CHAPTER 1 -----

Objective:

Understand the need, evidence, requirements, process, risks, benefits, cost, and outcomes of lung cancer screening to consider the need for patient navigation within your healthcare clinic or system.

Overview of lung cancer

Lung cancer is the leading cause of cancer death for both men and women in the United States, killing more people than breast, colon, and prostate cancers combined¹. There are two main types of lung cancer, small cell and non-small cell². Small cell lung cancer accounts for ~15% of all lung cancer cases and is typically more aggressive and faster growing². The remaining 85% of cases are non-small cell lung cancer². Lung cancer is usually diagnosed at advanced stages. 5-year survival of advanced lung cancer is less than 10%, with 5-year survival of early-stage lung cancer exceeding 55%³. The problem is that currently only 17% of patients are diagnosed with early stage disease³. Early detection is critical to reducing lung cancer specific mortality. Lung cancer screening with low dose CT is the only recommended test that finds lung cancer at an early stage when curative treatment options exist.

Evidence for lung cancer screening

1) <u>Lung cancer specific mortality reduction</u>: Screening efficacy has been described in several large trials, including a 20% relative reduction in lung cancer specific mortality in the landmark National Lung Screening Trial (NLST),⁴ and a 25% reduction (for men) in the Dutch-Belgian Lung Cancer Screening (NELSON) trial.⁵ Adherence to annual screening in these two large clinical trials exceeded 90%, directly contributing to lung cancer mortality reductions, with 58% and 73% of stage I lung cancers detected on annual imaging in the NLST and NELSON trials, respectively.^{4,5}

<u>2) Early detection of lung cancer</u>: Overall, 50% of all CT detected lung cancers diagnosed in the NLST were stage I.⁴ Similar rates of early lung cancer diagnoses were observed in the Nelson trial, with 59% of CT detected cancers reported as stage I.⁵ High rates of stage



Find out more about types of lung cancers and staging of lung cancer from the American Cancer Society!

www.cancer.org/cancer/lung-cancer/ detection-diagnosis-staging.html



Check your knowledge about lung cancer types and staging in the patient navigation online training.

I lung cancer diagnosis rates have also been reported outside of clinical trial settings, community healthcare systems and clinics have also reported stage I diagnosis rates of at least 63%.^{6,7}

<u>3) Initial low uptake of lung cancer screening</u>: As a new cancer screening modality, initial uptake of lung cancer screening has been low with only 2-16% of eligible individuals currently receiving screening.⁸⁻¹² While low uptake can be linked to barriers at the patient, provider, and system level, there is a general lack of awareness about lung cancer screening in the medical and lay communities.¹³ Continued education about screening is vital, so that one day low-dose CT screening will be as commonly known as mammography and colonoscopy for breast and colon cancer screenings.

<u>4) Lung cancer screening disparities</u>: Individuals that smoke tobacco, and are also potentially eligible for lung cancer screening, are likely to already face health disparities.¹⁴ This includes racial and ethnic minorities, sexual and gender minorities, individuals with low-socioeconomic status, and individuals that live in rural areas of the country.¹⁴ These populations also face increased lung cancer incidence and mortality with longer time to diagnosis and treatment.¹⁵ Anyone that works within a lung cancer screening program can help reduce these lung cancer disparities by thinking how best to reach these populations and educate them about lung cancer screening.

5) Patient navigation in lung cancer screening: Patient navigation has increased screening rates in a wide range of racial and ethnic groups in colon, breast, and cervical cancer screenings with both nurse navigators and lay navigators.¹⁶ Moreover, patient navigation has successfully reduced cancer rates by eliminating barriers for vulnerable populations¹⁷ and has recently been identified as a method to reduce disparities in lung cancer screening.¹⁵ The United States Preventive



Use this information to talk with your healthcare organization about implementing lung cancer screening using the 'Lung Cancer Screening Evidence Summary' tool.

