NCCN Guidelines® Insights

Lung Cancer Screening, Version 1.2015
Featured Updates to the NCCN Guidelines

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Abstract

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Lung Cancer Screening provide recommendations for selecting individuals for lung cancer screening, and for evaluation and follow-up of nodules found during screening, and are intended to assist with clinical and shared decision-making. These NCCN Guidelines Insights focus on the major updates to the 2015 NCCN Guidelines for Lung Cancer Screening, which include a revision to the recommendation from category 2B to 2A for one of the high-risk groups eligible for lung cancer screening. For low-dose CT of the lung, the recommended slice width was revised in the table on “Low-Dose Computed Tomography Acquisition, Storage, Interpretation, and Nodule Reporting.” (J Natl Compr Canc Netw 2015;13:23–34)

Please Note

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a statement of consensus of the authors regarding their views of currently accepted approaches to treatment. The NCCN Guidelines® Insights highlight important changes to the NCCN Guidelines® recommendations from previous versions. Colored markings in the algorithm show changes and the discussion aims to further the understanding of these changes by summarizing salient portions of the NCCN Guideline Panel discussion, including the literature reviewed.

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**Overview**
Lung cancer is the leading cause of cancer-related mortality in the United States and worldwide.¹⁻⁴ In 2014, it was estimated that 159,260 deaths (86,930 in men; 72,330 in women) from lung cancer would occur in the United States.¹ Currently, most lung cancer is diagnosed clinically when patients present with symptoms such as persistent cough, chest pain, and weight loss; unfortunately, patients with these symptoms usually have advanced lung cancer. Not surprisingly, the 5-year survival rate is only 16.8%.⁵⁻⁶ Early detection of lung cancer is an important opportunity for decreasing mortality. Data support using low-dose computed tomography (LDCT) to screen individuals at high risk for lung cancer.⁷⁻¹¹ Chest radiograph is not recommended for lung cancer screening.¹¹,¹²

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Lung Cancer Screening were developed in 2011 and have been updated for each new edition to ensure that the recommendations are based on the latest evidence and best practices. The current version, published in January 2015, reflects the latest findings and recommendations for lung cancer screening.

**NCCN Guidelines Insights**

**Overview**
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**RISK ASSESSMENT**

- Smoking history
- Present or past
- Radon exposure
- Occupational exposure
- Cancer history
- Family history of lung cancer
- Disease history (COPD or pulmonary fibrosis)
- Smoking exposure (second-hand smoke)
- Absence of symptoms or signs of lung cancer (if symptoms, see appropriate NCCN Guidelines)

**RISK STATUS**

<table>
<thead>
<tr>
<th>High risk:</th>
<th>Moderate risk:</th>
<th>Low risk:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 55-74 y and ≥30 pack-year history of smoking and Smoking cessation &lt;15 y (category 1) or Age ≥50 y and ≥20 pack-year history of smoking and One additional risk factor (other than second-hand smoke)</td>
<td>Age ≥50 y and ≥20 pack-year history of smoking or second-hand smoke exposure No additional risk factors</td>
<td>Age &lt;50 y and/or &lt;20 pack-year history of smoking</td>
</tr>
</tbody>
</table>

**Overview**
Lung cancer is the leading cause of cancer-related mortality in the United States and worldwide.¹⁻⁴ In 2014, it was estimated that 159,260 deaths (86,930 in men; 72,330 in women) from lung cancer would occur in the United States.¹ Currently, most lung cancer is diagnosed clinically when patients present with symptoms such as persistent cough, chest pain, and weight loss; unfortunately, patients with these symptoms usually have advanced lung cancer. Not surprisingly, the 5-year survival rate is only 16.8%.⁵⁻⁶ Early detection of lung cancer is an important opportunity for decreasing mortality. Data support using low-dose computed tomography (LDCT) to screen individuals at high risk for lung cancer.⁷⁻¹¹ Chest radiograph is not recommended for lung cancer screening.¹¹,¹²

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**NCCN Categories of Evidence and Consensus**

**Category 1:** Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

**Category 2A:** Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

**Category 2B:** Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

**Category 3:** Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

All recommendations are category 2A unless otherwise noted.

