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The Blueprint to Transform a Lung Cancer Screening Program

Developed by the End Lung Cancer Now Lung Cancer Screening Taskforce

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Dedication

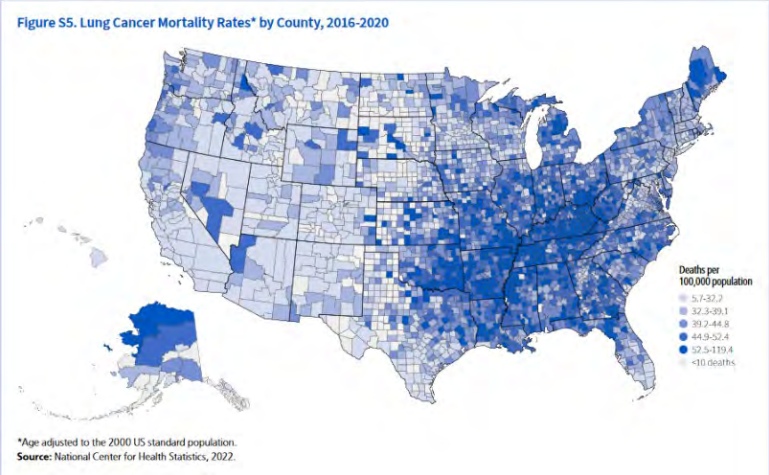
We dedicate this blueprint to the thousands of Hoosiers who have died from or have been impacted by lung cancer. As those who have borne witness to the needless and preventable suffering and death from lung cancer, it is our duty to act and transform lung cancer screening in Indiana. The transformational change for lung cancer screenings outlined in this document can save thousands of Hoosiers lives in the future. Lung cancer remains the number one cause of cancer-related death in Indiana, yet it wasn't that long ago that it was a rare cause of suffering and death. End Lung Cancer Now (ELCN), an initiative of the Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IU Simon Comprehensive Cancer Center), is committed to making it rare again.

ELCN's vision is to end the suffering and death from lung cancer in Indiana. To do this, our mission is to educate and empower community advocates to help eliminate tobacco use in Indiana, screen all eligible Hoosiers with lung cancer screening scans, increase participation in lung cancer research, and support lung cancer survivors and their caregivers. The values that drive this effort are accountability, inclusivity, integrity, partnership, passion, and a promise to patients.

Contents

Overview

Indiana is in the eye of the lung cancer storm.



According to the American Lung Association (ALA) State of Lung Cancer 2023 report, Indiana's smoking rate is below-average at 17.3%, higher than the national average of 13.5%. Indiana is also below-average for radon levels, with 40.2% of radon tests at or above the recommended level from the Environmental Protection Agency (EPA). Additionally, only 5.1% of Hoosiers who are eligible for lung cancer screenings participate in a lung cancer screening program. This is significantly lower than the screening rates for breast (74%), cervical (76%), and colorectal (71%) cancer in Indiana.[2] Despite national recommendations for lung cancer screening and CMS coverage, screening rates remain low due to a lack of public awareness and a scarcity of exemplary lung cancer screening programs in the United States.

Lung cancer remains the number one cause of cancer-related death in Hoosiers. By far. It kills more Hoosiers than colon, breast, and prostate cancers combined each year. In fact, 24% of all cancer-related deaths are attributable to lung cancer in Indiana.[1] This is true for men and true for women. This is true for Black Hoosiers, white Hoosiers, and Latinx Hoosiers. This is true for Hoosiers who live in urban areas and true for rural Hoosiers.

Just decades ago, the tobacco epidemic raged out of control. There was no effective screening for lung cancer. There were few effective treatments. There was a significant lack of research funding. There were high levels of stigma, shame, and guilt. **But the tide has turned.** Tobacco use is rapidly declining. The United States Preventative Services Task Force (USPSTF) published guidance and recommendations for lung cancer screenings in high-risk populations. There are far more effective therapeutic treatments now available due to advances in research. Education and awareness about lung cancer is slowly reducing the stigma and shame for survivors and their loved ones. **We've made progress, but it is not enough.**

In 2018, approximately 11% of adults aged 55-80 years were eligible for annual lung cancer screening in Indiana, which equates to more than 110,000 individuals.[31] The facts are simple. **One in seven** Hoosiers who are eligible for lung cancer screening **will get lung cancer**. If they participate in a lung cancer screening program, their life is likely to be saved. If they don't, they will likely be diagnosed with advanced disease and die within months to years. Currently, 66% of all lung cancers are diagnosed at advanced stages, and only 7% of these patients will survive 5 years after their diagnosis.[2] **However, there is hope**. When lung cancer is caught in the earliest stage, the 5-year survival is more than 80%.[2,3] **Lung cancer screening saves lives.**

Executive Summary

End Lung Cancer Now (ELCN), an initiative of the IU Simon Comprehensive Cancer Center, formed a multidisciplinary Lung Cancer Screening Taskforce that launched in March 2023 to develop the blueprint to **transform, scale, and centralize the lung cancer screening program** (LCSP) The ELCN Lung Cancer Screening Taskforce met over a six-month period to study and analyze the current LCSP to identify high-impact improvements that should be implemented, both short-term and long-term.

This blueprint is a compilation of the recommendations from the ELCN Lung Cancer Screening Taskforce and encompasses the characteristics of what an ideal and comprehensive LCSP should have. A high-level overview of each recommendation is included on the next page. Each recommendation is linked to the section of the report that provides the full details.

Overview of Recommendations

1. **Centralized structure with unified oversight** – It is recommended to implement a completely centralized LCSP with unified oversight of all screening sites. A centralized structure would lend itself to optimal care coordination, improved adherence rates of patients in the program, and remove unnecessary burden from referring providers. Please see Section 2.1 Program structure and workflow for more details.
2. **Adequate resource allocation** – Implementing a centralized structure will require additional resources and positions for the LCSP. A coordinated, centralized care team, including a chief of cancer screenings, LCSP deputy directors, APP leaders, nurse navigators and administrative support, with committed time and financial compensation is essential to success. See Section 2.2 Screening capacity and resources for more details.
3. **Update the electronic medical record (EMR) to identify eligible patients, notify healthcare professionals and patients, and automate reminders –** It is essential to ensure that the EMR system accurately captures required data points to effectively identify eligible patients and provide appropriate alerts and reminders to both healthcare professionals and patients. See Section 2.1 Program structure and workflow for more details.
4. **Improved shared decision making (SDM) and comprehensive tobacco treatment** - The SDM conversation is a required and integral piece of a LCSP. The SDM should be standardized and streamlined and should be integrated with a comprehensive tobacco treatment program. Intensive interventions such as multiple counselling sessions with or without pharmacological therapies might be most effective. See Section 2.3 Shared decision making and Section 2.4 Tobacco treatment for more details.
5. **Improved lung nodule management and multidisciplinary discussion** – In addition to continuing to use the Lung-RADS standardized reporting system, a multidisciplinary Lung Screening Review Board is essential to improve patient care and outcomes through collaborative discussion re: concerning findings. Representation from pulmonology, thoracic surgery, lung cancer screening navigation, and medical oncology is essential for success of this review board. See Section 2.5 Lung nodule management for more details.
6. **Tracking of quality metrics** –Quality metrics related to referral patterns, additional work-up, procedures, tobacco treatment services, etc. should be tracked to identify gaps, educational opportunities, and future improvements. The metrics can also be used to demonstrate the return on investment (ROI) as the LCSP continues to grow. Additionally, it is recommended that lung cancer screening becomes a quality metric to assess overall performance and effectiveness of healthcare professionals. See Section 2.6 structured reporting and quality management and Section 2.8 Patient and healthcare professional education for more details.

7. **Establish a mixed payer model** – Establishing a more balanced payer mix is essential to enhance accessibility for Hoosiers and improve long-term sustainability. A mechanism should be established to cover the cost of screenings, without cost-sharing to the patient, for those who are uninsured and cannot afford self-pay. This underscores the importance of philanthropic efforts to support this initiative. See Section 2.7 Program payer mix for more details.
8. **Comprehensive lung screening education for healthcare professionals and patients** – Adequate patient and healthcare professional education is pivotal to increase the rate of eligible Hoosiers who participate in a LCSP. Education and awareness must address the stigma and futility towards a lung cancer diagnosis. Multiple approaches (e.g. - educational aids for patients in waiting rooms and ER discharges, a personalized Screening and Prevention Prescription for each patient, continuing education strategies for healthcare professionals, etc.) must be applied. See Section 2.8 Patient and healthcare professional education for more details.
9. **Community engagement and advocacy** – Culturally appropriate recruitment strategies and educational materials should be utilized to engage patients and stop the perpetuation of health inequities. We know that socioeconomically disadvantaged Hoosiers smoke more than their higher income counterparts, Black Hoosiers are less likely to be diagnosed with early-stage lung cancer than White Hoosiers, and access barriers for rural and low socioeconomical status individuals exist. See Section 2.8 Patient and healthcare professional education for more details.
10. **Public health awareness campaigns** - In addition to targeted outreach for priority populations, executing public health awareness campaigns to promote lung cancer screenings is essential. These campaigns should be integrated with other cancer screening program promotions, the development of a Healthy Hoosier campaign to promote healthy behaviors, etc. could reach a wider audience and enhance messaging for all. See Section 2.8 Patient and healthcare professional education for more details.
11. **Implement a mobile CT program to reach rural Hoosiers** – Rural Hoosiers are at high-risk of lung cancer and have limited access to quality care. There is a correlation between lung cancer incidence, late-stage diagnosis, and mortality rates and where people live. . See Section 2.9 Mobile lung cancer screening for more details.

The evidence surrounding the benefits of lung cancer screening is extensive. Lung cancer screening is the single most effective cancer screening tool to reduce all-cancer mortality. The number needed to screen (NNS) to prevent one lung cancer death is estimated to be 255, which is significantly lower when compared to other cancer screening programs.

Cancer Type	Screening Method	NNS
Lung Cancer	Low-Dose CT	255
Breast Cancer	Mammography	645 – 1724
Colorectal Cancer	Flexible Sigmoidoscopy	850

The ALA's State of Lung Cancer 2023 Report also states that lung cancer screening has saved 80,000 additional years of life leading to an overall $40 million in healthcare savings. This would increase to 500,000 additional years of life and $500 million if all those eligible had been screened nationally.[2] Additionally, analyses have consistently demonstrated a profitable ROI for systems and hospitals. **Not only does lung cancer screening save lives, but it also makes fiscal sense.**

Back to top.

I. Context

1. Description of the Health Problem

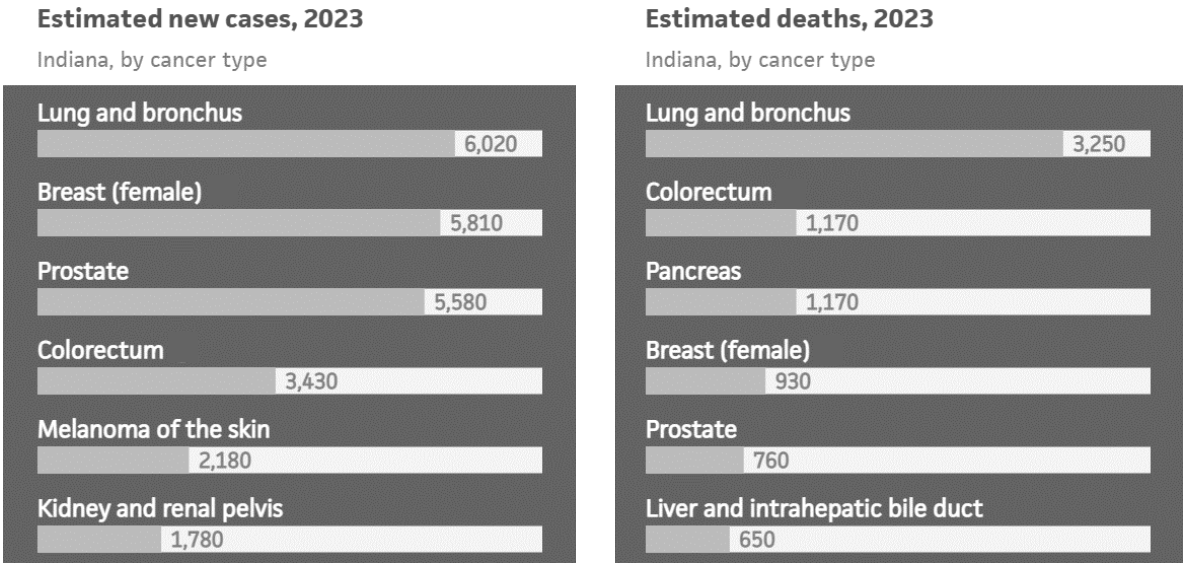
1.1 Lung cancer incidence, staging and mortality

Highlights

- Lung cancer kills more Hoosiers than colon, breast, and prostate cancer combined. Lung cancer is the most frequently diagnosed and deadliest cancer in Indiana.
- About 66% of lung cancer cases are diagnosed at advanced stages. An effective lung cancer screening program would allow for earlier detection of lung cancer cases, improve patient outcomes, and increase profits gained by health care institutions.