Services Task Force recommends several strategies to increase screening rates for breast, colon, and cervical cancers that can also be easily used for lung cancer screening (patient reminders, patient education, barrier reduction, small media, and provider reminders).¹⁸ Lung cancer screening programs can greatly benefit from the use of patient navigation to both optimize the screening process and improve patient outcomes with increased screening and **reduced** mortality rates!

Overview of lung cancer screening requirements and process

The goal of lung cancer screening is to find and diagnose early-stage disease before signs and symptoms occur. However, there are several elements of lung cancer screening that are different from other cancer screenings.

Lung cancer screening should be thought of as a process that requires several steps not required for other types of cancer screenings. Table 1-1 gives a broad overview of important elements to know and consider for high-quality lung cancer screening.

Screening Steps & Process	Important Elements and Considerations			
Determining Candidate Eligibility Screening of eligible individuals is extremely important to maximize the efficacy of lung cancer screening.	 In general, private insurance companies follow guideline recommendations from the US Preventive Services Task Force and Medicare beneficiaries follow the guidelines established from the Centers for Medicare and Medicaid Services. Lung cancer screening is also covered for Medicaid beneficiaries in some states. Finding potentially eligible screening candidates can be difficult because smoking history is not often accurate in the electronic medical record. 			
Shared Decision-Making (SDM) Counseling visit between the screening candidate and ordering provider to determine screening eligibility and discuss the risks and benefits of screening.	 Required by Medicare for reimbursement purposes and strongly recommended by the US Preventive Services Task Force. Must be completed prior to the low-dose CT procedure. Must be completed by a clinician (MD or advanced practice provider). Must utilize a decision aid to address risks and benefits. Completion of SDM visit must be recorded in the medical record. Historically, SDM was required to take place in-person, but telehealth options have recently been allowable due to the COVID-19 pandemic. 			
Tobacco Cessation Services Cessation services must be offered to all individuals that currently smoke cigarettes. Positive reinforcement of behavior for individuals that formerly smoke cigarettes should also be considered.	 Required by Medicare for reimbursement purposes and strongly recommended by the US Preventive Services Task Force. Must be completed prior to the low-dose CT procedure. Cessation services may include quitline referrals, referrals to tobacco treatment specialists, providing fact sheets and brochures, or prescriptions for cessation aids (Chantix, Wellbutrin, nicotine replacement, etc.). 			
The low-dose CT scan Individual and imaging information flows back and forth between the ordering provider and the imaging center to facilitate the screening process. Ensuring proper flow and completion of this information will help the screening process run smoothly	 Requires a written order documenting the patient's eligibility and confirming completion of shared decision-making and tobacco cessation. Recommended CT scan is completed at a screening facility accredited by the American College of Radiology that utilizes appropriate radiology dose recommendations and has trained thoracic radiologists for scan interpretation. The results should be read utilizing Lung-RADs (a standardized lung nodule identification, classification and reporting system) to report the low dose CT results and provides suggested follow-up guidelines. 			

Table 1-1. Overview of Lung Cancer Screening Process and Elements

Reporting and Follow-up Data collection can be time consuming but can lead to improved program processes and outcomes through continuous quality improvement.

- Information about all screening participants and CT, regardless of insurance payer, must be submitted to the American College of Radiology Lung Cancer Screening Registry to enable providers to meet quality reporting requirements. Transmitting information to the registry is often completed by the imaging center.
- Next steps following the low dose CT will depend on the results of the screening low dose CT scan. Tracking and sending follow-up reminders will ensure timely follow-up and decrease time to possible diagnosis or treatment.
- Screening programs should collect additional evaluation metrics (e.g. determination of eligible candidates, characteristics of screened patients, screening process and outcomes) to help understand who your program is screening and track important outcome metrics.



Other important lung cancer screening elements to remember and consider:

✓ Lung cancer screening is recommended on an <u>annual</u> basis. Adherence to the recommended follow-up is imperative to reach the maximum benefit of lung cancer screening at the individual and population level.

