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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Lung Cancer Screening, Version 1.2015

NCCN: Continuing Education

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Learning Objectives:
Upon completion of this activity, participants will be able to:
• Integrate into professional practice the updates to NCCN Guidelines for Lung Cancer Screening
• Describe the rationale behind the decision-making process for developing the NCCN Guidelines for Lung Cancer Screening

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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

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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.

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### Risk Assessment\(^a,b\)

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

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### Risk Status

- **High risk:**
  - Age 55-74 y and
  - ≥30 pack-year history of smoking and
  - Smoking cessation <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)

- **Moderate risk:**
  - Age ≥50 y and
  - ≥20 pack-year history of smoking or second-hand smoke exposure\(^h\)
  - No additional risk factors

- **Low risk:**
  - Age <50 y and/or
  - <20 pack-year history of smoking

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For patients eligible for screening, shared patient/physician decision making is required, including a discussion of benefits/risks.

See Screening and Findings (LCS-2)

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### Screening and Findings (LCS-2)

**High risk:**

For patients eligible for screening, shared patient/physician decision making is required, including a discussion of benefits/risks.

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**Moderate risk:**

Routine lung cancer screening not recommended

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**Low risk:**

Routine lung cancer screening not recommended

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\(^a\)It is recommended that institutions performing lung cancer screening use a multidisciplinary approach that includes the specialties of thoracic radiology, pulmonary medicine, and thoracic surgery.

\(^b\)Lung cancer screening is appropriate to consider for high-risk patients who are potential candidates for definitive treatment. Chest x-ray is not recommended for lung cancer screening.

\(^c\)All current smokers should be advised to quit smoking, and former smokers should be advised to remain abstinent from smoking (http://www.surgeongeneral.gov/initiatives/tobacco/index.html). For additional cessation support and resources, smokers can be referred to http://www.smokefree.gov. Lung cancer screening should not be considered a substitute for smoking cessation.

\(^d\)Documented high radon exposure.

\(^e\)Agents that are identified specifically as carcinogens targeting the lungs: silica, cadmium, asbestos, arsenic, beryllium, chromium, diesel fumes, nickel, coal smoke, and soot.

\(^f\)There is increased risk of developing new primary lung cancer among survivors of lung cancer, lymphomas, cancers of the head and neck, or smoking-related cancers.

\(^g\)Individuals exposed to second-hand smoke have a highly variable exposure to the carcinogens, with varying evidence for increased risk after this variable exposure. Therefore, second-hand smoke is not independently considered a risk factor for lung cancer screening.

\(^h\)Routine lung cancer screening not recommended

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**High risk:**

- Age 55-74 y and
- ≥30 pack-year history of smoking and
- Smoking cessation <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)

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**Moderate risk:**

- Age ≥50 y and
- ≥20 pack-year history of smoking or second-hand smoke exposure\(^h\)
- No additional risk factors

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**Low risk:**

- Age <50 y and/or
- <20 pack-year history of smoking

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**See Screening and Findings (LCS-2)**

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**Routine lung cancer screening not recommended**
updated every year. These guidelines (1) describe risk factors for lung cancer; (2) recommend criteria for selecting high-risk individuals for screening; (3) provide recommendations for evaluation and follow-up of nodules found during screening; (4) discuss the accuracy of LDCT screening protocols and imaging modalities; and (5) discuss the benefits and risks of screening. Updates to the 2015 version of these guidelines include a revision to the recommendation from category 2B to 2A for one of the high-risk groups eligible for lung cancer screening (see LCS-1, page 25, and “Selection of Individuals for Lung Screening Based on High-Risk Status,” page 27; to view the complete and most recent version of these guidelines, visit NCCN.org). Furthermore, for LDCT of the lung, the recommended slice width was revised (see LCS-A, above, and “Management of Nodules Found on LDCT,” page 29).

Tobacco smoking is a major modifiable risk factor in the development of lung cancer and accounts for most lung cancer–related deaths. 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. Tobacco smoke contains more than 7000 compounds, of which more than 50 are known carcinogens. 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 for smokers than for nonsmokers. Cessation of tobacco smoking decreases the risk for lung cancer. 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/), and former smokers should be encouraged to remain abstinent. Programs using behavioral counseling combined with FDA-approved medica-

<table>
<thead>
<tr>
<th>Acquisition</th>
<th>Small Patient (BMI ≤30)</th>
<th>Large Patient (BMI &gt;30)</th>
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<tr>
<td>Total radiation exposure</td>
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<td>≤5 mSv</td>
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<tr>
<td>kVp</td>
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<td>120</td>
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<tr>
<td>mAs</td>
<td>≤40</td>
<td>≥60</td>
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All Patients

| Gantry rotation speed | ≤0.5 |
| Detector collimation | ≤1.5 mm |
| Slice width | ≤2.5 mm; ≤1.0 mm preferred |
| Slice interval | ≤slice width; 50% overlap preferred for 3D and CAD applications |
| Scan-acquisition time | ≤10 seconds (single breath hold) |