Lung cancer is the malignant growth of cells in the lung that destroys nearby tissue and may spread (metastasize) to other parts of the body. Lung cancer is the most frequently diagnosed and most deadly cancer in Indiana (Figure 1).[1] In Indiana, it is estimated that 6,020 Hoosiers will be diagnosed with lung cancer in 2023 comprising 15% of all new cancer diagnoses (Table 1). Lung cancer is the leading cause of cancer-related deaths in the United States. In 2023, it is estimated that there will be 127,070 deaths due to lung cancer, accounting for 21% of all cancer deaths.[1] In fact, lung cancer kills more Americans than colon, breast, and prostate cancer combined. The same is true within the state of Indiana, where an estimated 3,250 deaths in 2023 will be from lung cancer, making it the leading cause of cancer-related deaths in this state.

Figure 1. The estimated number of new cancer cases and cancer-related deaths in Indiana in 2023 by cancer type



Source: American Cancer Society Cancer Statistics Center 2023.

Table 1. The estimated number of new cancer cases and deaths in the United States in 2023

State or Region	Lung cancer incident cases	All incident cancer cases	% of all cases	Lung cancer deaths	All cancer deaths	% of all cancer deaths
Indiana	6,020	40,270	15%	3,250	13,660	24%
Midwest	56,900	419,370	14%	30,710	136,850	22%
Northeast	44,290	366,240	12%	20,920	102,890	20%
South	97,710	763,830	13%	53,900	242,860	22%
West	39,450	408,890	10%	21,540	127,230	17%
All	238,340	1,958,310	12%	127,070	609,820	21%

Source: American Cancer Society Cancer Statistics Center 2023

The five-year relative survival for lung cancer is 23%, compared to 97% for prostate cancer, 91% for breast cancer, and 65% for colorectal cancer as calculated from U.S. data from 2012-2018.[1] The incidence and death rates of lung cancer are declining across the United States mainly due to successes in reducing population levels of smoking and advances in treatment over the past few decades. Nevertheless, the number of new cases of lung cancer and lung cancer-related deaths are still projected to increase in the United States by 2030 due to population growth and aging.

In its early stages, lung cancer is usually asymptomatic, with the absence of pain, cough, and shortness of breath. However, once a person experiences symptoms, the cancer has very likely progressed to an advanced stage. About 66% of lung cancer cases are diagnosed at advanced stages (Stages III and IV) when the cancer has already spread into the surrounding area and distant sites (i.e. metastasized).[2]

Only 26% of lung cancer cases in Indiana are diagnosed at early stages (I and II) (Table 2). If diagnosed earlier, lung cancer progression may be delayed, which would improve prognosis and reduce the number of deaths due to lung cancer. Treatment options also differ for early- and late-stage cancers. At an earlier stage, surgery with intent to cure is possible, but not at later stages. **The five-year survival for early-stage lung cancer is 61%, while for Stage IV the 5-year survival is 7% (Table 2), meaning that no more than 7% of patients diagnosed with advanced, Stage IV lung cancer survive 5 years.**

Table 2. The stage distribution and 5-year survival for lung cancer in Indiana in 2023

Stage	Stage distribution	5-year survival
Early (localized – confined to primary site)	27%	63%
Regional (spread to regional lymph nodes)	22%	35%
Distant (cancer has metastasized)	44%	8%
Unstaged tumors	8%	15%

Data source: American Lung Association State of Lung Cancer, 2023

Treatment for patients with early-stage lung cancer usually involves surgery with or without chemotherapy, with or without immunotherapy. Some patients may receive targeted therapies or stereotactic radiation.

Therefore, an effective lung cancer screening program will allow for the detection of lung cancer cases at earlier stages and improve patient outcomes. The financial return on investment (ROI) is well-documented.

Back to top.

1.2 Smoking as a major risk factor

Highlights

- Individuals who quit smoking at ages 55-64 have three times less risk of dying due to lung cancer than those who continue smoking.
- In 2022 Indiana's smoking rates was 16.2%, which is higher than the national average of 14.0%.
- Integration of tobacco treatment therapies alongside lung cancer screening reduces cancer-related morbidity and mortality more than either intervention alone, yielding more cost-efficient care.

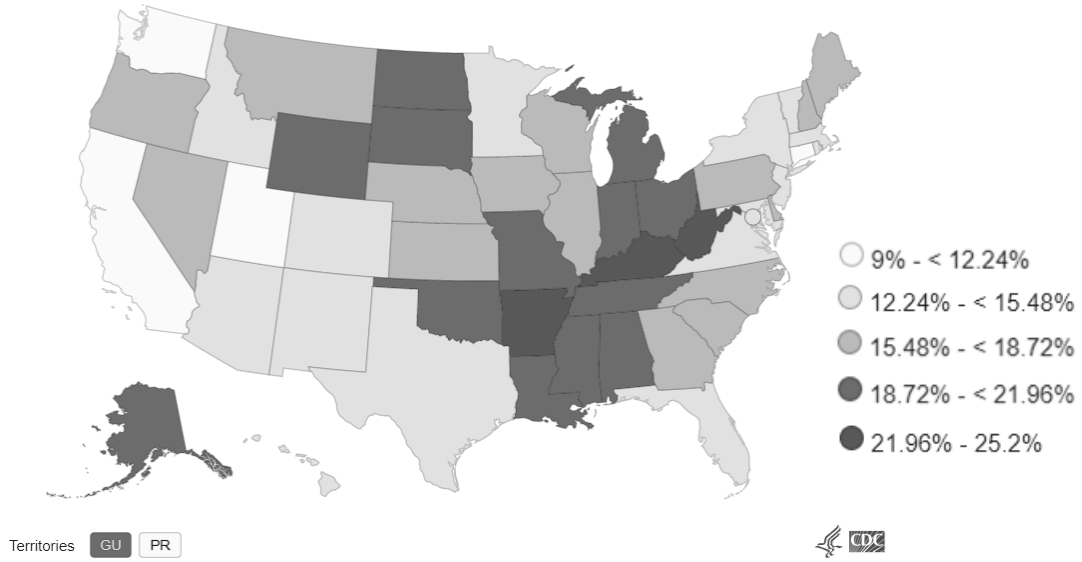
Smoking remains one of the main causes of lung cancer and accounts for 85% of cases.[18] A recent meta-analysis including a sample of over 7 million individuals showed that smoking increases the risk of lung cancer both among men and women.[19]

Lung cancer risk increases with the number of packs smoked and years of smoking. Smoking history is often measured in pack-years. One pack-year is the equivalent of smoking one pack (20 cigarettes) per day for one year. For example, if a person smoked 10 cigarettes per day for six years, then their smoking history is three pack-years. Between 2000 and 2020, smoking rates declined substantially from 23.3% to 12.5% in the United States as a result of comprehensive tobacco control efforts. [20] The national target is to achieve less than 5% tobacco use by 2030 with the efforts of the U.S. Healthy People 2030 Strategy.[21] Therefore, continued dedication to reducing smoking rates is needed.

Smoking rates vary geographically within the U.S (Figure 2). In 2019, smoking rates in the states varied from 7.9% in Utah to 23.8% in West Virginia.[22] In 2022, Indiana's smoking rates were 16.2% which is worse than the national average at14.0%[101].

Back to top.

Figure 2. Current cigarette use among adults (%) by state or territory in the United States in 2018



Source: Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion.

Tobacco treatment (previously referred to as "smoking cessation") remains the most important preventive measure for lung cancer and related deaths. A recent analysis of 216,917 adults in the US National Health Interview Survey (NHIS) showed that individuals who quit smoking at ages 55-64 had three times less risk of dying due to lung cancer than those who continue smoking.[23]

Although tobacco treatment is the most effective form of primary prevention, support for quitting smoking is not universally available to patients and cessation aid coverage varies widely.

Furthermore, tobacco treatment is a complex process; it may take an average of 5-30 attempts over a smokers' lifetime to quit successfully,[24] which is why tobacco treatment and relapse prevention programs with adequate and long-term coverage of nicotine replacement therapy (NRT), pharmacotherapy, and evidence-based counseling are important supports for current and recent smokers.

Unfortunately, heavy smokers remain at high risk of developing lung cancer even years after tobacco treatment. **In fact, 43% of people participating in lung cancer screening programs in Indiana during 2022 had already stopped smoking,[25,26] leaving lung cancer screening as the only further step available to them to reduce their risk of dying from lung cancer.**

Lung cancer screening paired with tobacco treatment has greater potential to reduce cancer related morbidity and mortality than either intervention alone, and recurring screening provides additional opportunities for systematic tobacco treatment. Having a reciprocal referral mechanism between lung cancer screening and tobacco treatment programs that are both available to the general population (e.g., quit lines) and for cancer patients in particular (e.g., within cancer treatment settings) will help to coordinate efforts and provide continuous

support to patients throughout their quit journey.

In Indiana during 2022, tobacco treatment was offered to only 65% of current smokers during their lung cancer screening appointment.[26] Economic analyses have shown that integration of tobacco treatment therapies alongside lung cancer screening significantly improves the cost-effectiveness of the lung screening program.[27,28] Mechanisms for tobacco treatment referrals and therapies need to be integrated within a lung cancer screening program to reduce risks to patients and improve program cost-effectiveness for health care institutions.

Back to top.

1.3 Status of screening in the United States and Indiana

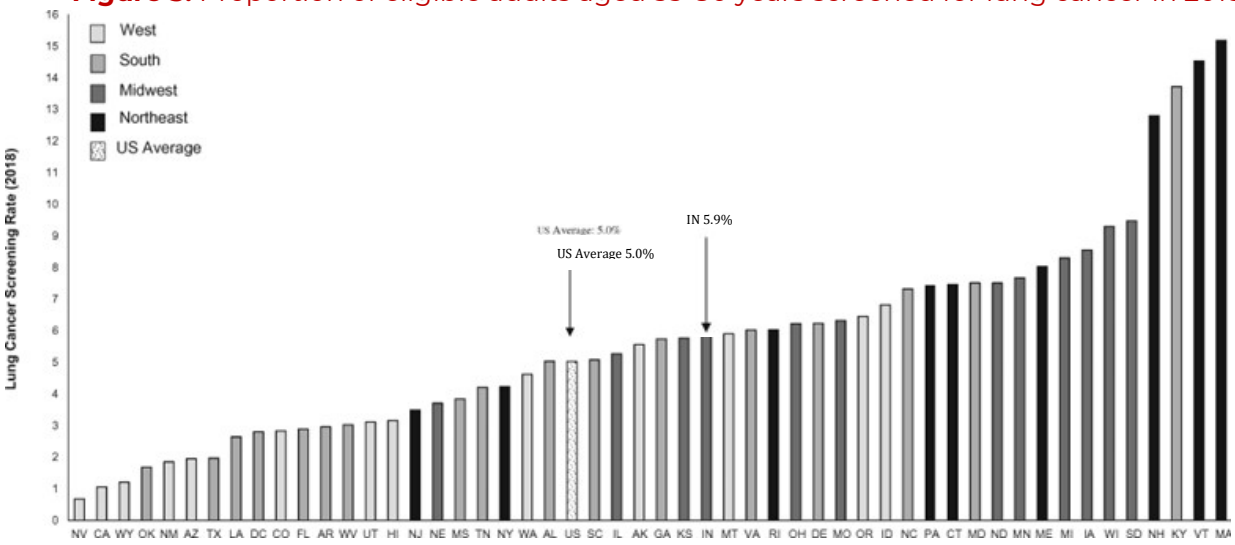
Highlights

- Uptake of lung cancer screening in eligible Hoosiers is low (5.1%) compared colorectal (76%), breast (74%), and cervical (76%) cancer screening.
- Nationwide, annual lung cancer screening is legally required to be covered by insurance without a copay for eligible individuals.
- Only approximately 6,500 of the 110,000 eligible Hoosiers currently participate in an annual lung cancer screening program. Therefore, there is significant room for growth.

Annual lung cancer screening in eligible adults has been recommended by the U.S. Preventive Services Task Force since 2013. Consequentially, under the terms of the Affordable Care Act, Medicare, Medicaid, and private payers were required to cover LDCT lung cancer screening for eligible individuals without a copay.[29] Despite these positive measures, uptake has been slow and variable across the United States. Multiple barriers to lung cancer screening have been reported, including minimal health system support and resources, lack of physician and patient awareness and education, and psychosocial and access barriers among screening candidates.[30]

In the Unites States in 2018, 8.07 million individuals were eligible for lung cancer screening, but only 5% of those individuals participated in a screening program (Figure 3).[31] Over the past 5 years, the national screening rate has fluctuated, but ultimately modestly increased from 3.4% in 2017 to 4.5% in 2023. Indiana has continually screened slightly above the national average and achieved a screening rate of 5.1% in 2023.[2] Nevertheless, there is significant room for improvement, especially in comparison to the high uptake of other cancer screening assessments. For example, the vast majority of eligible Hoosiers completed colorectal (71%), breast (74%), and cervical (76%) cancer screenings in 2021.[2]

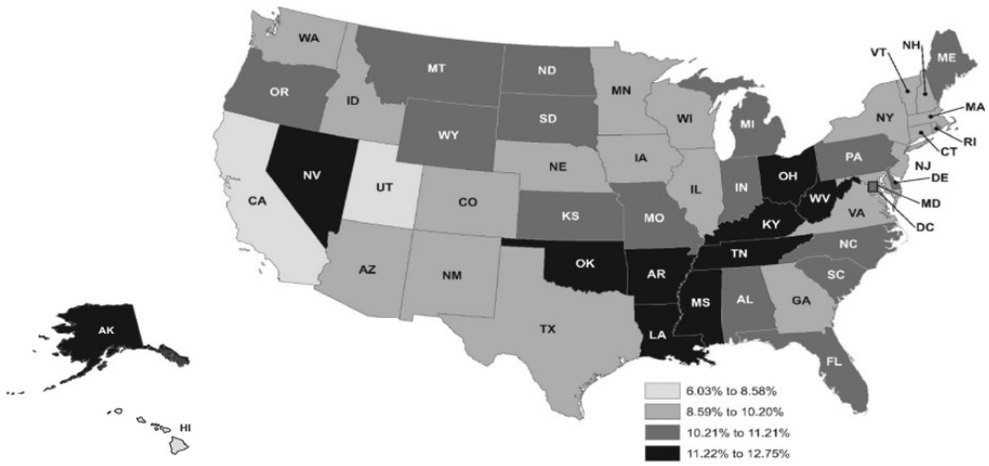
Figure 3. Proportion of eligible adults aged 55-80 years screened for lung cancer in 2018.