✓ Eligibility is based on a life-style choice that is heavily associated with the stigma of smoking. Patient navigators should focus on normalizing lung cancer screening as a way to maintain optimal health for those eligible and adopting person-first language when discussing lung cancer screening. For example, referring to people as 'a smoker' is stigmatizing language, instead say 'someone that smokes cigarettes.'

✓ It is important to confirm insurance coverage and eligibility prior to scheduling a shared decision-making or CT appointment, some may require pre-authorization.

✓ Become familiar with the imaging centers accredited by the American College of Radiology for lung cancer screening in your area. Know which ones offer extended or weekend hours!

See the 'Lung Cancer Screening Initial Outreach Tip Sheet' tool to learn more about person-first language and tips on how to reduce the stigma of cigarette smoking.



Learn more about the screening process and associated navigator duties in Chapter 2.

Lung cancer screening eligibility

Lung cancer screening is recommended on an annual basis by the US Preventive Services Task Force (USPSTF)¹⁹ and the Centers for Medicare and Medicaid Services.²⁰ These recommendations mean that screening is covered as a preventive service by commercial insurance companies, Medicare, and Medicaid (in some states).

Eligibility for lung cancer screening varies slightly between USPSTF and Medicare guidelines and is based on age, smoking status, and smoking history. The National Comprehensive Cancer Network (NCCN) also has recommendations for screening based on smoking history and other factors that can make an individual high risk for developing lung cancer.²¹ Table 1-2 presents the differences in eligibility for USPSTF, Medicare, and the National Comprehensive Cancer Network. In addition to basic eligibility requirements, there are other patient and clinical characteristics that patients and navigators should consider about being screened:

• Individuals showing signs of lung cancer (coughing up blood, unexplained weight loss, cough that won't go away) should not have a screening CT, but rather meet with a clinician to go over symptoms and possibly be referred for a diagnostic CT.

• Individuals with limited life expectancy due to other comorbid conditions or those that are poor surgical candidates should be screened with caution. Eligibility should be reviewed by a clinician.

• Individuals that are not willing to be treated should a lung cancer be found are unlikely to benefit from screening.

• Individuals that had a chest CT for another diagnostic reason in the past year should wait until a full year has passed before having a CT for lung cancer screening.

Read more about lung cancer screening eligibility guidelines for Medicare, USPSTF, and NCCN

• Medicare - <u>https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.</u> <u>aspx?NCAId=274</u>

 USPSTF - <u>https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-</u> screening

NCCN category 2 - https://www.nccn.org/patients/guidelines/content/PDF/lung_screening-patient.pdf

		Madiaana ²⁰	NOON Oata name 021
	USP51F"	Medicare	NCCN Category 2-
Age	50-80*	55-77	≥ 50
Smoking history	≥ 20 pack years*	≥ 30 pack years	≥20 pack years
Smoking status	Current or quit within	Current or quit within past	N/A
	past 15 years	15 years	
Additional criteria	 No signs or symptoms of lung cancer. 		 Radon or asbestos exposure
	 Patients with comorbiditi 	 COPD/ emphysema 	
	should be screened with	 Personal history of cancer 	
	 Willing to be treated if cancer is found. 		 Family history of lung cancer

Table 1-2 Lung Cancer Screening Eligibility Guidelines forUSPSTF, Medicare, and NCCN Category 2

*USPSTF expanded screening guidelines on March 9, 2021, lowering eligibility to 50 years of age and tobacco exposure to 20 pack years. Private insurance payers have until January 1, 2023 to adopt and cover the expanded guidelines but may voluntarily do so before that date. You may need to check with each private payer to verify if they are currently covering the expanded guidelines.



Find and determine potential eligible individuals from case studies in the companion navigator training.

When to stop screening for lung cancer?

The US Preventive Services Task Force recommends that individuals stop being screened when:

- They reach >80 years of age;
- They have quit smoking cigarettes >15 years ago;
- They develop a comorbid condition that limits life expectancy or the ability to have lung surgery.