Clinical trials: NCCN believes that the best management for any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.
Tobacco smoking is a major modifiable risk factor in the development of lung cancer and accounts for most lung cancer–related deaths.\textsuperscript{2–17} Smoking tobacco is also associated with other cancers and diseases, and an estimated 443,000 adults in the United States die from smoking-related illnesses each year.\textsuperscript{18} Tobacco smoke contains more than 7000 compounds, of which more than 50 are known carcinogens.\textsuperscript{19–21} The risk of developing lung cancer from smoking tobacco has been firmly established, with the relative risk for lung cancer being approximately 20-fold higher\textsuperscript{2,22} for smokers than for nonsmokers.

Cessation of tobacco smoking decreases the risk for lung cancer.\textsuperscript{23–26} However, even former smokers have a higher risk for lung cancer than never-smokers. Lung cancer screening is not a substitute for smoking cessation. Smokers, including those undergoing lung cancer screening, should always be encouraged to quit smoking tobacco (http://www.smokefree.gov/),\textsuperscript{27,28} and former smokers should be encouraged to remain abstinent. Programs using behavioral counseling combined with FDA-approved medica-
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Estimates are that lung screening with LDCT will cost $81,000 per quality-adjusted life-year (QALY) gained and $52,000 per life-year gained, which is less than a threshold level of $100,000 per QALY gained that some experts consider to be a reasonable value in the United States. Guidelines published before the CISNET (Cancer Intervention and Surveillance Modeling Network) modeling studies used by the USPSTF, including those from the American College of Chest Physicians and ASCO, recommend lung cancer screening for individuals who meet the high-risk criteria of the NLST (ie, smokers and former smokers at high risk based on age and smoking history [ages 55–74 years with a ≥30 pack-year smoking history]).

LDCT Screening

Results from the NLST support screening in select individuals who are at high risk for lung cancer. Although smoking tobacco is a well-established risk factor for lung cancer, other environmental and genetic factors also increase risk. Screening with LDCT should only be considered for select high-risk individuals if they are potential candidates for curative-intent therapy. The NCCN panel recommends lung cancer screening for high-risk individuals but not for moderate-risk and low-risk individuals (see LCS-1, page 25).

Selection of Individuals for Lung Screening Based on High-Risk Status

Current or past history of tobacco smoking is the biggest risk factor for the development of lung cancer. In the NCCN Guidelines, current and former smokers aged 55 to 74 years with a 30 or more pack-year history of smoking tobacco are selected as the highest-risk group for lung cancer and are recommended for screening (category 1) based on criteria for entry into the NLST (see LCS-1, page 25).

Former smokers with a 30 pack-year smoking history who quit smoking less than 15 years ago are also included in this highest-risk group (category 1). Data for determining whether individuals are at high risk for cancer are based on cigarette smoking and not on other kinds of tobacco products that may also put individuals at risk for cancer. Other risk factors for lung cancer include occupational exposure to carcinogens, radon exposure, cancer history, history of...
lung disease, and family history of lung cancer (see LCS-1, page 25). 16,50,51

The NCCN panel recommends lung cancer screening using LDCT for individuals with high-risk factors; 2 groups of individuals qualify as high risk (see LCS-1, page 25):

• Group 1: Aged 55 to 74 years; 30 or more pack-year history of smoking tobacco; and currently smoke or, if former smoker, have quit within 15 years (category 1). 11,13 This is a category 1 recommendation, because these individuals are selected based on the NLST inclusion criteria. 11,13 An NCCN category 1 recommendation is based on high-level evidence (ie, randomized controlled trial) and uniform consensus (≥85%) among panel members. Annual screening is recommended for these high-risk individuals for 2 years (category 1) based on the NLST. 11 Annual screening is recommended until the individual is no longer eligible for definitive treatment (category 2A). Uncertainty exists about the appropriate duration of screening and the age at which screening is no longer appropriate.