Source: J. Natl Cancer Inst. Volume 113, Issue 8. August 2021. Pages 1044-1052. doi.org/10.1093/jnci/djaa170

There is a large population that is eligible for lung cancer screening in Indiana. In 2018, approximately 11% of adults aged 55-80 years were eligible for annual lung cancer screening (Figure 4).[31] That equates to approximately 110,000 individuals eligible for annual lung cancer screening program participation in Indiana. In comparison, only 5,610 Hoosiers are currently participating in a lung cancer screening program. Therefore, there is significant room for growth as there is a large population of individuals eligible to receive lung cancer screening covered by insurance that currently does not participate in a lung cancer screening program. **Health care institutions that invest in scaling their lung cancer screening programs to meet this need will find demand for this service as well as return on the investment from the screening program and downstream revenue.**

Figure 4. Estimated proportion of adults aged 55-80 years eligible for LDCT lung cancer screening according to the USPSTF criteria by state in 2018.



Source: J. Natl Cancer Inst. Volume 113, Issue 8. August 2021. Pages 1044-1052. doi.org/10.1093/jnci/djaa170

Back to top.

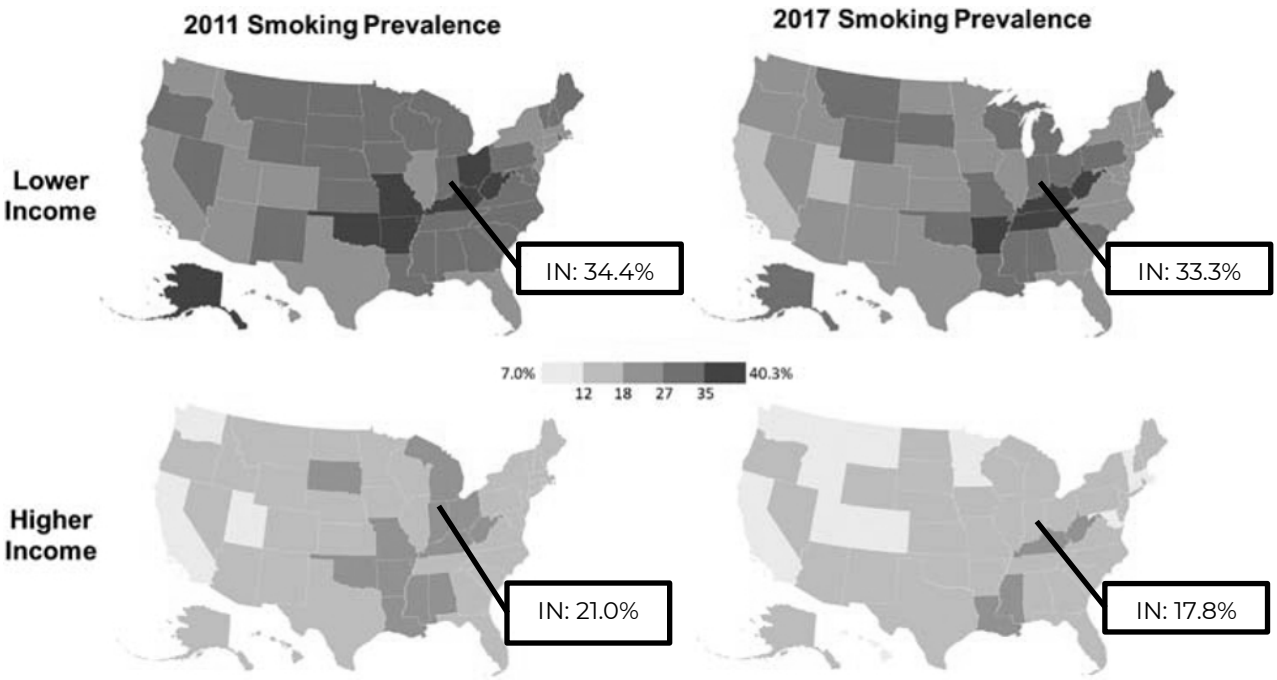
1.4 Ethical, social, and equity considerations

Highlights

- Socioeconomically disadvantaged Hoosiers smoke more than their higher income counterparts, and therefore, are more likely to be affected by lung cancer.
- Black Hoosiers are less likely to be diagnosed with early-stage, curative lung cancer than White Hoosiers and would benefit significantly from lung cancer screening.
- Access barriers for rural and low socioeconomical status individuals could be reduced through the implementation of a mobile lung cancer screening unit.
- Culturally appropriate recruitment strategies and educational materials should be utilized to engage patients and stop the perpetuation of health inequities.

As with any screening program, lung cancer screening may raise concerns about equity. Smoking is strongly associated with socioeconomic status (SES). Despite marked reductions in smoking prevalence in the United States, disparities in smoking by income persist. Mills et al 2020 reported that smoking levels remained significantly elevated in lower income Hoosiers compared to their higher income counterparts despite nationwide efforts to reduce smoking rates (Figure 5).[32] **This means that socioeconomically disadvantaged individuals are more likely to be affected by lung cancer and would benefit significantly from lung cancer screening.**

Figure 5. Cigarette use prevalence in 2011 and 2017 by income group across the United States



Source: Mills et al (2020). Preventive Medicine, Volume 133. doi.org/10.1016/j.ypmed.2020.106019

People experiencing low SES may have significant barriers to access preventive health services, such as transportation issues, cost of parking, or difficulties obtaining time off work. In fact, 11.9% of adults in Indiana report not having a primary care provider, and 7.7% of Hoosiers report not seeing a doctor in the past 12 months specifically due to costs.[33]

Transportation is also a barrier for many individuals living in rural communities. Limited access to facilities and long commute times deter some eligible individuals from participating in a lung cancer screening program. **Implementation of a mobile lung cancer screening unit would increase service accessibility to the rural and low SES community.**

Additionally, significantly fewer Black Hoosiers (22%) were diagnosed with early-stage lung cancer compared to White Hoosiers (26%) during 2022.[2] Lung cancer screening may detect lung cancer at an earlier stage, which is essential to survivorship because early-stage cancers have not yet spread throughout the body and are more likely to be curable. Lung cancer screening approaches should be accessible, culturally safe, and involve engagement with Black communities beyond the healthcare system.

Cultural and access barriers appear to influence lung cancer screening participation more than stigma. In focus group research, people at high risk of lung cancer were generally supportive of lung cancer screening.[34] Patients acknowledged that receiving a diagnosis of lung cancer would affect their quality of life in the short-term, but they felt empowered to have more time for planning and making the best use of the remaining time. They considered the risks associated with screening to be acceptable given the survival benefits.[34]

It is important that lung cancer screening programs are intentionally inclusive of all high-risk individuals and do not perpetuate or increase health inequalities across sociodemographic groups. Lung cancer screening may have a potential to reduce health inequities if the implementation of the program is accessible to these individuals at higher risk of lung cancer.

Back to top.

2. Summary of Technology and Clinical Evidence on Low-Dose Computed Tomography (LDCT) Screening

2.1 Technology for lung cancer screening

Highlights

- Lung cancer screening is effective. The technological development of low-dose computed tomography (LDCT) provides sufficient specificity to detect lung cancer at earlier stages where it is more likely to be cured, resulting in reduced mortality.
- Lung cancer screening is efficient. The number needed to screen to prevent one cancer death is significantly lower for lung cancer than breast or colorectal cancer.

Screening is a process of applying a test to detect a potential disease or condition in a person who has no known signs or symptoms of that disease or condition. The decision to utilize a test for cancer screening involves a complex interplay of factors related to the selection of the target population, the effectiveness of the test, the benefits and harms associated with screening, availability of effective treatments to extend lifespan, and healthcare related costs.

Lung cancer is an excellent candidate for screening. Lung cancer is a significant health issue, and 66% of all lung cancers are currently diagnosed at advanced stages in Indiana.[2] Lung cancer has a long, asymptomatic phase that presents opportunities for regular testing to find early-stage cancers that have a greater chance of successful treatment. For example, it typically takes about 8 years for a squamous cell carcinoma to grow to a size when it is commonly diagnosed (30 mm). By the time the individual becomes symptomatic, the risk of metastasis is considerable.[35]

The challenge, until recently, had been the lack of an effective screening test. Over the past several decades, chest radiography and sputum cytology were extensively studied for their potential as lung cancer screening tests. However, neither of these has been found to reduce mortality in randomized controlled trials,[36] likely due to the fact that neither of the tests had enough sensitivity to detect cancer at the earlier stages, where it is more likely to be cured.

Computed tomography (CT) scanning is a diagnostic test that uses x-rays to generate multiple cross-sectional images of internal organs. Low-Dose Computed Tomography (LDCT) uses less ionizing radiation (dose of ≤ 1.6 mSv)[37,38] than a conventional CT scan (dose of 8.2 mSv).[39] As a comparison, in North America, the average annual dose of background radiation is 1.8 mSv,[40] so properly done, LDCT provides a radiation dose similar to these annual background rates experienced by all Americans. It produces images of better quality at a lower radiation dosage. Furthermore, it requires no contrast and hence reduces risks to patients, simplifies scheduling, and reduces related costs.

Table 3. Number needed to screen (NNS) to prevent 1 death by cancer type

Cancer Type	Screening Method	NNS
Lung Cancer	Low-Dose CT	255
Breast Cancer	Mammography	645 – 1724
Colorectal Cancer	Flexible Sigmoidoscopy	850

Source: Tammemagi et al (2013). N Engl J Med, Volume 368. doi.org/10.1056/NEJMoa1211776.

The two largest randomized controlled trials (RCTs) of LDCT screening have shown a reduction in lung cancer mortality of 20-24% (NLST: n= 53,454 and NELSON: n = 13,195).[5,6] Among women, the NELSON trial found a 33% reduction in lung cancer mortality (n=2,594). The number needed to screen (NNS) to prevent one death was estimated to be 255 for LDCT, which is a considerably lower number compared to other cancer screening programs (Table 3).[7] For context, the NNS to prevent one breast cancer death varies from 645 to 1,724 in each age decade from 40 to 79 years for mammography[8] and the NNS to prevent one colorectal cancer death is 850 for flexible sigmoidoscopy.[9]

In 2021, the United States Preventive Services Task Force (USPSTF) recommended screening with LDCT for a high-risk population. Lung cancer screening programs should target a small population of high-risk individuals who meet the specific eligibility criteria.

The U.S. Preventive Services Task Force (2021) recommends
• LDCT annual screening* • for adults aged 50-80 years • current or former (quit ≤15 years) smokers** • with ≥20 pack-year smoking history

LDCT: low-dose computed tomography

* Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.[41]

**In November 2023, the American Cancer Society recommended removal of this criteria.[99]

Back to top.

2.2 What are the benefits of lung cancer screening?

Highlights

The overview of clinical studies provides definitive evidence that:

- Lung cancer could be diagnosed at an earlier stage, if low-dose computed tomography (LDCT) screening programs were implemented.
- Beyond stage shift, LDCT screening reduces lung cancer-related mortality in high-risk individuals. LDCT is the only test that has been shown to sufficiently increase early detection of lung cancer to result in fewer deaths.
- LDCT scans for lung cancer screening reduce lung cancer mortality by approximately 20% and all-cause mortality by 6%.

