

2016
NCCN CONGRESS SERIES™
National Comprehensive Cancer Network

LIVE WEBINARS

Minimizing Risk from Lung Cancer Screening

Presented by:
Douglas E. Wood, MD
*Fred Hutchinson Cancer Research Center/
Seattle Cancer Care Alliance*

July 22, 2016

Moderated by Shannon K. Ryan
NCCN, Conferences and Meetings Department

Supporters

- This activity is supported by educational grants from Ariad, AstraZeneca, Ethicon, Foundation Medicine, Genentech, Lilly, Novartis Pharmaceuticals Corporation, and Pfizer.
- This activity is supported by independent educational grants from Abbvie and Merck.

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- This webinar includes audience polling. When you see a polling slide appear, get ready to vote. Please note that it can take a few moments to collect the results.

Attendance Lists & Registration

- If you are participating with a group of peers, a list of everyone who attended in your group must be submitted within two weeks of the activity in order for the participants to be eligible to receive credit. This list is in addition to individual registration. Attendee lists will not be accepted after two weeks post-activity.
- Lists can be sent to education@nccn.org and should contain full contact information for each participant, including first and last name, credentials, mailing address, phone number, and e-mail address.
- If you have not individually registered, please register at: <http://www.cvent.com/d/dfqty3>.

Accreditation Information

Intended Audience

This educational program is designed to meet the educational needs of oncologists, nurses, pharmacists, and other health care professionals who manage patients with non-small cell lung cancer.

Learning Objectives

Following this program, participants should be able to:

- Describe the risks and benefits of lung cancer screening.
- Identify recent strategies to minimize risks from lung cancer screening.
- Participate in shared patient/physician decision making to determine whether lung cancer screening is appropriate for an individual patient.

Accreditation Information

Physicians

National Comprehensive Cancer Network (NCCN) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

National Comprehensive Cancer Network designates this web-based activity for a maximum of 1.0 *AMA PRA Category 1 Credit*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurses

National Comprehensive Cancer Network (NCCN) is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's (ANCC) Commission on Accreditation. NCCN designates this educational activity for a maximum of 1.0 contact hour. Accreditation as a provider refers to the recognition of educational activities only; accredited status does not imply endorsement by NCCN or ANCC of any commercial products discussed/displayed in conjunction with the educational activity.

Kristina M. Gregory, RN, MSN, OCN, is our lead nurse planner for this educational activity.

Accreditation Information

Pharmacists

Pharmacy Educational Objective: *After completing this activity, the participant should be able to:*

- Provide accurate and appropriate counsel as part of the treatment team.

Accreditation Statement



National Comprehensive Cancer Network is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Type of Activity: Knowledge

UAN: 0836-0000-16-075-L01-P

Credit Designation: National Comprehensive Cancer Network designates this continuing education activity for 1.0 contact hour (0.10 CEUs) of continuing education credit in states that recognize ACPE accredited providers.

Attention Pharmacists: ACPE and NABP have implemented CPE Monitor as a way to electronically track all ACPE-accredited CPE Units. In order to receive credit for this activity, please enter your six-digit NABP e-profile ID and birth date in the format of MMDD as part of the Overall Evaluation. If you have not already done so, please complete your e-profile at <http://www.nabp.net> to obtain your NABP e-Profile ID.

To comply with ACPE standards, pharmacists must complete all activity requirements within **30 days** of the live event date.

Accreditation Information

How to Claim Credit:

Within 5 business days after this educational program, you will receive an e-mail with information on how to claim credit for this activity. A statement of credit will be issued only upon completion of the activity evaluation form & immediate post-test within **30 days** of the activity date. A certificate will be electronically generated immediately upon completion of the evaluation.

All credit claiming must be done online through NCCN's continuing education portal at <http://education.nccn.org/node/79144>.

Should you not receive an e-mail within 5 days, please contact us at education@nccn.org.

Accreditation Information

- It is required by the ACCME that all educational activities are designed to change participant **competence, performance, or patient outcomes**.
- To meet this requirement, NCCN asks that all participants complete the outcomes measures described below:
 - The post-test and evaluation as indicated in e-mail you will receive within 3-5 business days of the conclusion of this activity. This is required to receive credits or your certificate of completion. You must be registered in advance to receive credits or certificate. Certificates will be generated automatically upon successful completion of this step.
 - There will be a separate WebEx evaluation at the conclusion of this program, which is optional and does not go to NCCN.
 - The follow-up post test (to be sent 30 days after the activity has ended to demonstrate an increase in participant competence)
- NCCN greatly appreciates your compliance with completing the aforementioned post-test and surveys. All of these measures will be available by logging into your account at <http://education.nccn.org>. Reminder e-mails will be sent to the participants via e-mail. If you have any questions or concerns, please e-mail education@nccn.org.

Disclosures

The ACCME/ANCC/ACPE defines "conflict of interest" as when an individual has an opportunity to affect CE content about products or services of a commercial interest with which he/she has a financial relationship.

ACCME, ACPE, and ANCC focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CE activity. ACCME, ACPE, and ANCC have not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME, ACPE, and ANCC defines "relevant financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

All faculty for this continuing education activity are competent in the subject matter and qualified by experience, training, and/or preparation to the tasks and methods of delivery.