A note about risk-based screening

Another method of selecting high-risk individuals for lung cancer screening is with the use of risk calculators that estimate an individual's risk of developing lung cancer over a prespecified time period. These risk calculators consider variables that heighten someone's risk of developing lung cancer, such as cigarette smoking, family history of lung cancer, personal history of COPD/ emphysema/ chronic bronchitis, and exposure to cancer causing agents such as radon and asbestos. Using risk calculators to determine lung cancer screening eligibility is not currently covered by insurance companies but is thought to efficiently select individuals for screening. Clinicians may also use risk calculators, such as the PLCO_{m2012} model²² available at www.shouldiscreen.com, to talk with individuals about the risks and benefits of screening.

Read more about using risk-based screening for participant selection: https://www.acpjournals.org/doi/abs/10.7326/M17-2701?journalCode=aim Explore lung cancer risk calculators here: http://lungcancerrisk.s3-website-us-east-1.amazonaws.com/

The Low Dose CT Procedure

Lung cancer screening is completed using a low-dose computed tomography (CT) scan. A CT scan is a series of x-rays that are taken from different angles and reconstructed by a computer to give a detailed look at bones, blood vessels, and soft tissues, such as heart and other organs in the chest region. The patient will be asked to lay on their back on table that will slide the patient into the CT scanner feet first.²³

The good news is that the low dose CT procedure requires no special or additional preparation. The patient simply needs to arrive at the right place at the right time. He/she will be asked to remove all metal from their body such as jewelry or belts. For women, you may want to instruct them to wear a bra without any underwire. Depending on the facility and what the person is wearing he/she may be asked to change into a gown.²³ The entire process should only take about 5 minutes!

The low dose CT Procedure vs Indication for Annual Lung Cancer Screening

A low dose CT refers to the technique of the CT procedure, meaning that the CT is performed with a low dose of radiation. Many CT procedures, including some diagnostic CTs, are performed as low-dose to minimize the amount of radiation a patient is receiving.

You may encounter a screening participant that is due for a yearly lung cancer screening as being due for an annual low dose CT. Remember that the low dose CT is the technique used for the CT scan, it is not meant to represent the indication or reason for the procedure (annual lung cancer screening.)

Benefits and Risks of Lung Cancer Screening

Benefits of lung cancer screening include:

- Lung cancer screening is the only proven way to detect cancer at an early stage!²⁴
- By finding more cancers at an early stage we can decrease the number of deaths caused by lung cancer!²⁴

Figure 1-1 shows the incidence rates of lung and bronchus (per 100,000 population) by state.

Figure 1-1. Incidence rates of lung and bronchus cancer by state.

Incidence rates, 2013-2017

by state, for lung and bronchus

Average annual rate per 100,000, age adjusted to the 2000 US standard population.



Data Sources: North American Association of Central Cancer Registries (NAACCR), 2020 © 2021 America Cancer Society

CancerStatisticsCenter.cancer.org

Visit the American Cancer Society's lung and bronchus cancer webpage to find specific lung cancer incidence and death rates for your state.

cancerstatisticscenter.cancer.org/#!/cancer-site/Lung%20and%20bronchus

Like any screening test, there are some risks associated with lung cancer screening:

• Lung cancer screening can result in false positives or false alarms, meaning a pulmonary nodule will be found but it will not be known if the spot is cancerous without further testing. The ordering provider may need to order additional tests to figure out if the spot is cancerous²⁴. Additional tests may include:

- More CT scans
- A PET scan
- A biopsy to take a small tissue sample of the spot.
- $_{\odot}$ $\,$ In some cases, surgery to remove the nodule may also be necessary.