Seven large-scale RCTs (NLST, DANTE, DLCST, MILD, NELSON, ITALUNG and LUSI) have published the results on effectiveness of lung cancer screening on mortality related outcomes (Appendix 2). The sample size of these trials ranged from 2,811 to 53,434. All seven studies recruited high-risk populations, though the definition of "high-risk" varied between trials. Most of the trials reported annual screening intervals up to five rounds, but the Italian MILD trial reported annual screening intervals up to 10 times. All trials but one compared lung cancer screening with usual care (i.e. no screening). The NLST trial compared low-dose computed tomography (LDCT) with chest X-ray. The two largest and best quality RCTs (NLST, NELSON) demonstrated a substantial reduction in lung cancer related mortality with LDCT screening at long term follow-up. In 2011, NLST found a 20% reduction at over 6.5 years of follow-up[5] and NELSON found a 24% reduction at 10 years.[6] The updated analysis of NLST trial released in 2019 extended to over 12 years of follow-up and reaffirms the original findings.[42] MILD and ITALUNG studies also demonstrated borderline reduction in mortality at >9 years of follow-up. Both studies showed greater survival benefits beyond 4-5th year of screening.[43,44]

The LUSI trial reported a 69% reduction in lung cancer mortality among women but not among men.[45] The NLST, MILD, and ITALUNG trials also reported reduction in all-cause mortality with borderline significance.[4,43,44] Two other studies (DANTE, DLCST) did not find any differences in lung cancer-related or all-cause deaths between LDCT screening and no screening arms.[46,47]

All seven trials showed that lung cancers detected in the LDCT screening arms were more likely to be early stage (I and II) than those in the control arms. For example, in the NELSON trial, among the screen-detected cases in the intervention arm, 58.6% were diagnosed at stage I, whereas only 13.5% of cases were diagnosed at stage I in the control arm.[6]

Back to top.

2.3 What are the potential harms of lung cancer screening

Highlights

- Standardized lung nodule reporting systems, such as Lung-RADS, should be utilized to minimize false positive findings, overdiagnosis, and major complications following diagnostic procedures.
- Consistent methods for identifying and reporting incidental findings should be utilized to avoid unnecessary diagnostic procedures while maintaining optimal clinical care.

A major challenge with any screening procedure is that no test is completely accurate. Below is a list of potential harms associated with lung cancer screening and mitigation strategies. Since the NLST and NELSON studies were conducted, other research has been done to demonstrate how harms could be reduced. Effective tools have been developed, such as lung nodule risk calculators and lung nodule management frameworks, to improve the effectiveness and efficiency of lung cancer screening.

False positive findings

False positive findings are one of the most common adverse effects of any screening program. Patients with positive screening results may undergo additional diagnostic procedures, incur additional healthcare costs, and experience unnecessary complications.

In the NELSON trial, 2.1% of scans (467 out of 22,600) were positive. Among those who were screen-positive, 43.5% were confirmed to have lung cancer. The false discovery rate (defined as the proportion of false positive screens among all positive screens) was 56.5% (264/467). Overall, only 1.2% (264 of 22,600) of the total scans performed had a false-positive result. Approximately 23% (67 out of 293) of participants with false-positive screen results underwent an invasive procedure, including surgeries or transthoracic biopsies[48] comprising <1% (67 out of 7,582) of all screened participants.

In the NLST, the false positive rate (defined as the proportion of positive screens among those who did not have cancer) was 23% and the false discovery rate was 96.4%. Roughly 2.2 % of all patients with a positive screen had undergone an invasive surgical procedure or biopsy.[4,5]

Current standardized reporting systems, such as Lung-RADS, differ from the NLST protocol in important ways to mitigate this issue (Appendix 3). They apply certain risk criteria (based on size and other nodule characteristics) to define an abnormality as potentially malignant, benign, or indeterminate, which can substantially reduce the number of false-positive findings and the subsequent need for additional invasive procedures.[49,50] The Lung-RADS standardized reporting system has shown good performance in discriminating benign nodules from malignant ones.[51]

Major complications following positive LDCT test result

The rate of major complications for patients undergoing invasive diagnostic procedures varies between 10.7% in NELSON[48] to 28.6% in DANTE[52] and 37.5% in DLCST.[53] In the NLST trial the rate of major complications was 12% for patients with confirmed lung cancer and 2.4% without confirmed lung cancer.[4,5] Postoperative death within 60 days of surgery was 1.6% and 0.1% for patients with and without confirmed lung cancer respectively.[4,5] Within a lung cancer

screening program, standardized diagnostic workup protocols will limit unnecessary procedures and related complications.

Overdiagnosis

Apart from detecting aggressive cancers, screening would also detect slow-growing tumors that would otherwise have remained silent, regressed, or would not cause clinical symptoms and death. Hence, overdiagnosis may lead to overtreatment, related complications, and incur unnecessary harms to the patient and costs to the systems. In the NLST study, the estimated rate of overdiagnosis was 3%.[42] As suggested earlier, the Lung-RADS standardized reporting system performs better than the NLST protocols in discriminating nodules, which would further reduce this rate.

Radiation exposure

LDCT uses an ionizing radiation dose of ≤ 1.6 mSv per screen.[37,38] As a comparison, the average annual dose of radiation per North American resident is 1.8 mSv.[40] No studies reported on radiation-related patient outcomes (e.g. radiation-induced lung cancer) at long-term follow-up. Based on the NLST results, Bach et al. estimated the lifetime risk to develop fatal cancer caused by radiation to be equal to 1:2,500.[54] Considering that the lifetime cancer risk in general population is 1:2 this additional risk is negligible. Within a lung cancer screening program, low dose protocols and routine quality control will ensure the maintenance of low dose levels of radiation.

Incidental findings

Clinically significant abnormalities (cardiovascular, thyroid, adrenal findings, extrapulmonary cancers) unrelated to lung cancer are often detected in lung cancer screening participants. However, the impact of incidental findings on morbidity and mortality remains unknown and warrants further research. People eligible for lung cancer screening are at elevated risk of cardiovascular disease. Therefore, timely diagnosis and preventive treatments can further improve survival of these patients.[55]

It has been shown that only 7-20% of incidental findings require further investigation, mainly non-invasive testing or additional consultation.[56,57,58] The rate of incidental findings with major clinical implications is less than 1%.

In the subgroup analysis of NLST (n = 17,309), incidental findings were found in 59% of participants; 20% were identified as clinically important, with the highest prevalence reported for cardiovascular findings (8.5%). Extrapulmonary malignancies were uncommon and found in 0.4% of participants. Authors concluded that indiscriminatory follow-up of incidental findings may significantly increase direct healthcare cost with little benefit, since detected extrapulmonary malignancies were rare.[57,59]

Similarly, in a subgroup analysis of NELSON participants (n=1,929), 129 (7%) had clinically relevant findings. Of those 118 (91%) required further diagnostic workup, mainly ultrasound. Only 21 (1%) participants had findings with clinical implications, including one patient with malignancy. Based on these results, the authors advised against systematically searching for incidental findings in lung cancer screening studies using LDCT.[56]

Back to top.

2.4 How could lung cancer screening programs mitigate harms?

Highlights

- The lung cancer screening program will ensure that eligible populations are screened and receive an appropriate, timely diagnostic workup for abnormal findings through centralized review processes.
- The systemic implementation of the Lung-RADS standardized reporting system and low-dose CT protocols will limit unnecessary risks and procedures.

1. Enforcing strict eligibility criteria as recommended by USPSTF to only screen high-risk individuals.

Unlike other cancer-screening programs (breast, cervical, colon) targeted for an average-risk population, lung cancer screening is recommended for only a small segment of the population who has an increased risk of developing lung cancer. Screening of lower or average-risk individuals could cause net harm to those individuals and increase associated costs. Primary care providers play an important role in initiating the lung cancer screening process. Lung cancer screening programs with mechanisms for primary care referrals and centralized eligibility review will help to ensure that only eligible individuals are screened and subsequently minimize false positive results and costly diagnostic workups.

2. Implementing low dose protocols and annual quality assurance to minimize radiation exposure.

LDCT uses radiation dose of ≤ 1.6 mSv per screen. However, scan protocols vary depending on individual machine capacities. The lung cancer screening programs will support the continued implementation of standardized technical protocols and conduct quality assurance check-ups to ensure that low radiation exposure protocols are maintained. This will minimize the risk of patients receiving excess radiation exposure.

3. Utilizing Lung-RADS standardized reporting system to minimize the risk of false positive/negative results.

Not all lung nodules require follow up. The Lung-RADS nodule management protocol applies certain criteria to define an abnormality as potentially malignant, benign or indeterminate, which can substantially reduce the number of false-positive findings and the subsequent need for additional diagnostic procedures.[49] The lung cancer screening program will ensure that qualified radiologists with expertise in early detection are involved in the interpretation of the screening results.

4. Developing patient management pathways to minimize the number of unnecessary procedures.

As indicated earlier, not all nodules require further diagnostic workup. The lung cancer screening program will develop and enforce standardized diagnostic workup protocols to limit unnecessary procedures (repeat imaging, diagnostic procedures, surgery) and related possible complications. Additionally, the screening program will include a centralized lung nodule review board for medical experts to discuss diagnostic and treatment pathways for concerning cases.

Back to top.

II. Program Implementation

1. Background on the ELCN Lung Cancer Screening Taskforce

All major medical organizations, including the United States Preventive Services Task Force (USPSTF) and Centers for Medicare & Medicaid Services (CMS), recommend annual lung cancer screening for individuals at high-risk of developing lung cancer. In addition to the USPSTF clinical practice guideline defining eligible populations, the American College of Chest Physicians (ACCP) and American Thoracic Society (ATS) have issued policy statements to ensure that the benefits of lung cancer screening outweigh harms.[29]

In November 2022, End Lung Cancer Now (ELCN) hosted its 2nd Annual Gathering with a focus on how to significantly improve the rate of lung cancer screenings. Experts from around the country, including Dr. Mary Reid from Roswell Park Comprehensive Cancer Center, Dr. Michael Gieske from St. Elizabeth Healthcare, and Dr. Raymond Osarogiagbon from Baptist Cancer Center joined as guest speakers to share best practices for lung cancer screening programs. Topics addressed included the importance of implementing a mobile lung cancer screening program to reach rural populations, expanding screening in underserved and underrepresented populations, and scaling lung cancer screening programs in heavy smoking populations with high lung cancer incidence and mortality.

As a result of the knowledge learned at this symposium, ELCN established a multidisciplinary taskforce (Appendix 1) in March 2023 to address this need. The goal of this Taskforce was to identify challenges, barriers, and opportunities to significantly improve lung cancer screening rates. This Blueprint outlines the key recommendations from the ELCN Lung Cancer Screening Taskforce and can serve as a roadmap to significantly transform and scale screening programs in Indiana.

Back to top.

2. Recommendations for Lung Cancer Screening Program Improvement

The recommendations outlined in this section underscore the importance of multidisciplinary collaboration and using a comprehensive approach for transformational change. These recommendations are closely aligned with other evidence-based approaches and will ensure lung screening programs deliver a sustainable and high-quality lung cancer screening program.[93]

Back to top.

2.1 Program structure and workflow

Highlights

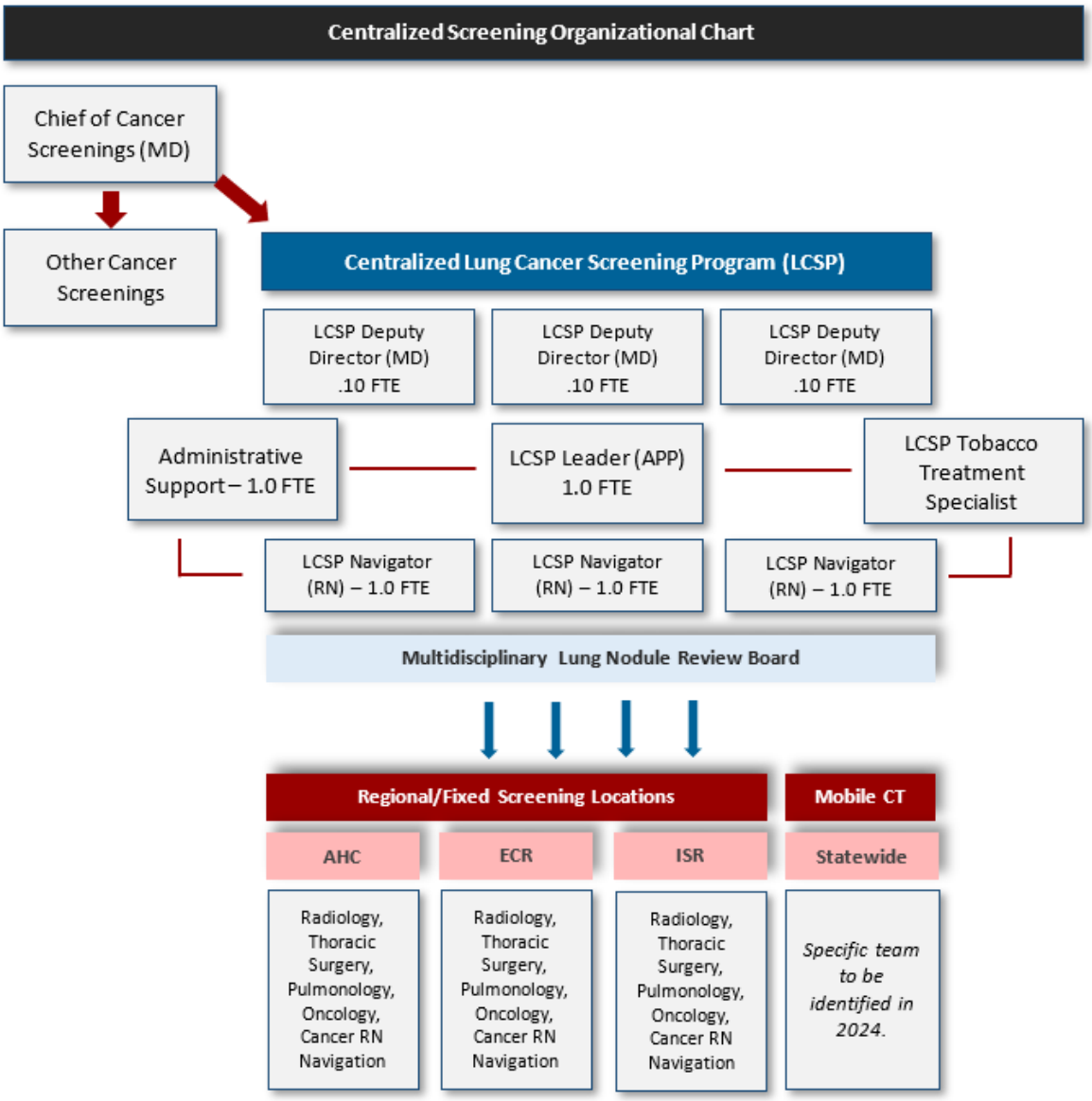
- It is recommended to implement a completely centralized lung cancer screening program.
- A centralized structure would lend itself to optimal care coordination and improved adherence rates of patients in the program.
- A centralized structure and workflow remove burdens from referring physician/APPs.
- Additional resources are needed to implement this structure.