Faculty Disclosures

Disclosure of Relevant Financial Relationships

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Faculty Disclosures

The faculty listed below have disclosed the following relevant financial relationships:

Douglas E. Wood, MD

Spiration: Scientific Advisor; Grant/Research Support

NCCN Staff Disclosures

NCCN Staff Disclosures

The activity planning staff listed below has no relevant financial relationships to disclose:

Ann Gianola, MA; Mark Geisler; Kristina M. Gregory, RN, MSN, OCN; Kristin Kline Hasson; Rose Joyce; Joan S. McClure, MS; Diane McPherson; Melanie Moletzsky; Deborah Moonan, RN, BSN; Lisa Perfidio; Liz Rieder; Shannon K. Ryan; Kathy Smith; Jennifer McCann Weckesser

The NCCN clinical information team listed below, who have reviewed content, has no relevant financial relationships to disclose:

Ellen Erkess; Kristina M. Gregory, RN, MSN, OCN; Miranda Hughes, PhD

Faculty Biography

Douglas E. Wood, MD, is Professor and Endowed Chair in Lung Cancer Research in the Department of Surgery at the University of Washington, where he also serves as Chief of the Division of Cardiothoracic Surgery and Interim Chair of the Department of Surgery.

Dr. Wood received his undergraduate and medical degrees from Harvard University and trained in general surgery and cardiothoracic surgery at Massachusetts General Hospital. He then was recruited to lead a new section of general thoracic surgery at the University of Washington. Dr. Wood now leads the multidisciplinary Thoracic Oncology Program where patients receive a comprehensive evaluation and care from a dedicated team of pulmonary physicians, thoracic surgeons, medical oncologists, and radiation oncologists.

Dr. Wood's clinical interests include lung cancer staging and complex surgical resections for locally advanced lung cancer. He is an international lecturer and has held leadership roles with a number of prominent cardiothoracic surgery professional organizations. He is Past Director of the American Board of Thoracic Surgery and Past Chair of the Accreditation Council for Graduate Medical Education Thoracic Surgery Residency Review Committee. He also has been elected as President of the Seattle Surgical Society, President of the Western Thoracic Surgical Association, and President of the Society of Thoracic Surgeons. Additionally, Dr. Wood is a Fellow of the American College of Surgeons and a member of the American College of Chest Physicians.

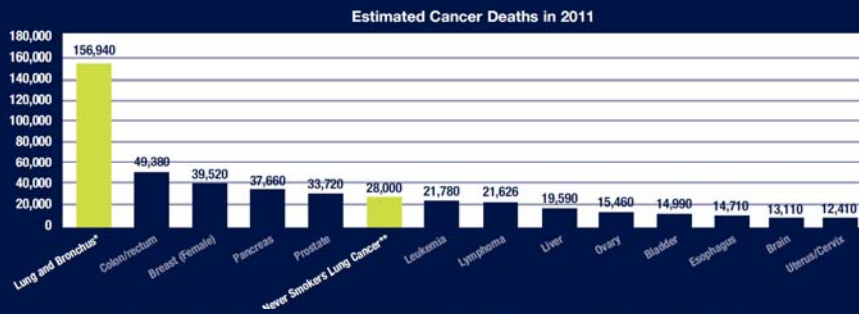
Dr. Wood is the Chair of the NCCN Lung Cancer Screening Panel, Vice-Chair of the NCCN Non-Small Cell Lung Cancer Panel, and a member of the editorial board for the *Journal of the National Comprehensive Cancer Network (JNCCN)*.

LUNG CANCER SCREENING

Minimizing Risk and Development of Policy

Douglas E. Wood, MD, FACS, FRCSEd (*ad hom*)
 Professor and Interim Chair
 Department of Surgery
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 University of Washington

Lung Cancer is the Leading Cause of Cancer Death in Every Ethnic Group



Lung Cancer is the Second Leading Cause of all Deaths in the United States

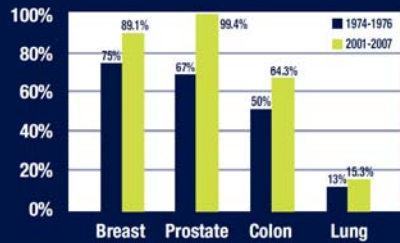
Actual Deaths in 2009

Heart disease	598,607	Breast cancer:	41,115	Homicide	16,591
Lung cancer	158,105	Suicide	36,547	Ovarian cancer	14,513
Lower respiratory disease	137,082	Pancreatic cancer	35,872	Bladder cancer	14,315
Stroke:	128,603	Septicemia	35,587	Brain cancer	14,192
Accident:	117,176	Liver disease	30,444	Esophageal cancer	13,916
Alzheimers:	78,889	Prostate cancer	28,154	Kidney cancer	13,027
Diabetes:	68,504	Leukemia	22,697	Stomach cancer	11,139
Colorectal cancer	52,462	Lymphoma	21,626	HIV/AIDS	9,424
Pneumonia	50,774	Parkinson's disease	20,552	Melanoma	9,254
Kidney disease	48,714	Liver cancer	19,311	Lip/oral cancers	7,913

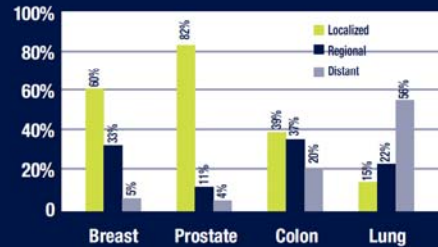
* Includes COPD, emphysema, asthma, bronchitis
 Source: National Center for Health Statistics; http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_04_tables.pdf

Cancer Screening – Early Detection

Why is the Survival Rate for Lung Cancer Still So Low?



Because so Few Cases are Diagnosed at Early Stage When Cancer is Most Curable



Cancer screening coverage

Breast
Prostate
Colon

Lung cancer disparities

Elderly
Low socioeconomic group
Racial
“Self-inflicted” disease

Which of the following is true regarding insurance coverage for lung cancer screening?

- There is no coverage for lung cancer screening
- Medicare covers screening for high-risk patients
- Private insurers cover screening for high risk patients
- Both Medicare and private insurers cover screening for high-risk patients
- Medicare and private insurers cover all patients for screening

At the present time, the NCCN panel does not recommend the routine use of screening CT as standard clinical practice (category 3). Available data are conflicting and thus, conclusive data from ongoing clinical trials are necessary to define the benefits and risks....