• Group 2: Aged 50 years or older, 20 or more pack-year history of smoking tobacco, and one additional risk factor (other than second-hand smoke) (category 2A). This is a category 2A recommendation, because these individuals are selected based on lower level evidence, such as nonrandomized studies, observational data, and ongoing randomized trials. 40,54-60 Most panel members (≥85%) would recommend LDCT for these individuals. 61 Additional risk factors include cancer history, lung disease history, family history of lung cancer, radon exposure, and occupational exposure to carcinogens. 16,50,51,53,62-65 The NCCN panel does not believe that exposure to secondhand smoke is an independent risk factor, because the data are either weak or variable.

In the NCCN Guidelines, the age range for LDCT was extended for individuals in the high-risk group 2 for several reasons. The NCCN panel feels that individuals in group 2 are also at high risk for lung cancer based on data from the NLST and other studies as discussed later. NCCN panel members feel that limitation to the NLST criteria alone is arbitrary and naïve, because the NLST used only age and smoking history for inclusion criteria and did not consider other well-known risk factors for lung cancer. Others share this opinion. 48,66 Three ongoing phase III randomized trials are screening younger individuals aged 50 to 55 years and older individuals up to 70 to 75 years. The NELSON and UKLS trials are assessing LDCT in individuals 50 to 75 years of age. 34,35,37,40 The Danish Lung Cancer Screening Trial (DLCST) is screening individuals 50 to 70 years of age. 54,67 Several studies have assessed LDCT using an extended age range of 50 to 85 years. 68-70

For the 2015 update, the NCCN panel unanimously voted to revise the recommendation from category 2B to 2A for individuals aged 50 years or older with a 20 or more pack-year smoking history and 1 additional risk factor (other than second-hand smoke) (see LCS-1, page 25). 15 In earlier versions of the NCCN Guidelines, the panel recommended consideration of screening for this group, but without uniform consensus. The panel feels that it is important to expand screening beyond the NLST criteria to a larger group of at-risk individuals. 15,71 Using just the narrow NLST criteria, shown in group 1 of the NCCN high-risk category (eg, individuals aged 55–74 years with a ≥30 pack-year smoking history), only 27% of patients currently being diagnosed with lung cancer will be covered. 71 A study reported that expanding the high-risk groups eligible for screening, for example including individuals aged 50 or more years with a 20 or more pack-year smoking history and 1 additional risk factor (other than second-hand smoke), may save thousands of additional lives. 15

**Age Cutoff and Duration of Screening**

What the age cutoff should be at which screening is no longer appropriate is uncertain. 46 The NCCN Guidelines acknowledge that select high-risk individuals older than 74 years are also eligible for LDCT. At diagnosis of lung cancer, the median age of patients is 70 years. 5 Approximately 53% of lung cancer is diagnosed in patients aged 55 to 74 years, and approximately 28% is diagnosed in older patients aged 75 to 84 years; screening may benefit the latter population. 72 The USPSTF recommends LDCT for individuals aged 55 to 80 years. 48 Similarly, the American Association for Thoracic Surgery (AATS) recommends LDCT for individuals aged 55 to 79 years who are high risk. 48 In addition, data from...
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modeling studies suggest that the most advantageous age range for screening is 55 to 80 years old. Thus, annual LDCT seems reasonable for select individuals who are at high risk and older than 74 years and are eligible for definitive treatment, generally defined as curative intent therapy, including surgery, chemotherapy, and stereotactic body radiation therapy (SBRT) (also known as stereotactic ablative radiotherapy [SABR]).

In patients with negative LDCT scans or those whose nodules do not meet the size cutoff for more frequent scanning or other intervention, the NCCN Guidelines recommend considering annual LDCT until individuals are no longer eligible for definitive treatment (see the complete version of these guidelines at NCCN.org). Uncertainty exists about the appropriate duration of screening. After the 3 rounds of LDCT in the NLST, new cases (n=367) of lung cancer were frequently diagnosed during the 3.5 years of follow-up (median, 6.5 years). The NLST data show that lung cancer continues to occur over time in individuals who are at high risk. The incidence of and death rate from lung cancer did not change during the 7 years of the NLST. Thus, the NLST data support annual LDCT for at least 2 years but do not define a time limit on efficacy.