Structure

The ELCN Lung Cancer Screening Taskforce recommends implementing a centralized structure for the lung cancer screening program (LCSP). A centralized care team should be established, with protected time and financial compensation offered for each position. A centralized LCSP not only lends itself to optimal care coordination through clear and standardized workflows, but also can significantly improve the annual adherence rates of patients participating in the LCSP.[94]

The centralized LCSP should be overseen by a physician leader and should be managed under the co-directorship of physicians from pulmonology and thoracic surgery. The LCSP should have a screening program leader who is an advanced practice provider (APP) that oversees a team of LCSP navigators and administrative support staff. Figure 9 sketches the recommended organizational structure for the centralized LCSP with the required FTE to run optimally.

Figure 9. Centralized Lung Cancer Screening Program Organizational Chart



Workflow

The workflow described in this section is based on recommendations from the ELCN Lung Cancer Screening Taskforce. This workflow concept is supported by a centralized program model developed by the GO2 Foundation for Lung Cancer. GO2's model is included as Appendix 5.

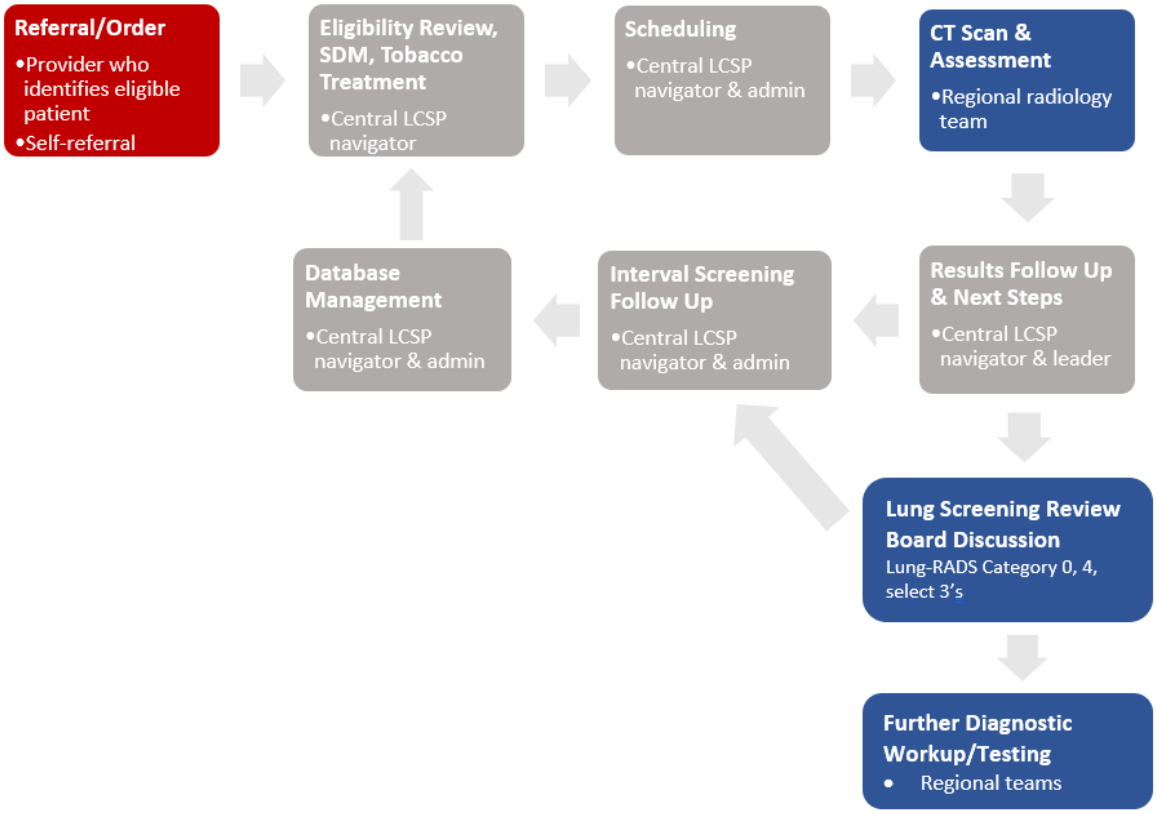
The recommended workflow for a centralized lung cancer screening program (LCSP) is briefly outlined below with Figure 10 providing a visual description.

1. A patient is identified as eligible for lung cancer screening through an alert notification.
2. The patient is referred to the "Lung Cancer Screening Program" by any healthcare professional who

identifies the patient as eligible. This can be a primary care provider, ED physician/APP, subspecialty physician/APP, etc.

3. The program referral goes to a centralized LCSP navigator. The LCSP navigator will confirm eligibility, conduct the shared decision making (SDM) conversation, identify tobacco treatment counseling needs, and schedule the patient for imaging at one of the regional sites, based on availability and patient geographical location.
4. The regional radiology team will perform the low-dose CT scan and conduct the imaging assessment.

Figure 10. Centralized lung cancer screening program (LCSP) workflow.



5. The LCSP navigator will receive the assessment, discuss the results with the LCSP leader, and present the patient case at the Lung Screening Review Board if needed.
6. The LCSP navigator will provide the screening results to patients for Lung-RADS 1, 2, and 3. The LCSP leader will provide the screening results to Lung-RADS 3 patients, if requested, and Lung-RADS 4 patients. The LCSP leader will also provide recommendations to patients for further follow-up or diagnostic work-up.
7. The LCSP navigator and/or LCSP leader will contact referring physician to provide screening results and LCSP recommendations for the patient.
8. The LCSP navigator and administrative team will track the follow-up reminders for subsequent screening (either annually or more frequently when needed) and manage the ongoing participation of the patient.
9. The regional team(s) will take over a patient's care only if a referral is made for diagnostic workup.

A more detailed description of the workflow and the proposed changes in each step of the process is included below.

Patient Identification and Referral

Typically, primary care providers (PCPs) refer patients to receive a low-dose CT scan for lung cancer screening. However, any physician/APP who identifies that a patient is eligible can refer them to the screening program.

Eligibility Review, Shared Decision-Making, and Tobacco Treatment

Once a patient is referred to the program, the centralized LCSP navigator will contact the patient to complete an initial eligibility assessment. This will save valuable time in ensuring patients are eligible for a lung cancer screening prior to scheduling their initial scan. If the patient is confirmed to be eligible, the LCSP navigator will then conduct a shared decision-making (SDM) conversation using standardized documentation and identify and connect the patient with the necessary tobacco treatment resources. There are more details related to recommendations for the SDM conversation and tobacco treatment resources in following sections.

Scheduling

After eligibility is confirmed, the SDM conversation occurs, and the tobacco treatment resources are discussed, the LCSP navigator will schedule the patient to receive their scan at a regional site, based on the patient's location, preference, and appointment wait times. The LCSP co-directors would become the physician of record for all patients participating in the LCSP. Additionally, if a patient is a current smoker it would be ideal to have them also referred to a tobacco treatment specialist at this time.

LDCT Scan & Assessment

The patient will attend their LCSP visit and complete their LDCT scan. The radiology team physically located at each site will conduct this appointment. The l radiology team will conduct the scan assessment using the Lung-RADS standardized reporting system (Appendix 3) as they currently do. Results of the scan and assessment would then be added to the patient's chart and shared with the central LCSP team.

Results Follow Up and Next Steps

Based on the findings of the assessment, the LCSP navigator would confirm next steps with the LCSP leader(s) and conduct the patient follow-up. For all Lung-RADS Category 1 and 2, the patient should receive their results via an automated letter and the patient would be put in a queue for annual (or another interval deemed appropriate) follow-up. All Lung-RADS Category 0 and 4 cases and select Lung-RADS 3 cases should be presented at the multidisciplinary Lung Screening Review Board for discussion. The LCSP navigator would follow-up with the patient after the Lung Screening Review Board discussion to share results and discuss next steps.

If a 3–6-month interval LDCT was deemed most appropriate, the LCSP navigator team would manage this process and the patient would remain in the program. If further diagnostic work-up is required, the patient would be referred to a specialist at a regional site for appropriate follow-up care and would be discharged from the program at this time.

Further Diagnostic Workup/Testing

It is essential for the LCSP navigation team to manage the work-up and/or referrals to the appropriate specialists at the regional sites if further diagnostic testing and/or care is required. Once a patient is connected to the appropriate team and scheduled to see a specialist at one of these sites, the patient would be transferred to their care and no longer under the care of the LCSP team. It is important to note, however, that there must be a workflow in place to ensure that the LCSP can peripherally follow the patient through diagnosis and possible treatment to capture critical metrics (e.g., received diagnostic testing, confirmed positive cancers, treatment, etc.) retrospectively.

If the patient receives a negative diagnostic evaluation, the regional specialty care team should refer the patient back to the central LCSP so that the central LCSP navigation team can continue to engage with the patient for annual LCSP participation.

Back to top.

Database Management

The central LCSP administrative team would complete all database entry for required reporting outcomes as well as assist the LCSP navigation team with scheduling as needed.

Interval Screening Follow Up

It is recommended that patients are scheduled for their next interval lung cancer screening appointment when results from the initial scan are shared.

It is also recommended that an integrated workflow with a customer relationship management (CRM) system, is developed to provide patients with reminders of upcoming or missed appointments. Cerner EMR notifications should remind physician/APPs of patient eligibility and follow up appointments. These various touchpoints will assist in ensuring that long-term patient adherence is improved.

2.2 Screening capacity and resources

Highlights

- Implementing a centralized lung cancer screening program will require additional resources and support.
- A coordinated, centralized care team, including nurse navigators and administrative support, with committed time and financial compensation is essential to success.
- As the LCSP grows over time, it may be necessary to obtain additional equipment (i.e. – CT scanners) to accommodate for increased capacity.
- Collaboration with other health systems is essential for statewide success.

The recommended centralized lung cancer screening program (LCSP) will require the addition of new resources to implement successfully. Enhancing resources will enable the system to increase its capacity to reach a larger patient population and capitalize on downstream profits. **The positions outlined in this section would be new positions and essential to implement**

the recommendation of a centralized LCSP.

Medical Director This position should live within the office of the Chief Medical Officer and should hold an MD or equivalent degree and should be compensated through a medical directorship and should have fiduciary responsibilities with a budget to be determined on a bi-annual (every 2 year) basis. This position will directly oversee the co-directors of the centralized LCSP. This individual should also oversee all cancer screening programs and lead the effort to coordinate screenings between programs (e.g. – mammography and lung screening, colorectal and lung screening, etc. A pilot program to coordinate similar measures is underway.)

Lung Cancer Screening Program Deputy Directors – The deputy directors of the LCSP will oversee the operations of the centralized LCSP. They will have direct oversight of the central team and serve as the physician of record for the patients in the LCSP. Ideally, each regional/fixed site will identify a deputy director with an MD or equivalent degree to serve in this role. Each deputy director would require 0.10 FTE dedicated time to oversee this program and should be compensated for their screening efforts. It is also recommended that the team of LCSP deputy directors is multidisciplinary in nature with a diverse representation.

Lung Cancer Screening Program Leader – The centralized LCSP leader should be an advanced practice provider (APP) and would be responsible for overseeing the work of the centralized LCSP navigation team. They will serve as the intermediary between the navigation team and screening deputy directors who can place the order for screening. This should be a 1.0 FTE position dedicated only to lung cancer screenings.

Additionally, the recommended APP to RN/lung cancer screening navigator ratio is 1:3-5. This is important to keep in mind as the program continues to grow.

Lung Cancer Screening Program Navigators – The LCSP navigators will manage and oversee most of the workflow for the lung cancer screening program. They will be the patients' first point of contact and will guide each patient through the program from initial scan to all subsequent follow-ups. They will ensure patients return for their annual screenings as well as ensure patients are referred to the right specialists and connected to the appropriate follow-up care. Implementing a navigation team would reduce the burden of the referring healthcare professional, as well as the deputy directors and program leader. The recommendation is to have (3) 1.0 FTE navigators dedicated to the centralized program. Additional resources will be needed as the LCSP continues to grow. It is estimated that the addition of (1) navigator could equate to ~4,000 screens per year.