LUNG CANCER SCREENING Background

Previous studies have established lower stage distribution, and improved resectability and survival BUT not lower mortality

No randomized trial has had an appropriate control
Randomized control trial very difficult to perform
Previous trials have had increased incidence in screened groups - ? Overdiagnosis, length, or lead time bias

National Lung Screening Trial

Primary aim: to determine whether lung cancer screening using low-dose helical CT reduces lung cancer-specific mortality relative to screening with chest radiographs in a high-risk cohort.

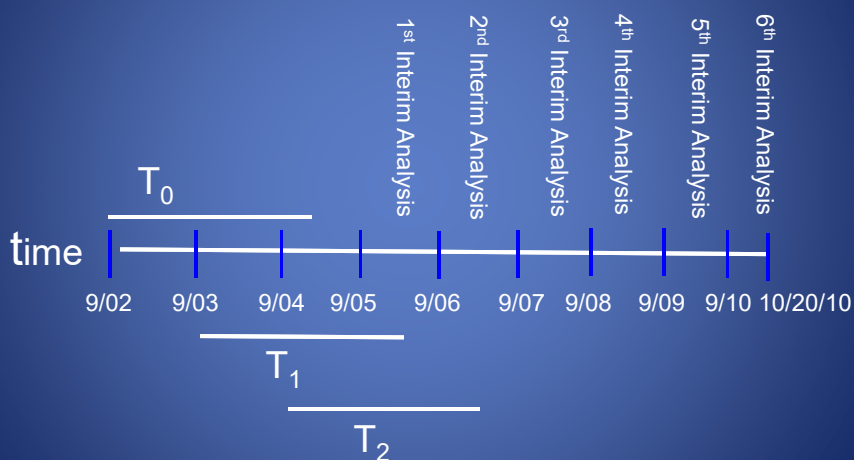


National Lung Screening Trial (NCI)

- Study design: Randomized controlled trial
- Interventions: 3 screenings performed over 2 years:
- 1° Outcome: Lung cancer mortality assessed after 5 years of follow-up
- Major eligibility criteria:
 - Age 55 to 74 years
 - A cigarette smoking history of at least 30 pack-years
 - Current cigarette smokers and former smokers who quit within 15 years of randomization
- Enrollment: 53,454 participants at 33 sites
 - 90% statistical power to detect a 20% reduction in lung cancer mortality
 - Secondary endpoint of all cause mortality

National Lung Screening Trial NEJM 2011

NLST Timeline



National Lung Screening Trial Results

Lung Cancer Specific Mortality

Trial Arm	Person Years (py)	Lung Cancer Deaths	Lung Cancer Mortality per 100,000 py	Reduction in Lung Cancer Mortality (%)	95% CI	p Value
LDCT	144,103	356	247	20.0	6.8 to 26.7	0.004
CXR	143,368	443	309			

All Cause Mortality

Trial Arm	Person Years (py)	Deaths	All-cause Mortality per 100,000 py	Reduction in All-cause Mortality (%)	95% CI	p Value
LDCT	167,389	1877	1121	6.7	1.2 to 13.6	0.02
CXR	166,382	2000	1202			

National Lung Screening Trial NEJM 2011

Conclusion

Screening with low dose chest CT conclusively reduces mortality from lung cancer in high risk patients.

National Lung Screening Trial NEJM 2011



JNCCN

JNCCN.org

Journal of the National Comprehensive Cancer Network

Lung Cancer Screening

Douglas E. Wood, George A. Eapen, David S. Ettinger, Lifang Hou, David Jackman, Ella Kazerooni, Donald Klippenstein, Rudy P. Lackner, Lorriana Leard, Ann N. C. Leung, Pierre P. Massion, Bryan F. Meyers, Reginald F. Munden, Gregory A. Otterson, Kimberly Peairs, Sudhakar Pipavath, Christie Pratt-Pozo, Chakravarthy Reddy, Mary E. Reid, Arnold J. Rotter, Matthew B. Schabath, Leticia V. Sequist, Betty C. Tong, William D. Travis, Michael Unger and Stephen C. Yang

J Natl Compr Canc Netw 2012;10:240-265

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NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Lung Cancer Screening

Version 2.2016

NCCN.org

NCCN Guidelines for Patients® available at www.nccn.org/patients

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NCCN Guidelines Version 2.2016 Lung Cancer Screening

RISK ASSESSMENT

- Smoking history
- Radon exposure
- Occupational exposure
- Cancer history
- Family history of lung cancer in first-degree relatives
- 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

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)

In candidates for screening, shared patient/physician decision making is recommended, including a discussion of benefits/risks

Moderate risk:

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

Lung cancer screening not recommended

Low risk:

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

Lung cancer screening not recommended



NCCN Guidelines Version 1.2013 Lung Cancer Screening

EVALUATION OF SCREENING FINDINGS

- Solid or part solid nodule
 - ≤ 4 mm → Annual LDCT for 2 years (category 1) and consider annual LDCT until patient no longer eligible for definitive treatment
 - > 4-6 mm → LDCT in 6 mo → If no increase in size, LDCT in 12 mo
 - > 6-8 mm → LDCT in 3 mo → If no increase in size, LDCT in 6 mo
 - > 8 mm → Consider PET/CT
 - Low suspicion of lung cancer → LDCT in 3 mo → If increase in size → Surgical excision
 - Suspicion of lung cancer → Biopsy or Surgical excision
 - No cancer → Annual LDCT for 2 years (category 1) and consider annual LDCT until patient no longer eligible for definitive treatment
 - Cancer confirmed → See appropriate NCCN Guidelines
- Solid endo-bronchial nodule
 - LDCT in 1 mo (immediately after vigorous coughing) → If no resolution → Bronchoscopy