• There is a possibility that lung cancer screening will detect a cancer that is very slow growing and would not have caused any problems for the patient in their lifetime. This is called overdiagnosis, meaning that this type of cancer may lead to unnecessary testing, treatment or surgery. The harms from overdiagnosis can be mitigated through proper monitoring of the suspicious area and following established radiology guidelines (Lung-RADs).^{24, 25}

• The patient will receive a small dose of radiation from the low dose CT. Exposure to low levels of radiation, such as environmental exposures, does not cause any immediate health risks but contributes slightly to one's overall cancer risk. The dose of radiation a person receives from a low dose CT scan is about the same amount receiving from the environment over one year.²⁵

• Stress and psychological distress - As with any type of medical screening, stress and distress can occur. Fear and anxiety can come from the screening process itself, anticipation of results, or when learning of a positive screen. It is essential to talk to and educate the patient about potential screening results and listen to their concerns before moving forward.²⁴



The cost of lung cancer screening

Cost of screening for the candidate/ patient

Lung cancer screening is a reimbursable preventive service for patients that meet eligibility guidelines and have commercial (private) insurance and Medicare. Medicaid also provides coverage in some states and requires preauthorization. Screening is a preventive service under



Visit Chapter 3 to read more about Medicaid coverage of lung cancer screening and determining if your screening program should offer a self-pay coverage option.

the Affordable Healthcare Act and patients that meet eligibility criteria should not have associated co-pays. You should always verify insurance coverage for screening candidates prior to scheduling them for shared decision-making or a low-dose CT. Your screening program may also decide to offer a self-pay option for individuals that do not have insurance or would like to be screened but do not meeting current eligibility criteria.

It is also important to remember that reimbursement of screening as a preventive service only covers the cost of the shared-decision making and low-dose CT scan. If there is additional recommended follow-up the cost of these procedures will be billed to insurance coverage.

Billing for Lung Cancer Screening Services

Reimbursement is available for two aspects of lung cancer screening: 1) Shared Decision-Making (for Medicare beneficiaries) and 2) the low-dose CT.

To bill for lung cancer screening services the following codes must be used (information from the American College of Radiology)²⁶:

• G0296 — Counseling visit to discuss need for lung cancer screening using low-dose CT scan (service is for eligibility determination and shared decision making)

• 71271— Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s). *Prior to January 2021, the billing code for the low dose CT was G0297. The old code should no longer be used.*

These services must also be billed with a nicotine dependence ICD-10 diagnosis code. Medicare will deny G0296 and 71271 for claims that do not contain these ICD-10 diagnosis codes:

- Z87.891 for individuals who formerly smoke cigarettes (personal history of nicotine dependence).
- F17.21 for individuals who currently smoke cigarettes (nicotine dependence).



Visit the American College of Radiology website for more information about insurance coverage and billing for lung cancer screening services.

www.acr.org/Clinical-Resources/Lung-Cancer-Screening-Resources/FAQ

See the 'Checklist for Billing and Coding for Shared Decision-Making Visit' tool for an individual level perspective of coding requirements for shared decision-making.

Screening outcomes and follow-up

Results for lung cancer screening low dose CT scans are reported using the Lung Imaging Reporting and Data System (Lung-RADs). Lung-RADs is a structured reporting system that contains information on technique, comparison date, description of findings, impression, Lung-RADS category and specific management recommendations.



Explore more about Lung-RADs here:

www.acr.org/-/media/ACR/Files/RADS/ Lung-RADS/LungRADSAssessment Categoriesv1-1.pdf

Overview of Lung-RADS scoring

The Lung-RADS assessment category for each lung cancer screening examination is an alphanumeric score composed of two parts: category (part 1) plus modifier (part 2). Part 1 classifies nodules into categories 0–4 on the basis of morphology and size. Part 2 addresses findings other than lung nodules and uses the modifiers X, C, and S. Results of Lung-RADs 1 or 2 are considered a negative result and a result of Lung-RADs 3 or 4 is a positive result and additional follow-up is recommended.

In general, a Lung-RADs result of 1 or 2 is considered a negative screen with recommended follow-up in one year for annual screening. A Lung-RADs result of is considered a positive screening for a lung cancer that needs shorter-term follow-up to watch the nodule for growth or change or to biopsy if the health care team thinks it is necessary.