Administrative Support – The central LCSP administrative team will supplement the work of the LCSP navigators and program leaders to reduce the burden of data entry for required reporting outcomes. The administrative team could also assist in the scheduling and follow-up coordination of patients as needed. The proposed LCSP will require at least (1) 1.0 FTE administrative assistant, with the ability to scale as the capacity for the program increases.

Increased volume of healthcare services associated with the screening, diagnostic, and treatment pathways may affect wait times for the following healthcare professionals or require additional staff.

Qualified radiologists with expertise in early detection will be involved with interpretation

of the screening results. The proposed LCSP may require additional radiologists at the regional sites to manage the predicted increase in volume. We need a radiology champion for the fixed as well as the mobile programs. They will work with the deputy directors of the program to ensure the demand for screening is covered by radiology resources.

Additional equipment (i.e., low-dose CT scanners) will be required as the program continues to grow and reach maximum capacity.

Physicians (e.g., pulmonologists, thoracic surgeons, medical oncologists, radiation oncologist, etc.) may need to be recruited to manage the predicted increase in patient volume at each regional site, for services outside of the LCSP. These services could include but are not limited to diagnostic interventions, nodule resections, ultrasounds, cancer care and treatment, etc.

Navigation teams at each regional site will be essential in ensuring the patients who do have positive findings receive timely and coordinated care. Ensuring each regional site is equipped with this resource should be considered as volumes continue to grow.

Additionally, when considering the eligible population for lung cancer screenings in Indiana (about 110,000 individuals), it is unrealistic to expect one health system to accommodate all Hoosiers. It is important to consider, and plan for, the potential need to share resources and collaborate with other health systems. Health systems must work together to to significantly improve lung cancer screening rates to more closely align with other cancer screening programs, such as mammography (75.9%) and colonoscopy (71.8%).[100]

Back to top.

2.3 Shared decision-making

Highlights

- The SDM conversation is a required and integral piece of a lung cancer screening program.
- The SDM should be standardized, streamlined, and conducted by the LCSP navigation team.

As mentioned previously, the shared decision-making (SDM) conversation is an integral piece of the lung cancer screening program. This guided conversation typically takes approximately 15-minutes to complete and reviews the risks and benefits of lung cancer screening. The conversation concludes with the patient consenting or declining to continue in the program. Currently, the SDM conversation is conducted slightly differently at each screening site by the regional LCSP coordinator. In the proposed centralized structure, the lung cancer screening navigator will be responsible for this step. **It is proposed that the SDM conversation is standardized across all sites for the program to improve efficiencies and reduce the burden on both the patient, the primary care team, and the LCSP team.** There are a variety of models and online tools that can be referenced when establishing the standardized SDM for the lung cancer screening program.

2.4 Tobacco treatment

Highlights

- Lung cancer screening programs should be integrated with a tobacco treatment program.
- Intensive interventions such as multiple counselling sessions with pharmacological therapies are most effective.
- The lung cancer screening program at should have a dedicated tobacco counselor resource to refer patients.

Lung cancer screening programs (LCSP) should be integrated with a tobacco treatment program. Evidence-based interventions including nicotine replacement therapy, pharmacotherapy, and counseling should be utilized. Studies of tobacco treatment interventions have shown that intensive interventions such as multiple counselling sessions with pharmacological therapies are most effective, with less intensive interventions such as providing brochures or performing brief counselling having a smaller effect on tobacco treatment rates.[85]

Approximately two thirds of screened individuals may be current smokers. All current smokers undergoing screening should be referred to a tobacco treatment program, which may include counselling, nicotine replacement therapy, and pharmacotherapy.

In Indiana in 2018, 56% of screened individuals were current smokers, and only 78% of current smokers were offered tobacco treatment during screening.[26]

It is recommended that in addition to referring patients to the Indiana Tobacco Quitline, the centralized LCSP should have a dedicated tobacco treatment specialist that patients can be referred to. Patients identified as current smokers through the EMR system should be automatically referred to and scheduled with the tobacco counselor. Patients should then be offered continual support throughout their tobacco treatment and lung cancer screening journey. This may require an additional hire to ensure capacity can be met.

Back to top.

2.5 Lung nodule management

Highlights

- The lung cancer screening program should use the Lung-RADS Reporting and Data System.
- A multidisciplinary Lung Screening Review Board is essential to improve patient care and outcomes through collaborative discussion re: concerning findings.
- Representation from pulmonology, thoracic surgery, lung cancer screening navigation, and medical oncology is essential for success of this review board.

The lung cancer screening programs (LCSP) currently use the Lung-RADS Reporting and Data System (Appendix 3), to identify concerning nodules and systematically escalate care of the concerning nodules through PET imaging, non-surgical, and minimally invasive surgical approaches. It is recommended that the Lung-RADS standardized reporting system should be used as a tool to guide robust multidisciplinary discussion. Prior to August 2023, there was no pathway for multidisciplinary discussion to advise on the evaluation of nodules at high-risk of malignancy across all regional screening sites. The discussion and management of these findings was the sole responsibility of the regional screening program teams.

Based on recommendations from the ELCN Lung Cancer Screening Taskforce, a Lung Screening Review Board was launched in August 2023 to close this gap and improve patient care and outcomes. This Lung Screening Review Board has representation from medical oncology, pulmonology, thoracic surgery, lung cancer screening navigation, and the lung cancer screening program teams. This group currently meets once every 2-weeks to discuss all Lung-RADS Category 0, 3, and 4 cases. In some instances, patients with a Lung-RADS Category 2 result requires further discussion. The decision to present and discuss at the Lung Screening Review Board should be left up to the discretion of the central LCSP leadership team.

It is the recommendation of the ELCN Lung Cancer Screening Taskforce that all Lung-RADS Category 0 and 4 cases and select Lung-RADS Category 3 cases are discussed. It will be the responsibility of the LCSP leadership and navigation team to identify the appropriate Lung-RADS Category 3 cases for discussion. The LCSP navigation and administrative teams will be integral to the success of patient tracking and Review Board discussions.

The ELCN Lung Cancer Screening Taskforce anticipates that with increased screening rates and the implementation of a centralized structure, the Lung Screening Review Board will likely need to start meeting once per week as the program expands.

2.6 Structured reporting and quality management

Highlights

- Internal quality metrics should be collected to identify gaps, educational opportunities, and future improvements.
- Quality metrics related to additional work-up, procedures, tobacco treatment services, etc. should be tracked to demonstrate ROI as program continues to grow.

While the requirement to report lung cancer screening cases to the American College of Radiology was lifted in the 2022 CMS update, **it is recommended by the ELCN Lung Cancer Screening Taskforce that the LCSP navigators and/or the administrative team(s) complete data entry for patient tracking and internal reporting and provide summary results to the centralized LCSP leadership team on an ongoing basis.** The frequency of this reporting should be left up to the discretion of the leadership and navigation teams.

The ELCN Lung Cancer Screening Taskforce also recommends that quality metrics be collected to ensure that at least 90% of screened subjects match the program's stated eligibility policy. Although anyone can suffer from lung cancer, it is strategically important to screen the USPSTF-identified high-risk population, especially while the screening rate in this population is low and screening resources are limited. Strategies to implement the program's eligibility policy include educating referring clinicians on eligibility criteria, establishing EMR-based clinical reminders, conducting human reviews, and providing targeted feedback when ineligible patients are repeatedly referred for screening. The recommended educational strategies are more clearly defined in *Section 2.8 – Patient and Physician/APP Education.*

Additionally, quality metrics should be collected to evaluate the number of surveillance and diagnostic imaging tested performed, non-surgical and surgical biopsies performed for malignant and benign screen-detected nodules, cancer diagnoses, procedure-related adverse events, and the portion of active smokers who are offered, and who participate in, a tobacco treatment intervention. Tracking this information will enable the LCSP team to improve patient outcomes.

Back to top.

2.7 Program payer mix

Highlights

- Establishing a more balanced payer mix is essential to enhance accessibility and improve long-term sustainability.
- A mechanism should be established to cover the cost of screenings for those who are uninsured and cannot afford self-pay.
- Standardizing the approach for reimbursement is critical.
- There is a significant need to increase philanthropic efforts to support patients who are uninsured and cannot pay.

It is the recommendation of the ELCN Lung Cancer Screening Taskforce to have a balanced payer mix of the central LCSP between private insurance, Medicare and Medicaid, and self-pay options for all patients. A diverse payer mix is crucial to ensure accessibility and sustainability.

By encompassing a range of payers—such as private insurance, Medicare, Medicaid, or even self-pay options—LCSPs can effectively cater to a wider population, reducing disparities in healthcare access and ensuring continued support and funding for these critical screenings. This mix facilitates broader participation and enables a more comprehensive reach to underserved communities who might otherwise lack access to such screenings. Additionally, a diverse payer mix supports the financial viability of these programs by mitigating over-reliance on a single source of funding, thereby safeguarding against fluctuations or limitations in reimbursement policies.

Back to top.

There should be a mechanism and/or funding in place to cover the costs, without cost-sharing, for those who are at high-risk, uninsured, and cannot afford a self-pay option. It is recommended by the ELCN Lung Cancer Screening Taskforce that fundraising for foundational support is implemented to support this need.

2.8 Patient and physician/APP education

Highlights

- Adequate patient and physician/APP education is pivotal to increase the rate of eligible Hoosiers who participate in a lung cancer screening program (LCSP).
- Education and awareness must address the stigma and futility towards a lung cancer diagnosis.
- Multiple approaches must be put into place to effectively educate and empower both physicians/APPs and patients.
- Lung cancer screening should become a quality metric in assessing overall performance and effectiveness for physicians/APPs.

Adequate patient and physician/APP education regarding lung cancer screening is pivotal to increase the rate of eligible Hoosiers who participate in a lung cancer screening program (LCSP). Physician/APPs must be well-informed about the latest guidelines, methodologies, and eligibility criteria for lung cancer screening so that they can effectively identify eligible patients and clearly communicate risks and benefits of screenings with those patients. **Patients who are educated are more empowered and better equipped to make informed decisions about their care.**

The ELCN Lung Cancer Screening Taskforce identified a multitude of approaches to improve outreach and education efforts for both patients and physician/APPs. This section outlines key recommendations from the Taskforce that could significantly enhance the overall quality of patient-provider interactions and outcomes in lung cancer prevention, screening, and management.

Physician/APP Education & Support

The ELCN Lung Cancer Screening Taskforce recommends the following approaches to improve physician/APP education, training, and support strategies to improve lung cancer screenings. Combining these strategies would enable the health system to better support and incentivize physician/APPs to actively refer eligible patients to the LCSP and ultimately improve early detection rates and patient outcomes.

Incentivize Physicians/APPs

It is recommended that lung cancer screening becomes a quality metric in assessing their overall performance and effectiveness Additionally, performance-based incentives could be offered based on specified referral targets and feedback loops should be implemented to ensure physician/APPs are informed about the outcomes of the patients they have referred to the LCSP.

Continuing Education

It is recommended that standardized continuing education opportunities related to lung cancer screenings are offered to and required for healthcare professionals within the health system to ensure they are adequately trained to discuss lung cancer screening with patients. Methods to accomplish this include grand round presentations, department meeting presentations, audits, and feedback to individual physician/APPs based on referral patterns. This approach would require collaboration between the LCSP teams, primary care and specialty leaders, and the system's quality care and improvement teams. It is recommended that educational materials be developed and implemented after the recommended

electronic medical record (EMR) changes are in place.

The ELCN Lung Cancer Screening Taskforce also recommends that a needs assessment is conducted prior to developing and implementing any educational opportunities. This will provide a better understanding of the current challenges and barriers for referring physician/APPs and enable the team to develop materials and trainings that are most impactful and relevant.

Individualized Risk Assessment for the Clinical Setting

It is recommended that an individualized cancer risk assessment tool is developed to evaluate a person's likelihood of developing lung cancer. The risk score generated by this tool would be based on various factors such as age, smoking history, exposure to environmental toxins, family history, and potentially genetic markers. This tool would use a sophisticated algorithm to analyze the patient's responses and generate personalized recommendations for preventive care and screenings. Ideally, this risk assessment tool would pull data from the patient's EMR records, past imaging, genetic profiling, etc. to provide a comprehensive risk profile for all cancers and generate a comprehensive "Screening & Prevention Prescription" for the patient. This "Screening & Prevention Prescription" could serve as an educational aid for both the physician/APP and the patient.

This tool should be easily accessible, include simple questions, provide clear action items, and be quick to complete. There should be ample opportunity for discussion of the results between the physician/APP and the patient to ensure there is a clear understanding of the results.

Patient Education & Outreach

The ELCN Lung Cancer Screening Taskforce recommends the following approaches to improve patient education and community awareness for lung cancer screenings. Educated patients are more likely to proactively engage in discussions with their healthcare providers, ask relevant questions, and participate in lung cancer screening programs (LCSP).

Educational Aids & Resources

Educational aids and resources for patients about lung cancer screenings should aim to inform, empower, and encourage participation. The components of general educational resources used for patients in the health system's catchment area should include:

- General information on the importance of lung cancer screening and early detection.
- Risk factors and eligibility criteria and emphasis on who should be screened.
- Clear explanation of the LCSP process and what to expect.
- Risks and benefits of participating in a LCSP.
- Emotional support and coping mechanisms to manage any anxiety or stress associated with screening.