FOLLOW-UP OF SCREENING FINDINGS

Annual LDCT for 2 years (category 1) and consider annual LDCT until patient no longer eligible for definitive treatment

LDCT in 6 mo → If no increase in size, LDCT in 12 mo

LDCT in 3 mo → If no increase in size, LDCT in 6 mo

LDCT in 3 mo → If increase in size → Surgical excision

Biopsy or Surgical excision → No cancer → Annual LDCT for 2 years (category 1) and consider annual LDCT until patient no longer eligible for definitive treatment

Biopsy or Surgical excision → Cancer confirmed → See appropriate NCCN Guidelines

If no resolution → Bronchoscopy

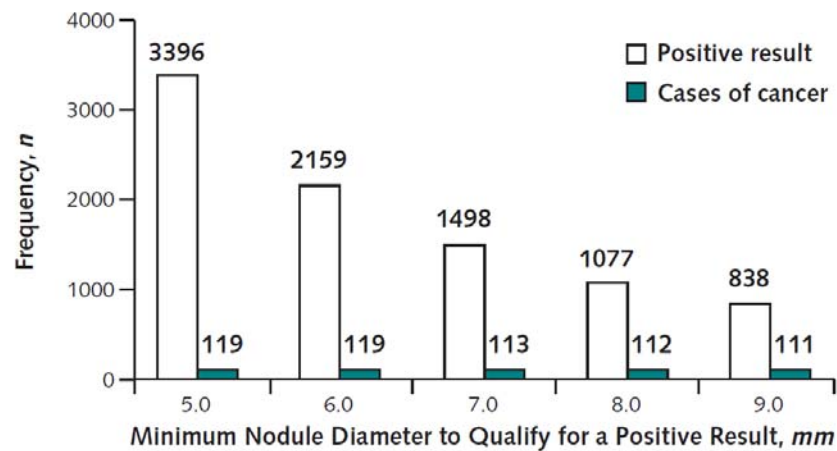
Definition of a Positive Test Result in Computed Tomography Screening for Lung Cancer

A Cohort Study

Claudia I. Henschke, PhD, MD; Rowena Yip, MPH; David F. Yankelevitz, MD; and James P. Smith, MD, for the International Early Lung Cancer Action Program Investigators*

Ann Intern Med. 2013;158:246-252.

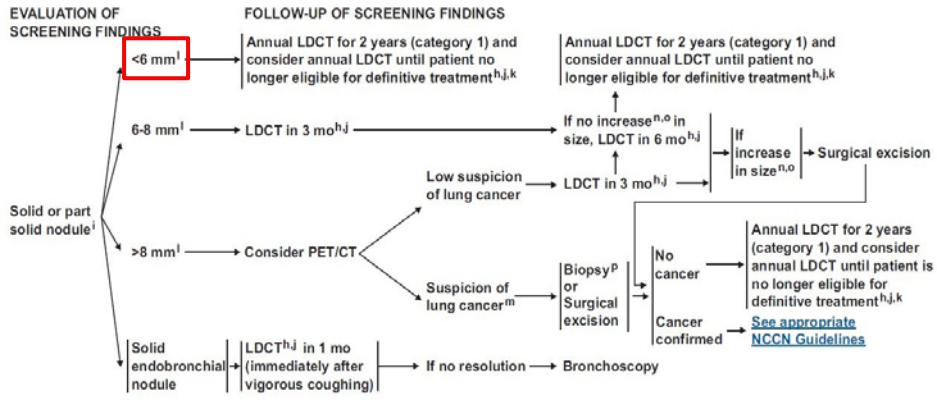
Figure. Frequency of a positive result and cases of lung cancer diagnosed within 12 mo of baseline enrollment.



Henschke C., et al. *Ann Intern Med.* 2013; 158-246-252.



NCCN Guidelines Version 1.2014 Lung Cancer Screening

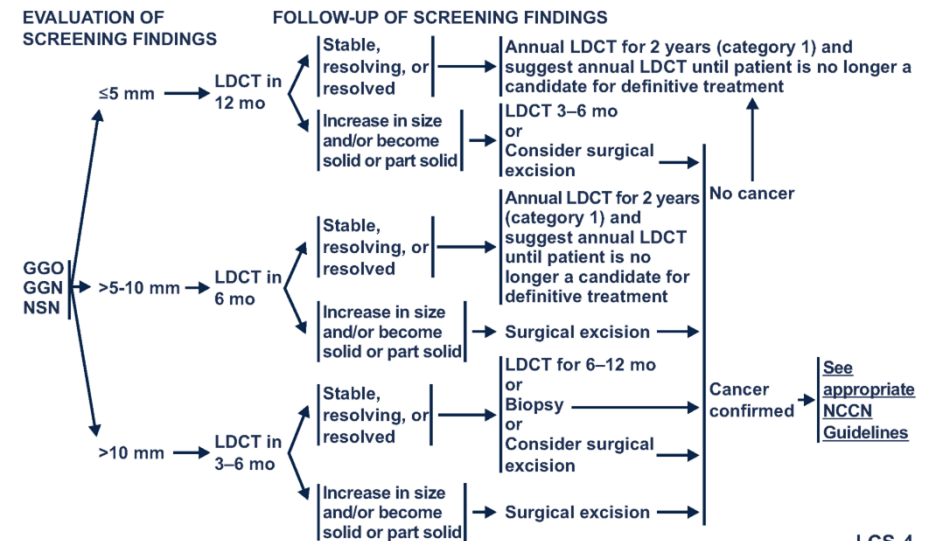


Version 1.2014, Page LCS-3

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NCCN Guidelines Version 2.2016 Lung Cancer Screening