Care pathways are examples of follow-up based on pulmonary nodule management algorithms defined by the Lung-RADs results. Exact recommendations for individual patients will be listed on the screening CT radiology report. Table 1.3 gives an overview of each Lung-RADs category with description, probability or malignancy and recommended follow-up.

		Probability of	Recommended Follow-
Category	Description	Malignancy	up
0	Incomplete	N/A	N/A
1	Negative	<1%	12-month annual screening low dose CT
2	Benign appearance or behavior	<1%	12-month annual screening low dose CT
3	Probably benign	1-2%	6-month follow-up diagnosis low dose CT
4A		5-15%	Short term diagnostic
4B	Suspicious	>15%	CT, PET/ CT, or tissue sampling
S	Clinically significant finding that requires additional follow-up	N/A	Per clinical protocols/ guidelines
С	Prior lung cancer	N/A	N/A

Table 1-3 Overview of Lung-RADs Categories

A note about nodule care pathways.

Exact follow-up of positive screens (those with a result of Lung-RADs 3 or 4) is a complex decision of nodule location, clinician recommendation, and patient preference. Scenarios presented here are examples of possible diagnostic follow-up based on radiologist recommendations.

When is it no longer screening?

Once a patient is diagnosed with lung cancer, further diagnostic management is often necessary (including additional imaging such as PET/ CT) for the purposes of lung cancer staging. These additional diagnostic procedures are no longer elements of screening.

Estimates of Lung-RAD results by population prevalence

The prevalence of Lung-RADs 1 and 2 result distribution may differ between areas in the country that have endemic fungal infections, commonly aspergillus, histoplasmosis, coccidiomycosis, and cryptococcosis.²⁷ Fungal infections can cause small pulmonary nodules, resulting in a higher distribution of Lung-RAD 1 (no nodules) results in areas without endemic fungal infections and a higher distribution of Lung-RADs 2 (small nodules not concerning for cancer) results in areas with endemic fungal infections. This difference is illustrated in Figure 1-2, comparing results from the University of Colorado, ²⁸ where endemic fungus is not a big concern and from Cleveland Clinic,²⁹ and area of the United States with endemic fungus.



Incidental findings and significant incidental findings

An incidental finding is an abnormality that is found and is unrelated to the purpose of the scan. When a low dose CT is completed and viewed by the radiologist much more than lung cancer can be found. In a CT scan of the chest the lungs, heart, liver, breast tissue, thyroid, pancreas, gall bladder, spleen. intestines, and spinal column can all be seen and will be looked over by the radiologist. Though the focus is on the lungs, all areas will be checked and any abnormalities will be reported.



This is very common with lung cancer screening. In fact up to 50% will have an incidental finding.²⁹ It will be important for the provider to go over these findings and, if necessary, make additional referrals.

Common incidental findings include:29

- o Emphysema
- o Bronchial wall thickening
- Coronary Artery Disease
- Congestive Heart Failure
- Adrenal nodules
- Thyroid nodules
- o Degenerative Joint Disease
- o Hiatal hernia
- o Liver disease
- \circ Renal issues

Significant incidental (S) findings are incidental findings for which further medical evaluation is recommended. The American College of Radiology Lung Cancer Screening Registry collects information on the following S findings:

- Aortic aneurysm
- Coronary arterial calcification moderate or severe
- Pulmonary fibrosis
- Mass, please specify, e.g., neck, mediastinum, liver, kidneys, other
- Other interstitial lung disease, specify type if known

Management of incidental findings

Discovery of incidental findings should be reported to the primary care provider or referring physician so they can be evaluated as indicated by following existing guidelines. Much like a positive screening result, exact management and evaluation of an IF will depend on clinician recommendation and patient preference. The screening radiology report may offer recommendations on the management of the incidental finding as well.

Navigation Key Points

The most common incidental findings are pulmonary related and coronary arterial calcification, both present in up to 50% of screened patients.

All incidental findings should be reported to the patient's primary or referring physician so a care plan can be established if needed.

It is important to collect and track information on the rate and type of each incidental finding.

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