This information should be presented in a variety of formats such as infographics, videos, and interactive tools and apps to cater to different learning styles. All information should be easily accessible and written in plain language. These materials should be available in waiting rooms of clinics, hospitals, and urgent care facilities as well as in discharge summaries from emergency departments and hospitalizations. Additionally, this information should be shared with patients who participate in other screening programs, like mammography or colonoscopy.

The ELCN Lung Cancer Screening Taskforce also recommends developing educational materials that are individualized for patients. As mentioned above, a risk assessment tool

and "Prevention Prescription" should be developed as a resource for both patients and physician/APPs to guide informed healthcare decisions.

Community Outreach & Engagement

It is the recommendation of the ELCN Lung Cancer Screening Taskforce to enhance community outreach efforts to promote lung cancer screenings as a mechanism to reach underserved and high-risk populations to increase awareness, access, and equity. Many individuals who are eligible for lung cancer screening likely do not engage with the healthcare system regularly. It is imperative to meet the community where they are through targeted approaches. ELCN is closely aligned with the Office of Community Outreach and Engagement (OCOE) at the IU Simon Comprehensive Cancer Center and uniquely positioned with hundreds of lung cancer advocates to drive these efforts.

The ELCN Lung Cancer Screening Taskforce identified a list of priority groups as a starting point for these outreach endeavors. The engagement plan for these priority groups will vary based on the unique needs and shared interests of each group. Recruiting and training lay-health advocates to attend community events to raise awareness about lung cancer screenings and provide culturally appropriate educational materials to reduce stigma will enable the lung cancer screening program to engage minority and underserved populations who have been historically underrepresented in lung cancer screening efforts statewide.

Public Health Awareness Campaigns

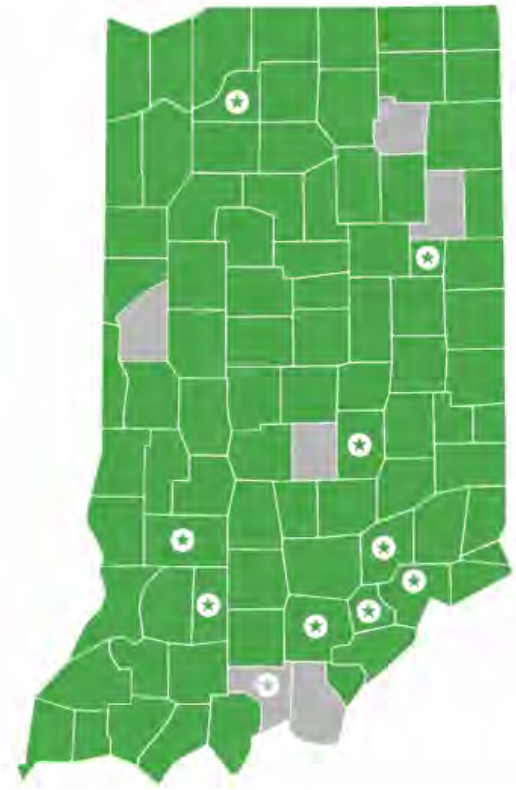
In addition to the targeted outreach for priority populations, **the ELCN Lung Cancer Screening Taskforce recommends developing public health awareness campaigns to promote lung cancer screenings along with other healthy behaviors.** This would require coordination and collaboration with other health-related organizations and would lend itself to a wider audience reach and enhanced messaging for all. This "Healthy Hoosier" campaign would coordinate the efforts amongst a variety of engaged advocates statewide to promote both lung cancer screening efforts along with efforts to reduce obesity, cardiac health, etc.

Additionally, Indiana passed Senate Bill 4 in the 2023 legislative year. This bill incentivizes local health departments to improve their core public health services through additional funding. The state approved a significant funding increase, with $75M allocated for fiscal year 2024 and $150M allocated for 2025. Out of Indiana's 92 counties, 87 "opted in" to receive the additional funding. The total funding provided is determined by population size and the health vulnerability of residents.[95]

The ELCN Lung Cancer Screening Taskforce identified Indiana's top 10 counties related to highest lung cancer incidence and mortality rates, population density, and smoking rates. It is the recommendation of the Taskforce to connect with the county health officers to encourage them to use some of the provided funds to improve education and service efforts for lung cancer screenings. These efforts could be patient or physician/APP focused.

Figure 11 shows which counties have opted in to receive the increased public health funding. Those highlighted green have opted in while those highlighted in gray have opted out. Those with a star have been identified by the ELCN Lung Cancer Screening Taskforce as priority counties and the table provides more details on the incidence, mortality, and smoking rates along with population density for these counties.

Figure 11. Priority counties for public health collaboration to promote lung cancer screenings.



County	Lung Cancer (LC) Mortality	LC Incidence	Current Smokers	Ever Smoked	Population
Scott	74.4 (61.3, 89.7)	92.2 (77.6, 108.9)	33.4 (24.4, 42.5)	58.2 (48.8, 67.5)	24,355
Jennings	72.8 (60.5, 87.0)	87.1 (73.6, 102.5)	33.3 (24.5, 42.1)	56.4 (47.2, 65.7)	27,409
Crawford	66.4 (49.6, 87.9)	71.5 (54.1, 93.8)	31.5 (20.8, 42.1)	53.8 (43.2, 64.5)	10,514
Starke	66.3 (54.5, 80.3)	100.5 (85.6, 117.5)	29.0 (20.1, 37.8)	53.5 (44.1, 62.8)	23,372
Blackford	63.1 (48.2, 82.0)	87.8 (69.4, 110.3)	27.4 (20.1, 34.8)	48.6 (40.4, 56.8)	12,091
Jefferson	62.2 (52.0, 74.0)	85.3 (73.2, 99.0)	28.6 (20.7, 36.5)	55.0 (46.2, 63.8)	33,141
Washington	62.0 (51.0, 74.7)	89.1 (75.9, 104.2)	31.8 (22.6, 40.9)	57.6 (48.0, 67.2)	28,102
Greene	61.2 (51.5, 72.5)	75.6 (64.7, 88.2)	34.2 (24.7, 43.7)	55.3 (45.7, 64.9)	30,786
Martin	61.2 (44.8, 82.6)	72.0 (54.0, 94.9)	36.0 (25.0, 47.1)	60.7 (50.1, 71.3)	9,780
Shelby	59.0 (50.5, 68.5)	88.6 (78.0, 100.3)	31.8 (23.2, 40.4)	57.3 (48.2, 66.3)	45,039

Source: Health First Indiana, available at: https://www.in.gov/health/directory/office-of-the-commissioner/gphc/health-first-funding-updates/

Back to top.

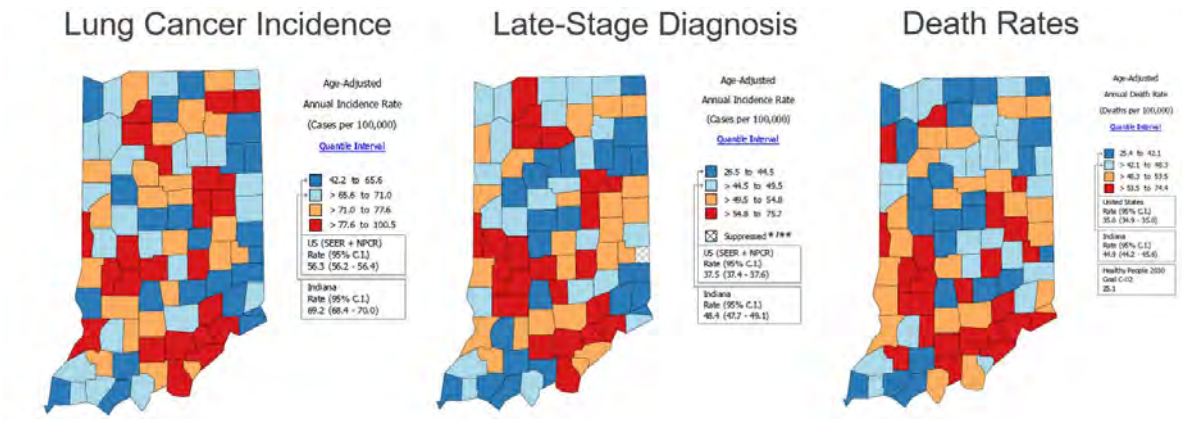
2.9 Mobile lung cancer screening

Highlights

- Rural Hoosiers are at high-risk of lung cancer and have limited access to quality care.
- There is a correlation between lung cancer incidence, late-stage diagnosis, and mortality rates and where people live.
- A mobile lung cancer screening program is planned to launch in 2025 and will become part of the lung cancer screening program.

The ELCN Lung Cancer Screening Taskforce recognizes that there are many factors contributing to the disparities in lung cancer and lung cancer screenings. These factors include, but are not limited to, race/ethnicity, socioeconomic status, rurality, and access to care. Figure 12 includes three heat maps of the counties in Indiana with the highest lung cancer incidence, late-stage diagnosis, and lung cancer mortality rates. The similarities in these maps indicate the correlation between these and where Hoosiers live.

Figure 12. Lung cancer incidence, late-stage diagnosis, and death rates in Indiana

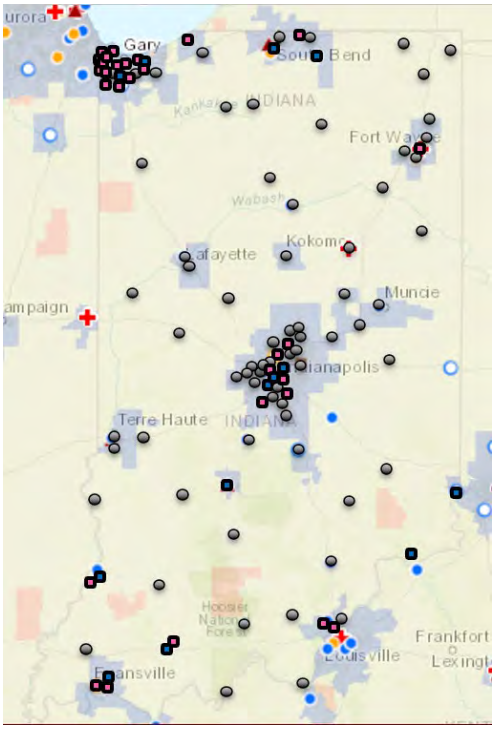


Source: Current State of Lung Cancer 2023 presented at 3rd Annual ELCN Gathering, November 2023; Available at: https://cancer.iu.edu/community/elcn/events/20231103-annual_gathering.html

Many quality lung cancer screening centers are in urban locations – leaving rural patients with poor access to quality care. If you compare the clusters of the screening facilities available across the state in Figure 13 with the cluster of red counties in the lung cancer heat maps, it underscores the need that we must do more for our rural Hoosiers.

Indiana's first-ever mobile lung cancer screening program is scheduled to screen its first patient in early 2025. A mobile screening taskforce has been organized and is tasked with developing a detailed implementation plan. This plan will be released in late 2024.

Figure 13. Locations of lung cancer screening facilities in Indiana



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Appendices

Appendix 1. Lung Cancer Screening Taskforce group members

Name	Title	Taskforce Role
MacKenzie Church	Thoracic Oncology Program Manager, IU Simon Comprehensive Cancer Center; Executive Director, End Lung Cancer Now	Taskforce Co-Chair
Dr. Nasser Hanna	Tom and Julie Wood Family Foundation Professor of Lung Cancer Clinical Research, IU Simon Comprehensive Cancer Center; Chair, End Lung Cancer Now	Taskforce Co-Chair
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Amie Blumling	Patient Advocate	Advocacy Subcommittee Member
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Deborah Buckles	Tobacco Control Branch Lead, Indiana University Simon Comprehensive Cancer Center, Office of Community Outreach & Engagement; Program Director, Rethink Tobacco Indiana	Public Health Subcommittee Member
Becky Butts	Coordinator of Community Education, Indiana University Health	CT Implementation Subcommittee Member
Dr. DuyKhanh Ceppa	Thoracic Surgeon, Indiana University School of Medicine	CT Implementation Subcommittee Member