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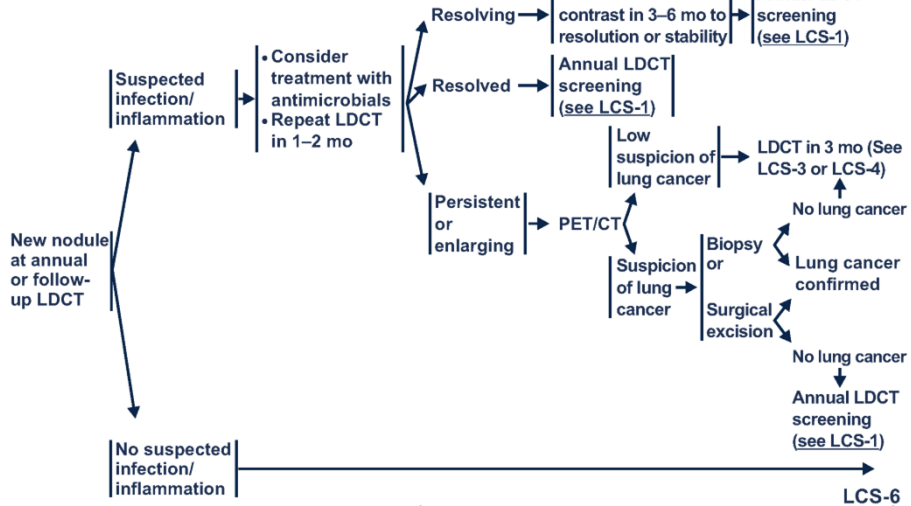
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NCCN Guidelines Version 2.2016 Lung Cancer Screening

EVALUATION OF SCREENING FINDINGS

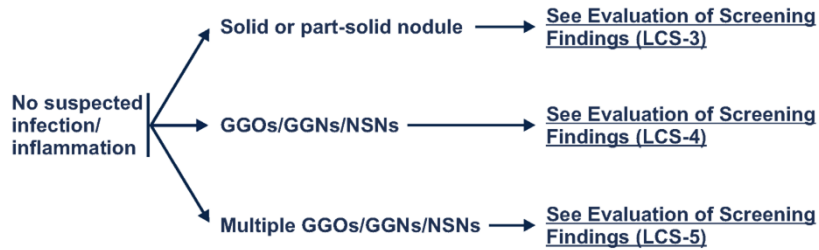
FOLLOW-UP OF SCREENING FINDINGS



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NCCN Guidelines Version 2.2016 Lung Cancer Screening

RISKS/BENEFITS OF LUNG CANCER SCREENING

RISKS

- Futile detection of small aggressive tumors or indolent disease
- Quality of life
 - Anxiety of test findings
- Physical complications from diagnostic workup
- False-positive results
- False-negative results
- Unnecessary testing and procedures
- Radiation exposure
- Cost
- Incidental lesions

BENEFITS

- Decreased lung cancer mortality
- Quality of life
 - Reduction in disease-related morbidity
 - Reduction in treatment-related morbidity
 - Improvement in healthy lifestyles
 - Reduction in anxiety/psychosocial burden
- Discovery of other significant occult health risks (eg, thyroid nodule, severe but silent coronary artery disease, early renal cancer in upper pole of kidney, aortic aneurysm, breast cancer)

LCS-B

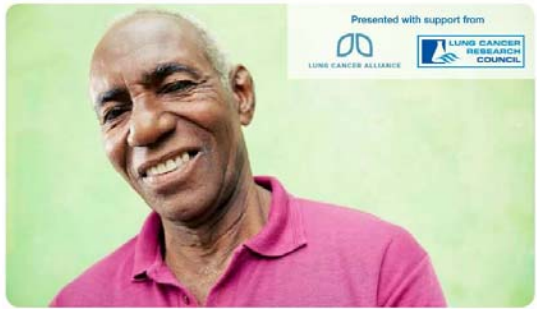
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Lung Cancer Screening



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U.S. Preventive Services Task Force

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Draft Recommendation Statement

Note: This draft Recommendation Statement is not the final recommendation of the U.S. Preventive Services Task Force. This draft is distributed solely for the purpose of pre-release review. It has not been disseminated otherwise by the USPSTF. It does not represent and should not be interpreted to represent a USPSTF determination or policy.

This draft Recommendation Statement is based on an evidence review that was published on July 30, 2013 (available at <http://www.uspreventiveservicestaskforce.org/uspstf13/lungcancer/ansart.htm>).

The USPSTF makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service, and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decisionmaking to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

This draft Recommendation Statement was available for comment from July 30 until August 26, 2013 at 5:00 PM ET. A fact sheet that explains the draft recommendations in plain language is available [here](#).

Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement

DRAFT

Summary of Recommendation and Evidence

The U.S. Preventive Services Task Force (USPSTF) recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in persons at high risk for lung cancer based on age and smoking history.

This is a [Grade B recommendation](#).

March 12, 2014

Tamara S. Syrek Jensen, J.D.
Acting Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

By Online Submission

Re: National Coverage Analysis for Lung Cancer Screening with Low Dose Computed Tomography (CAG-00439N)



The Society
of Thoracic
Surgeons



THE WALL STREET JOURNAL.

OPINION

Medicare's Puzzling Refusal to Cover Lung-Cancer Screening

We know screening can save thousands of lives every year. But it's not provided to the group most likely to benefit.

By DOUGLAS E. WOOD And ELLA A. KAZEROONI

June 17, 2014 7:11 p.m. ET

If you could save thousands of lives, would you do it?

That's the question Medicare officials are now considering—whether to approve lung-cancer screening for Medicare beneficiaries, which we estimate could save 14,000 lives each year in that group alone. Most patients are discovered with lung cancer at a stage already too late for a cure, and cancer screening for early detection has been recommended for other common cancers for decades. The procedure has turned thousands of people into survivors rather than victims.