Management of Nodules Found on LDCT

As shown in the algorithm, LDCT is recommended for detecting noncalcified nodules that may be suspicious for lung cancer depending on their type and size (see the complete version of the NCCN Guidelines for Lung Cancer Screening at NCCN.org). Most noncalcified nodules are solid. Solid and subsolid nodules are the 2 main types of pulmonary nodules. Subsolid nodules include nonsolid nodules, also known as ground glass opacities or ground glass nodules, and part-solid nodules, which contain both ground glass and solid components. Nonsolid nodules are mainly adenocarcinoma in situ or minimally invasive adenocarcinoma, formerly known as bronchioloalveolar carcinomas. Patients have a 5-year disease-free survival rate of 100% if completely resected. Noncalcified nodules are mainly minimally invasive adenocarcinomas, formerly known as bronchioloalveolar carcinomas. Patients have a 5-year disease-free survival rate of 100% if completely resected. Data suggest that many nonsolid nodules resolve, and most that persist may not progress to clinically significant cancer. Solid and part-solid nodules are more likely to be invasive, faster-growing cancers, factors that are reflected in the increased suspicion and follow-up of these nodules.

The NCCN recommendations are an adaptation of the Fleischner Society guidelines for solid and subsolid nodules, NLST data, and the International Early Lung Cancer Action Program (IELCAP) protocol guidelines (http://www.ielcap.org/protocols). Studies suggested that the definition of a positive result from an LDCT scan should be revised, because the original definition from the NLST was associated with a high percentage of false-positive results. Thus, the cutoff sizes for assessing lung nodules currently recommended by NCCN and the American College of Radiology (ACR) have been increased to 6 mm rather than the 4 mm originally used in the NLST and earlier versions of the NCCN Guidelines for Lung Cancer Screening.

The NCCN-recommended cutoff sizes for solid and subsolid nodules detected on LDCT scans are shown in the algorithm (see the complete version of the guidelines at NCCN.org). For nodules that are immediately suspicious for malignancy, diagnostic procedures and/or surgical excision is recommended. For nodules of borderline concern, assessment with interval LDCT scans is often recommended to determine whether the nodule is changing to a suspicious form by increasing in size and/or having a new or growing solid component. For solid or part-solid nodules, the NCCN definition of a positive scan is a solid nodule measuring 6 mm; nodules of this size require a short-term follow-up LDCT scan in 3 months to assess for malignancy. For nonsolid lesions, the NCCN-recommended cutoff is greater than 5 mm; nodules of this size require a short-term follow-up LDCT scan in 6 months to assess for malignancy. NCCN Guidelines emphasize that nonsolid lesions must be evaluated using thin slices (<1.5 mm) to increase the sensitivity for a solid component and to detect subtle changes over time.

The ACR has developed the Lung Imaging Reporting and Data System (Lung-RADS) to standardize the reporting and management from LDCT lung examinations. The use of Lung-RADS has been reported to decrease false-positive results. The NCCN panel is working to harmonize the NCCN Guidelines for Lung Cancer Screening with Lung-RADS.

LDCT Technical Parameters

Multidetector CT (MDCT) has made it possible to detect and better characterize small lung nodules using fast single-breath-hold acquisitions of the entire
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Lung cancer screening with LDCT should be part of a program of care and should not be performed in isolation as a freestanding test. \(^{112,113}\) Trained personnel and an organized administrative system for contacting individuals to achieve compliance with recommended follow-up studies are required for an effective lung screening program. \(^{112}\) NCCN-recommended follow-up intervals for LDCT assume compliance with follow-up recommendations. To help ensure good image quality, all LDCT screening programs should use CT scanners that meet quality standards equivalent to or exceeding the accreditation standards of the ACR. Lung-RADS has been shown to improve the detection of lung cancer and decrease the false-positive rate to approximately 1 in 10 screened individuals compared with more than 1 in 4 in NLST. \(^{16,96,112}\)

**Benefits and Risks of Screening**

The goal of screening is to identify disease at an early stage while it is still treatable and curable. The potential huge benefits of lung cancer screening include a reduction in mortality and an improvement in quality of life. \(^{114,115}\) Risks of lung screening include false-negative and false-positive results, radiation exposure, overdiagnosis of incidental findings, futile detection of aggressive disease, anxiety, unnecessary testing, complications from diagnostic work-up, and financial costs. \(^{115–119}\) Most lung nodules found on LDCT are benign; if possible, these nodules should be assessed using noninvasive procedures to avoid the morbidity of invasive procedures in patients who may not have cancer. \(^{77,117}\)

