with printing materials and advertising the screening program.

- ✓ Mailing costs for sending reminder and results letters.
- ✓Costs to provide tobacco cessation services, such as brochures or personnel training.
- \checkmark Costs associated with evaluation of screen detected pulmonary nodule or other incidental findings. These costs could include PET scanners or biopsy services.

To read more about costs associated with lung cancer screening program set-up see Table 4 in the American Thoracic Society/ American College of Chest Physicians joint policy statement about implementation.

www.ncbi.nlm.nih.gov/pmc/articles/PMC4613898/

Program Implementation

 Offer screening to the right people at the right time and have systems in place to find high-risk individuals and confirm screening eligibility.⁸ Additionally, there should be consideration given to offering education to ineligible patients and providers that refer ineligible providers about why lung cancer screening may not be the best choice for low-risk individuals or persons with competing comorbidities that limit life expectancy.8

· Consider details for effective shared decision-making to help patients and providers determine that screening is appropriate and patient preferences are being considered.8 Offer training or education to primary care providers conducting shared decisionmaking and have decision aids that are easily assessable in paper or electronic format.8



Use the 'Patient Eligibility

Checklist and Tips to

Smoking History' tool

for suggested questions

to ask during screening

eligibility assessment.

Collect an Accurate



Go to the Resources section to find suggested shared decision-making and training resources available for providers.



• Tobacco cessation needs to be integrated into the screening program to maximize health benefits and reduce mortality for screening candidates that currently smoke cigarettes.⁸ Programs should know who will provide tobacco cessation services and what local and national resources are available to support these cessation efforts.

• Standardize the low CT procedure and abnormal exam follow-up to ensure that lung cancer screening participants are receiving high quality care.⁸ Imaging centers or departments that offer lung cancer screening low dose CT services should meet the requirements set forth by the Centers for Medicare and Medicaid Services for radiation exposure and structured interpretation and management of pulmonary nodules (Lung-RADs) to help minimize patient harms. If a decentralized screening program does not have these systems in place they should seek out referral partners and develop business relationships with lung cancer screening programs accredited by the American College of Radiology and multi-disciplinary pulmonary nodule programs.

• Track and send reminders when patients are due for follow-up to maximize the efficacy of screening and ensure timely time to follow-up and diagnosis.⁸ Both patients that need shorter term follow-up for pulmonary nodules worrisome for cancer and those due for annual screening due to be tracking, scheduled, and reminded for appropriate follow-up. Not retaining these patients in the screening program jeopardizes the individual and population health benefits of screening and programs need a program in place to retain these individuals and remind them for follow-up and annual screening. Tracking of follow-up of incidental findings should also be done, if not being completed by the primary care provider. See examples of tracking tables for annual, Lung-RADs 3, Lung-RADs 4, and incidental finding follow-up in the 'Individual Follow-up Tables' tool.

Program Maintenance

• Ongoing collection of program metrics is imperative to help pinpoint areas in your program that may need improvement and help the overall process and success of the screening program.⁸

> Link to the 'Lung Cancer Screening Evaluation Metrics' tool for a list of suggested evaluation metrics. Those highlighted in yellow are the minimum recommended elements.





Visit the Resources section to find nationally available tobacco cessation services.

See the 'Tip Sheet for Lung Cancer

Use the 'American College of Radiology Accredited Screening Center Detail Template' and the 'Pulmonary Nodule Management & Multidisciplinary Tumor Board Referral Partner Detail Template' tools for items to consider when selecting referral partners.



Barriers and facilitators of real-world lung cancer screening program implementation

Community hospitals and organizations that adopted lung cancer screening early offer insight into barriers and facilitators encountered during lung cancer screening implementation. Lessons learned from lung cancer screening programs centered in safety net healthcare systems are highlighted below, and additional detail provided in the case studies found in the toolkit resources section. Figure 3-6 emphasizes implementation facilitators (highlighted in green boxes) and barriers (highlighted in red boxes) along the entire lung cancer screening process.



Figure 3-6. Facilitators (green) and barriers (red) across the lung cancer screening process

Overview of cases studies by phase of program set-up – find the case study in the resources section Planning phase – Case Study 1

A rural, stand-alone safety net hospital not formally connected to a lung cancer screening imaging center found that prioritizing acute care over preventive cancer screenings, facing low numbers of eligible candidates, and tracking screened patients without use of a shared electronic medical record were difficult barriers for successful lung cancer screening implementation.

Implementation phase – Case Study 2

An urban primary care system with a formal relationship with an established lung cancer screening program found keys to adopting screening included working with the specialty program to confirm eligibility, having engaged providers to perform shared decision-making, and having a shared electronic medical record to transfer results and patient information.

Maintenance phase – Case Study 3

Within a statewide cancer program safety net community, a common theme found after implementation of lung cancer screening is that tracking and follow-up is vital to ensure patients attend appointments and are rescheduled if the appointment is missed. Central components of tracking include dedicated workflows and navigation practices.

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