Congress Urges Medicare to Cover Lung Cancer Screening

Roxanne Nelson

June 05, 2014

Politicians have gotten involved and are campaigning to have lung cancer screening covered by Medicare, which insures people 65 years of age and older. Members of the US House and Senate are asking the Centers for Medicare & Medicaid Services (CMS) to approve coverage of lung cancer screening with low-dose CT.

The Senate letter has 45 signatories, and points out that the US Preventive Services Task Force has evaluated low-dose CT and given it a [positive recommendation](#). "This means that patients with private insurance are gaining access but Medicare beneficiaries are still waiting," they write.

Low-dose CT is already covered by the Department of Veterans Affairs, the Department of Energy, and a number of large private insurers, such as WellPoint, Blue Cross Blue Shield affiliates, and Anthem affiliates.

In the letter from the House, the 134 signatories point out that "Americans pay into Medicare throughout their working lives and deserve to have access to potentially life-saving evidence-based screening."

Many major medical societies have come out in favor of lung cancer screening, including the American Association for Thoracic Surgery, the American Cancer Society, the American College of Radiology, the American Society of Clinical Oncology, the Lung Cancer Alliance, and the Society for Thoracic Surgeons.

<http://www.medscape.com/viewarticle/826255>

September X, 2014

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7500 Security Boulevard
Baltimore, MD 21244

Re: National Coverage Analysis for Lung Cancer Screening with Low Dose Computed Tomography (CAG-00439N)

Dear Ms. Syrek Jensen:

In follow up to the stakeholder letter dated March 12th, 2014 and the June 19th, 2014 meeting with the Centers for Medicare and Medicaid Services Coverage and Analysis Group (CMS CAG), the undersigned organizations and groups continue to strongly support broad national coverage for **annual screening for lung cancer with low-dose computed tomography**

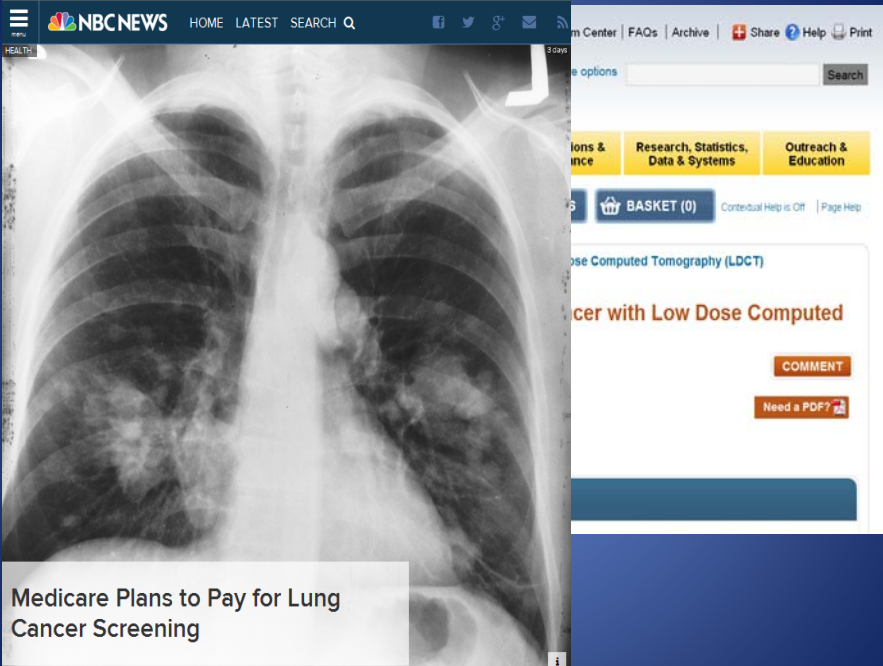


The Society
of Thoracic
Surgeons





The American Association of Physicists in Medicine
 The Academy of Radiology Research
 American Association for Thoracic Surgery (AATS)
 The American Board of Radiology (ABR)
 The American Board of Radiology Foundation
 American College of Surgeons' Commission on Cancer
 American Roentgen Ray Society (ARRS)
 American Society for Radiation Oncology (ASTRO)
 Association of University Radiologists (AUR)
 Blanchard Valley Hospital, Findlay, Ohio
 The Fleischner Society
 Global Institute of Public Health, New York University
 Henry Ford Medical Group
 Hollings Cancer Center
 Houston Methodist Hospital
 International Association for the Study of Lung Cancer
 International Early Lung Cancer Action Program
 Lahey Hospital and Medical Center
 Mary Horrigan Connors Center for Women's Health
 Massachusetts General Hospital
 Montefiore Einstein Center for Cancer Care
 National Council of Asian Pacific Islander Physicians
 National Comprehensive Cancer Network (NCCN)
 National Jewish Health Lung Cancer Screening CT Program
 Oakland University
 William Beaumont School of Medicine
 Penn Lung Center of the University of Pennsylvania
 Prevent Cancer Foundation
 Quantitative Imaging Biomarkers Alliance (QIBA)
 Radiological Society of North America (RSNA)
 Society of Chairs of Academic Radiology Departments
 Society of Computed Body Tomography and Magnetic Resonance
 Society of Thoracic Radiology (STR)
 Tobacco Exposure Program at City of Hope Medical Center
 The University of Chicago
 University of Michigan Comprehensive Cancer Center
 Upstate Medical University
 WellStar Medical Group.