**Shared Decision-Making**

Because of the high percentage of false-positive results and the downstream management that ensues for many individuals, the risks and benefits of lung cancer screening should be discussed before a screening LDCT scan is performed. \(^{73,89,114,120–122}\) Shared patient/physician decision-making may be the best approach before deciding whether to perform LDCT lung screening, especially for patients with comorbid conditions (see LCS-1, page 25). \(^{41–43}\) Smoking cessation counseling is recommended. \(^{123}\) Lung screening is not recommended for individuals who are not able or willing to have curative therapy because of health problems or other major concerns. \(^{31}\) Institutions performing lung cancer screening should use a multidisciplinary approach that may include specialties, such as chest radiology, pulmonary medicine, and thoracic surgery. \(^{124}\)
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Summary

These NCCN Guidelines Insights focus on some of the major updates to the 2015 NCCN Guidelines for Lung Cancer Screening. The NCCN panel voted to revise the recommendation for LDCT screening from category 2B to 2A for individuals aged 50 years or more with a 20 or more pack-year smoking history and 1 additional risk factor (other than second-hand smoke) (see LCS-1, page 25). This recommendation was revised because the panel feels that it is important to expand screening beyond the NLST criteria to a larger group of at-risk individuals. Using just the narrow NLST criteria, which are individuals aged 55 to 74 years with 30 or more pack-year smoking history, only 27% of patients currently being diagnosed with lung cancer will be covered. Shared decision-making is important when a patient begins a program of annual lung cancer screening, especially for those with comorbid conditions. For LDCT of the lung, the recommended slice width was revised (see LCS-A, page 26). The preferred slice width was revised to 1.0 mm or less (from ≤1.5 mm) and the acceptable slice width was revised to 2.5 mm or less (from ≤3.0 mm) based on Lung-RADS (see LCS-A, page 26). The table discussing LDCT parameters was moved from the discussion text to the algorithm to increase awareness of this important information (see LCS-A, page 26). The ACR’s recently developed Lung-RADS structured reporting and management system seems to improve the detection of lung cancer and decrease the false-positive rate.

References


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Instructions for Completion
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Posttest Questions
1. Lung cancer screening using LDCT is recommended by the NCCN Guidelines for which of the following individuals?
   1. Individuals 55 to 74 years of age who have smoked fewer than 10 packs of cigarettes in their lifetime.
   2. Former smokers 55 to 74 years of age who smoked 1 pack of cigarettes/day for less than 10 years, quit smoking more than 15 years ago, and have a family history of lung cancer.
   3. Current smokers 55 to 74 years of age who have smoked 2 pack of cigarettes/day for at least 15 years.
   4. Former smokers 55 to 74 years of age, who quit less than 15 years ago, but who previously smoked 1 pack of cigarettes/day for at least 30 years.
   There is only one correct answer.
   a. 1 and 2
   b. 2 and 3
   c. 3 and 4
   d. 2 and 4
2. True or False: Pack years of smoking history is defined as the number of packs of cigarettes smoked every day multiplied by the number of years of smoking.
3. Clinician/patient shared decision-making is an excellent approach when deciding whether to recommend lung cancer screening using LDCT to individuals determined to be at high risk for lung cancer for which of the following reasons?
   1. Individuals at high risk need to know that lung screening with LDCT may lead to invasive procedures for a problem that turns out to be benign.
   2. Individuals at high risk need to know that lung screening with LDCT may result in a diagnosis of advanced lung cancer, which cannot be cured by treatment.
   3. Individuals at high risk should also be offered other effective lung screening options, such as chest radiography.
   4. Elderly patients with comorbid conditions who are at high risk because of their smoking history should be persuaded that lung screening with LDCT will not harm them and is very advantageous.
   There is only one correct answer.
   a. 1 and 2
   b. 2 and 3
   c. 2 and 4
   d. 1 and 4