Dr. Victoria Champion	Associate Director for Cancer Control, Indiana University Simon Comprehensive Cancer Center Office of Community Outreach & Engagement	Public Health Subcommittee Member
Dr. Francesca Duncan	Assistant Professor of Clinical Medicine, Indiana University School of Medicine; Pulmonologist, Indiana University Health	Advocacy Subcommittee Member
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Dr. Greg Kiray	Senior Vice President of Population & Community Health, Indiana University Health; Primary Care Physician, Indiana University Health	Engaging Health Systems Subcommittee Member
Dr. Christopher Kniese	Pulmonologist, Indiana University Health	CT Implementation Subcommittee Member
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Dr. Wade Kvatum	Assistant Professor of Clinical Family Medicine, Indiana University School of Medicine, Department of Family Medicine; Primary Care Physician, Indiana University Health	Primary Care Subcommittee Member
Katie McGill, MSM	Vice President for Clinical Services, Indiana University Health; Associate Director of System Integration, Indiana University Simon Comprehensive Cancer Center	Engaging Health Systems Subcommittee Member
Dr. Nicholas Pettit	Emergency Medicine Physician; Assistant Professor of Emergency Medicine, Indiana University School of Medicine	Primary Care Subcommittee Member
Leo Rafail	Advocate Engagement Coordinator, End Lung Cancer Now	Advocacy Subcommittee Member
Calvin Roberson	Operations Director, Indiana University Simon Comprehensive Cancer Center Office of Community Outreach & Engagement	Advocacy Subcommittee Member
Dr. Catherine Sears	Lung Cancer Screening Program Lead, Roudebush Veterans Administration (VA) Medical Center; Co-Director of the Pulmonary Oncology Clinic, Roudebush VA Medical Center	CT Implementation Subcommittee Member
Dr. William Tierney	Associate Dean of Population Health and Health Outcomes, Indiana University-Purdue University Indianapolis, Fairbanks School of Public Health	Engaging Health Systems Subcommittee Member
Dana Toussant, NP	Pulmonary-Critical Care NP, Indiana University Health West	CT Implementation Subcommittee Member
Dr. Mark Unroe	Assistant Professor of Clinical Medicine, Indiana University School of Medicine; Director of ICU at Indiana University Health West	CT Implementation Subcommittee Member

Appendix 2. Mortality related outcomes: summary of randomized controlled trials

Study, country, sample size	Eligibility	Intervention	Screening frequency	Duration of follow-up	Mortality
NLST[4], USA, n=53,452 **NLST[71] , USA, n=53,452**	55-74 years & ≥30 pack-year smoking	LDCT vs CXR	3 annual scans	> 6.5 years median 12.3 years	LC related mortality RR = 0.84 (0.75 to 0.95) All-cause mortality RR = 0.93 (0.88 to 1.00) LC related mortality RR = 0.89 (0.80 to 0.99) All-cause mortality RR = 0.97 (0.94 to 1.01)
NELSON[6], Netherlands/Belgium, n=13,195 (men), 2,594 (women)	55-75 years & ≥15 pack-years smoking	LDCT vs no screening	4 scans (years 0, 1, 3, 5.5)	> 10 years	LC related mortality RR (men) = 0.76 (0.61 to 0.94) RR (women) = 0.67 (0.38 to 1.14) All-cause mortality RR=1.01 (0.92 to 1.11)
DLCST[47,53], Denmark, N=4,104	50-70 years & ≥20 pack-years smoking	LDCT vs no screening	5 annual scans	median 9.8 years	LC related mortality HR = 1.03 (0.66 to 1.60) All-cause mortality HR = 1.02 (0.82 to 1.27)

MILD[43], Italy, n=4,099	>49 years & ≥20 pack-years smoking	LDCT vs no screening	10 annual scans or 5 biennial scans	> 10 years	LC related mortality HR = 0.61 (0.39 to 0.95) All-cause mortality HR = 0.80 (0.62 to 1.03)
DANTE[52], Italy, N=2,450	60 -74 years & ≥20 pack-years smoking	LDCT vs no screening	4 annual scans	median 8.4 years	LC related mortality HR = 0.99 (0.69 to 1.43) All-cause mortality HR = 0.95 (0.77 to 1.17)
ITALUNG[44], Italy, N=3,206	55 -69 years & ≥20 pack-years smoking	LDCT vs no screening	4 annual scans	median 9.3 years	LC related mortality RR = 0.70 (0.47 to 1.03) All-cause mortality RR = 0.83 (0.67 to 1.03)
LUSI[45], Germany, N=4,052	50 - 69 years & ≥15 cigarettes/day for ≥25 years or ≥10 cigarettes/day for ≥30 years	LDCT vs no screening	5 annual scans	median 8.8 years	LC related mortality HR = 0.74 (0.46 to 1.19) Men: HR = 0.94 (0.54–1.61), Women: HR = 0.31 (0.10–0.96) All-cause mortality HR = 0.99 (0.79 to 1.25)

HR: hazard ratio; LC: lung cancer, LDCT: low-dose computed tomography; CXR: chest X-ray; RR: rate ratio.

Appendix 3. Lung-RADS standardized reporting system v2022

(Assessment Category Release Date: November 2022)

American College of Radiology

Lung-RADS® v2022

Release Date: November 2022

Lung-RADS	Category Descriptor	Findings	Management
0	**Incomplete** Estimated Population Prevalence: ~1%	Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT;
		Part or all of lungs cannot be evaluated	Additional lung cancer screening CT imaging needed;
		Findings suggestive of an inflammatory or infectious process (see note 10)	1-3 month LDCT
1	**Negative** Estimated Population Prevalence: 39%	**No lung nodules OR**	12-month screening LDCT
		Nodule with benign features: • Complete, central, popcorn, or concentric ring calcifications **OR** • Fat-containing	
2	**Benign** - Based on imaging features or indolent behavior Estimated Population Prevalence: 45%	**Juxtapleural nodule:** • < 10 mm (524 mm^3) mean diameter at baseline or new **AND** • Solid, smooth margins, and oval, lentiform, or triangular shape	
		Solid nodule: • < 6 mm (< 113 mm^3) at baseline **OR** • New < 4 mm (< 34 mm^3)	
		Part solid nodule: • < 6 mm total mean diameter (< 113 mm^3) at baseline	
		Non solid nodule (GGN): • < 30 mm (< 14,137 mm^3) at baseline, new, or growing **OR** • ≥ 30 mm (≥ 14,137 mm^3) stable or slowly growing (see note 7)	
		Airway nodule, subsegmental - at baseline, new, or stable (see note 11)	
		Category 3 lesion that is stable or decreased in size at 6-month follow-up CT **OR** Category 4B lesion proven to be benign in etiology following appropriate diagnostic workup	
3	**Probably Benign** - Based on imaging features or behavior Estimated Population Prevalence: 9%	**Solid nodule:** • ≥ 6 to < 8 mm (≥ 113 to < 268 mm^3) at baseline **OR** • New 4 mm to < 6 mm (34 to < 113 mm^3)	6-month LDCT
		Part solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm^3) with solid component < 6 mm (< 113 mm^3) at baseline **OR** • New < 6 mm total mean diameter (< 113 mm^3)	
		Non solid nodule (GGN): • ≥ 30 mm (≥ 14,137 mm^3) at baseline or new	
		Atypical pulmonary cyst: (see note 12) • Growing cystic component (mean diameter) of a thick-walled cyst	
		Category 4A lesion that is stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	
4A	**Suspicious** Estimated Population Prevalence: 4%	**Solid nodule:** • ≥ 8 to < 15 mm (≥ 268 to < 1,767 mm^3) at baseline **OR** • Growing < 8 mm (< 268 mm^3) **OR** • New 6 to < 8 mm (113 to < 268 mm^3)	3-month LDCT; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm^3) solid nodule or solid component
		Part solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm^3) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm^3) at baseline **OR** • New or growing < 4 mm (< 34 mm^3) solid component	
		Airway nodule, segmental or more proximal - at baseline (see note 11)	
		Atypical pulmonary cyst: (see note 12) • Thick-walled cyst **OR** • Multilocular cyst at baseline **OR** • Thin- or thick-walled cyst that becomes multilocular	

Continued on next page.

American College of Radiology

Lung-RADS® v2022

Release Date: November 2022

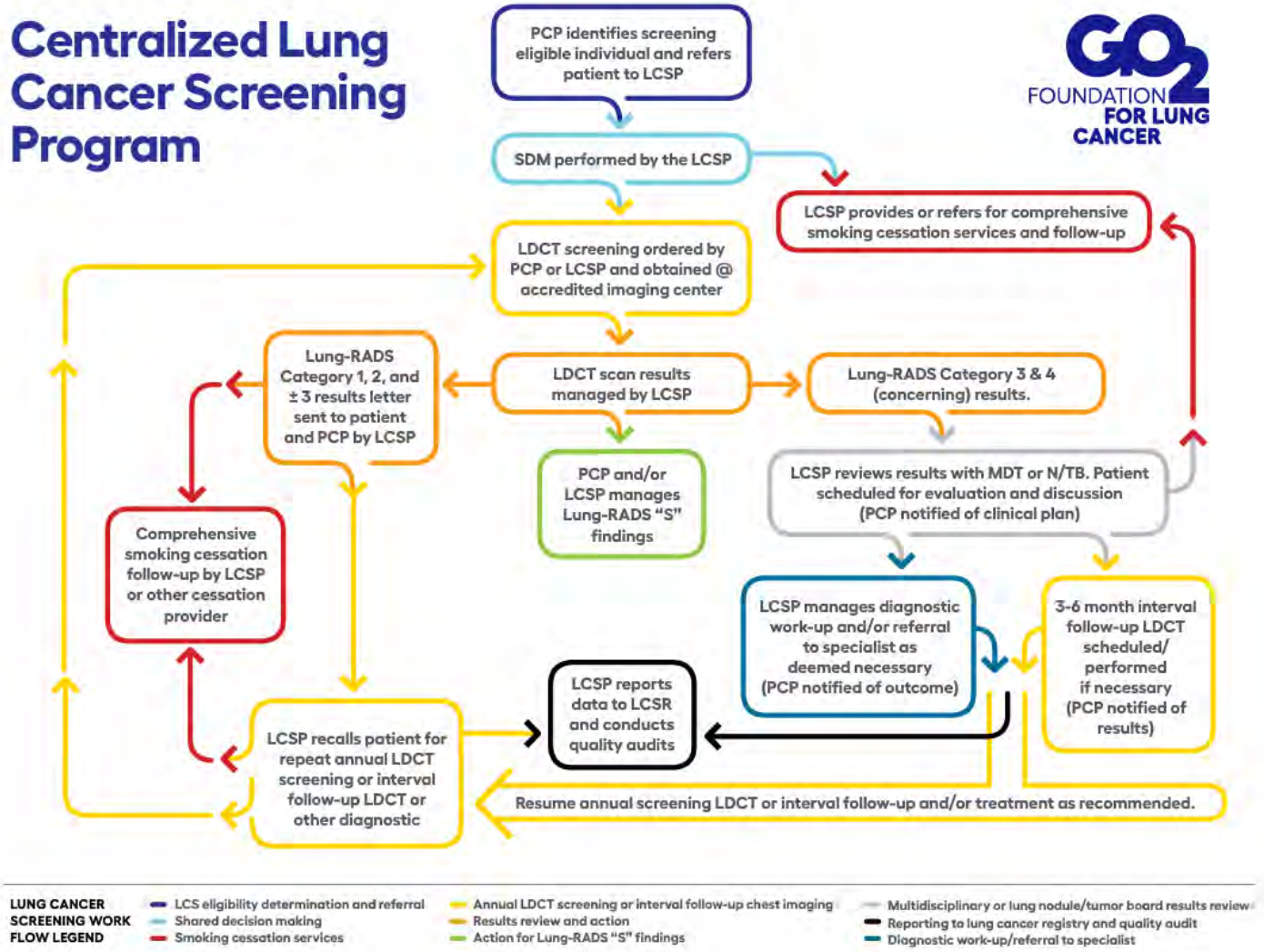
Lung-RADS	Category Descriptor	Findings	Management
4B	**Very Suspicious** Estimated Population Prevalence: 2%	**Airway nodule**, segmental or more proximal - stable or growing (see note 11)	Referral for further clinical evaluation
		Solid nodule: • ≥ 15 mm (≥ 1767 mm^3) at baseline **OR** • New or growing ≥ 8 mm (≥ 268 mm^3)	Diagnostic chest CT with or without contrast; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm^3) solid nodule or solid component; tissue sampling; and/or referral for further clinical evaluation Management depends on clinical evaluation, patient preference, and the probability of malignancy (see note 13)
		Part solid nodule: • Solid component ≥ 8 mm (≥ 268 mm^3) at baseline **OR** • New or growing ≥ 4 mm (≥ 34 mm^3) solid component	
		Atypical pulmonary cyst: (see note 12) • Thick-walled cyst with growing wall thickness/nodularity **OR** • Growing multilocular cyst (mean diameter) **OR** • Multilocular cyst with increased loculation or new/increased opacity (nodular, ground glass, or consolidation)	
		Slow growing solid or part solid nodule that demonstrates growth over multiple screening exams (see note 8)	
4X	Estimated Population Prevalence: <1%	Category 3 or 4 nodules with additional features or imaging findings that increase suspicion for lung cancer (see note 14)	
S	**Significant or Potentially Significant** Estimated Population Prevalence: 10%	**Modifier:** May add to category 0-4 for clinically significant or potentially clinically significant findings unrelated to lung cancer (see note 15)	As appropriate to the specific finding

Source: American College of Radiology: https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads

Appendix 4. List of Abbreviations

CI	Confidence interval
CT	Computed tomography
ELCN	End Lung Cancer Now
HR	Hazard ratio
ICER	Incremental cost-effectiveness ratio
LCSP	Lung cancer screening program
LDCT	Low-dose computed tomography
LC	Lung cancer
LY	Life years
NRT	Nicotine replacement therapy
RCT	Randomized controlled trial
RR	Relative risk
QALY	Quality adjusted life years
SES	Socio-economic status
THETA	Toronto Health Economics and Technology Assessment
USPSTF	United States Preventive Services Task Force

Appendix 5. GO2 Foundation for Lung Cancer – Centralized Program Workflow



Available at: https://go2.org/for-professionals/screening-program-structure-models/