Medicare Plans to Pay for Lung Cancer Screening

Lung Cancer Screening Status

LDCT now established with a significant mortality benefit for lung cancer screening in high risk groups

USPSTF recommendation requires coverage as a benefit under the ACA

Medicare now providing coverage for beneficiaries

Probably biggest impact on lung cancer management and outcomes in our generation

Concerns about Lung Cancer Screening

Benefit overestimated

Harm underestimated

Close balance of benefits and harms

Hippocrates – “Do no harm”

But in preventive services, harm presents in two forms:

Unintended consequences of evaluation/treatment

Denying preventive services from those who may benefit

Issues Debated in Lung Cancer Screening


- Does it work?
- Which patients should be screened?
 - What level of evidence?
- Minimizing harms
- Balancing unintended harms with benefit
- Lowering barriers to access

All major guidelines groups agree that this patient cohort is high-risk and appropriate for lung cancer screening:

- A. Age ≥ 50 and ≥ 20 pk/yr smoking history
- B. Age ≥ 50 and ≥ 20 pk/yr smoking history with one additional risk factor
- C. Age 55-74 and ≥ 30 pk/yr smoking history
- D. Age ≥ 60 , independent of smoking history
- E. Patients with COPD or pulmonary fibrosis

Lung Cancer Guidelines	NLST	USPSTF	CMS	Canadian Task Force on Preventive Health Care CTFPHC	Cancer Care Ontario	NCCN	ALA	ACCP	AAFP	AATS	ERS ERS
Age	55-74	55-80	55-77	55-74	55-74	≥55	NS	55-74	NO	55-79	55-80
Smoking	≥30	≥30	≥30	≥30	≥30	≥30	NS	≥30	NO	≥30	≥30
Cessation	≤15	≤15	≤15	≤15	≤15	≤15	NS	≤15	NO	≤15	≤15
Other risk factors	NO	NO	NO	NO	NO	YES	YES	NO	NO	YES	
Extended criteria	NA	NO	NO	NO	NO	>50 >20 pk-yr Add risk factor	Risk calc	NO	NO	>50 >20 pk-yr Add risk factor	

Which Patients Should be Screened?



National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2016

Lung Cancer Screening

RISK ASSESSMENT

- Smoking history
- Radon exposure
- Occupational exposure
- Cancer history
- Family history of lung cancer in first-degree relatives
- 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

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)

→ In candidates for screening, shared patient/physician decision making is recommended, including a discussion of benefits/risks

Moderate risk:

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

→ Lung cancer screening not recommended

Low risk:

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

→ Lung cancer screening not recommended

LCS-1
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Which Patients Should be Screened?

What the NLST did do:

Demonstrate a mortality reduction in patients with substantial risk factors for lung cancer

What the NLST did not do:

Define risk factors for lung cancer

NLST was a clinical trial, eligibility criteria were never meant to define the extent of "high risk" or be the basis of public policy

Only considered age and smoking history

No consideration of occupational/environmental exposure, cancer history, family history, other diseases

Which Patients Should be Screened?

Key principle of NCCN Group 2 is the consideration of additional risk factors

USPSTF and CMS only considered age and smoking history (presumably on the assumption that only the NLST provides data about lung cancer risk)

Mortality benefit of patients with a certain level of lung cancer risk

What if we identified patients with a similar level of risk?

Could they be extrapolated to have a similar level of mortality benefit?

Do we know any risk factors for lung cancer other than age and smoking history?

Which Patients Should be Screened?

NCCN position

Group 1 high risk patients - NLST inclusion (Category 1 recommendation)

Group 2 high risk patients approximate the risk of patients included in the NLST – Category 2A “uniform consensus” from panel

Issues Debated in Lung Cancer Screening

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Which Patients Should be Screened? NCCN Group 2

Evidence from randomized trial is a critical foundation

Reality that additional randomized trial data limited

Occupational exposure

Past cancer or family history

Is it possible to extrapolate non-randomized data regarding additional risk factors to known outcomes?

Is this more pragmatic and equitable in providing access to preventive health services?

Risk Factors for Lung Cancer NCCN Group 2

NCCN Group 1

NLST/USPSTF/CMS

Age

Smoking

NCCN Group 2

Age

Smoking

Occupational/environmental

Asbestos, radon, silica, etc.

Cancer history

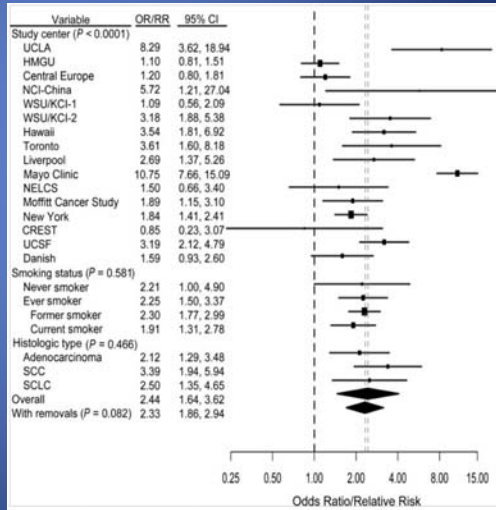
Family history

Disease history

COPD and pulmonary fibrosis

**Previous Lung Diseases and Lung Cancer Risk:
A Pooled Analysis From the International Lung Cancer Consortium**

Emphysema odds ratio 2.3



Brenner, DR, et al. Am J Epidemiol. 2012 Oct 1; 176(7): 573-585.
Published online 2012 Sep 17. doi: 10.1093/aje/kws151

Lung Cancer Risk Assessment

	NLST	USPSTF	CMS	Brock	AATS	Bach	CLEAR	MyLungRisk	WashU
Age	+	+	+	+	+	+	+	+	+
Smoking	+	+	+	+	+	+	+	+	+
Cessation	+	+	+	+	+	+	+	+	+
Gender				+	+	+	+	+	+
Ca hist				+	+			+	+
Fam hist				+	+		+	+	+
Asbestos						+		+	+
Exposure					+		+		+
COPD				+	+		+	+	+
Educ				+	+				
BMI				+	+				
Race				+					
X-ray					+			+	