Breathing

| Contrast | No oral or intravenous contrast |

CT scanner detectors

| Storage | All acquired images, including thin sections; MIPs and CAD renderings if used |

Interpretation Tools

| Platform | Computer workstation review |
| Image type | Standard and MIP images |
| Comparison studies | Comparison with prior chest CT images (not reports) is essential to evaluate change in size, morphology, and density of nodules; review of serial chest CT exams is important to detect slow growth |

Nodule Parameters

| Size | Largest mean diameter on a single image* |
| Density | Solid, ground-glass, or mixed† |
| Calcification | Present/absent; if present: solid, central vs. eccentric, concentric rings, popcorn, stippled, amorphous |
| Fat | Report if present |
| Shape | Round/ovoid, triangular |
| Margin | Smooth, lobulated, spiculated |
| Lung location | By lobe of the lung, preferably by segment, and if subpleural |
| Location in dataset | Specify series and image number for future comparison |
| Temporal comparison | If unchanged, include the longest duration of no change as directly viewed by the interpreter on the images (not by report); if changed, report current and prior size |

BMI = body mass index; CAD = computer-aided diagnosis; CT = computed tomography; MIP = maximum intensity projection.
*Mean of the longest diameter of the nodule and its perpendicular diameter, when compared to the baseline scan.
†Mixed; otherwise referred to as part solid.
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Randomized Trials for Lung Screening

Disease-specific mortality, which is the number of cancer deaths relative to the number of individuals screened, is considered the ultimate test of screening effectiveness and is the only metric without bias. Randomized controlled screening trials are essential for determining whether cancer screening decreases disease-specific mortality. Nonrandomized trials are subject to biases that may cause an apparent increase in survival. Multiple randomized trials are assessing LDCT screening for lung cancer among high-risk groups, including the National Lung Screening Trial (NLST), sponsored by the NCI; the Dutch-Belgian randomized trial (NELSON); and the UK Lung Cancer Screening Trial (UKLS). Results from the NLST show that LDCT decreased the risk of death from lung cancer by 20% (95% CI, 6.8–26.7; \( P = .004 \)) in high-risk smokers compared with chest radiography alone, and that to prevent 1 lung cancer death, it is necessary to screen 320 high-risk individuals. Although the NLST also reported a 7% decrease in all-cause mortality, the apparent decrease was not significant after lung cancer mortality had been subtracted.

Lung Cancer Screening Guidelines

NCCN was the first major organization to develop lung cancer screening guidelines using LDCT based on the NLST data. The US Preventive Services Task Force (USPSTF) recommends lung screening for 55- to 80-year-old individuals with a 30 pack-year or more history of smoking who are either current or former smokers who quit within the last 15 years. Their grade B recommendation means that lung screening is required to be covered by private payers as an essential health benefit without copay under the Affordable Care Act beginning in January 2015. In November 2014, the Centers for Medicare & Medicaid Services (CMS) released their draft coverage decision to pay for lung cancer screening in 55- to 74-year-old individuals with the same smoking history used by the USPSTF, with requirements such as documented shared decision-making and participation in a clinical registry. The final decision will be posted in February 2015. The cost-effectiveness of lung screening with LDCT was calculated for the NLST study.

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]). Many other organizations have also developed guidelines for lung cancer screening.

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 naive, 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.34,67 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.41 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...
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
Lung cancer screening with LDCT should be part of a screening program. 

LDCT as Part of a Screening Program

Lung cancer screening with LDCT should be part of a program of care and should not be performed in isolation as a freestanding test. 

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. 

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. 

LDCT as Part of a Screening Program

Lung cancer screening with LDCT should be part of a program of care and should not be performed
Lung Cancer Screening, Version 1.2015

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-A, page 26). 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
To participate in this journal CE activity: 1) review the learning objectives and author disclosures; 2) study the education content; 3) take the posttest with a 66% minimum passing score and complete the evaluation at http://education.nccn.org/node/59435; and 4) view/print certificate. After reading the article, you should be able to answer the following multiple-choice questions. Credit cannot be obtained for tests completed on paper. You must be a registered user on NCCN.org. If you are not registered on NCCN.org, click on “New Member? Sign up here” link on the left hand side of the Web site to register. Only one answer is correct for each question. Once you successfully answer all posttest questions you will be able to view and/or print your certificate. Software requirements: Internet.

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