Risk Calculator Assessment

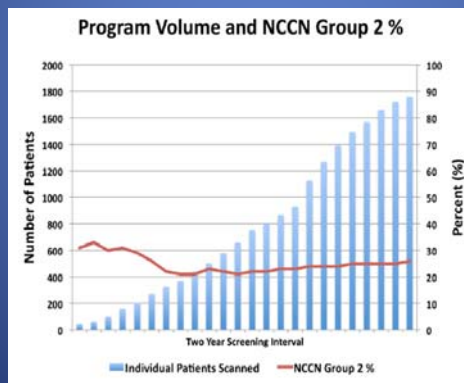
	Tammemagi	Bach	Hoggart	LLP
NCCN 1 low	0.6%	0.6%	1.8%	0.9%
NCCN 1 med	4.2%	2.3%	4.4%	2.0%
NCCN 1 high	18.9%	4.6%	5.7%	6.0%
NCCN 2 low	1.1%	0.2%	1.5%	1.3%
NCCN 2 med	4.9%	0.7%	0.1%	3.1%
NCCN 2 high	12.8%	1.7%	1.0%	6.9%

58 yo male 30 pk-yr, stopped 13 years ago, no other risk factors
 65 yo male 40 pk-yr, stopped 5 years ago, family history
 74 yo female 55 pk-yr, current smoker, previous cancer
 50 yo female 25 pk-yr, stopped 15 years ago, previous cancer
 65 yo male 25 pk-yr, current smoker, asbestos, pulmonary fibrosis
 78 yo male 35 pk-yr, stopped smoking 1 year ago, previous cancer, COPD

Experience With a CT Screening Program for Individuals at High Risk for Developing Lung Cancer

Brady J. McKee, MD^a, Jeffrey A. Hashim, MD^d, Robert J. French, MD^d, Andrea B. McKee, MD^b, Paul J. Hesketh, MD^e, Carla R. Lamb, MD^d, Christina Williamson, MD^e, Sebastian Flacke, MD, PhD^f, Christoph Wald, MD, PhD^g

J Am Coll Radiol 2015;12:192-197.



Experience With a CT Screening Program for Individuals at High Risk for Developing Lung Cancer

McKee, B.J., et al. *J Am Coll Radiol*. 2015 Feb;12(2):192-7

Table 2. Prevalence Exam Results

Result	Total Screened (n = 1,760)		NCCN Group 2 (n = 464)		NCCN Group 1 (n = 1,296)		P (Group 2 vs Group 1)	NLST (TO)
	Count	Percentage	Count	Percentage	Count	Percentage		
Total positive	481	27.3%	116	25.0%	365	28.2%	0.1	27.3%
Probably benign	412	23.4%	103	22.2%	309	23.8%	NR	NR
Suspicious	69	3.9%	13	2.8%	56	4.3%	NR	NR
Probable infection	114	6.5%	28	6.0%	86	6.6%	0.8	NR
Significant incidental findings	108	6.1%	28	6.0%	80	6.2%	0.1	10.2%

Table 4. Malignancy rate and average follow-up

Variable	Overall	Group 2	Group 1
Overall malignancy rate	23/1,328 (1.7%)	6/331 (1.8%)	17/997 (1.7%)
Average follow-up (mo)	12.5	12.1	12.7
Annualized malignancy rate	1.6%	1.8%	1.6%
Time to diagnosis (mo)	4.1	5.6	3.7
Average follow-up from diagnosis (mo)	7.8	5.3	8.6

NCCN guidelines identify which additional patient cohort beyond the NLST that is considered high-risk and appropriate for lung cancer screening:

- A. Age ≥ 50 and ≥ 20 pk/yr smoking history
- B. Age ≥ 50 and ≥ 20 pk/yr smoking history with one additional risk factor
- C. Age 55-74 and ≥ 30 pk/yr smoking history
- D. Age ≥ 60 , independent of smoking history
- E. Patients with COPD or pulmonary fibrosis

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Minimizing Harms of Lung Cancer Screening

Limit Access

- Further narrow, or prevent widening of, eligibility criteria
- Expose fewer people to risks
- Use policy to override shared decision-making
- Disenfranchise and potentially harm others at high risk

Improve management

- Refine management algorithms to minimize false positives
- Require expertise in evaluation/treatment to optimize outcomes
- Empower shared decision-making
- Provide access to similar risk patients
- Add cost to payers
- Risk of evaluation/treatment added to new patients with less proof of benefit

LungRADS 2014

Category	Category Descriptor	Category	Findings	Management	Probability of Malignancy	Estimated Population Prevalence
Incomplete	-	0	prior chest CT examination(s) being located for comparison part or all of lungs cannot be evaluated	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed	n/a	1%
Negative	No nodules and definitely benign nodules	1	no lung nodules	Continue annual screening with LDCT in 12 months	< 1%	90%
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	solid nodule(s): < 6 mm new < 4 mm			
			part solid nodule(s): < 6 mm total diameter on baseline screening			
			non solid nodule(s) [GGN]: < 20 mm OR ≥ 20 mm and unchanged or slowly growing category 3 or 4 nodules unchanged for ≥ 3 months			
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	solid nodule(s): ≥ 6 to < 8 mm at baseline OR new 4 mm to < 6 mm	6 month LDCT	1-2%	5%
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	solid nodule(s): ≥ 8 to < 15 mm at baseline OR growing < 8 mm OR new 6 to < 8 mm	3 month LDCT, PET/CT may be used when there is a ≥ 8 mm solid component	5-15%	2%
			part solid nodule(s): ≥ 6 mm with solid component ≥ 6 mm to < 8 mm OR with a new or growing < 4 mm solid component			
		4B	solid nodule(s): ≥ 15 mm OR new or growing, and ≥ 8 mm	chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component.	> 15%	2%
part solid nodule(s) with: a solid component ≥ 8 mm OR a new or growing ≥ 4 mm solid component						
		4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			

Annals of Internal Medicine

ORIGINAL RESEARCH

Performance of Lung-RADS in the National Lung Screening Trial

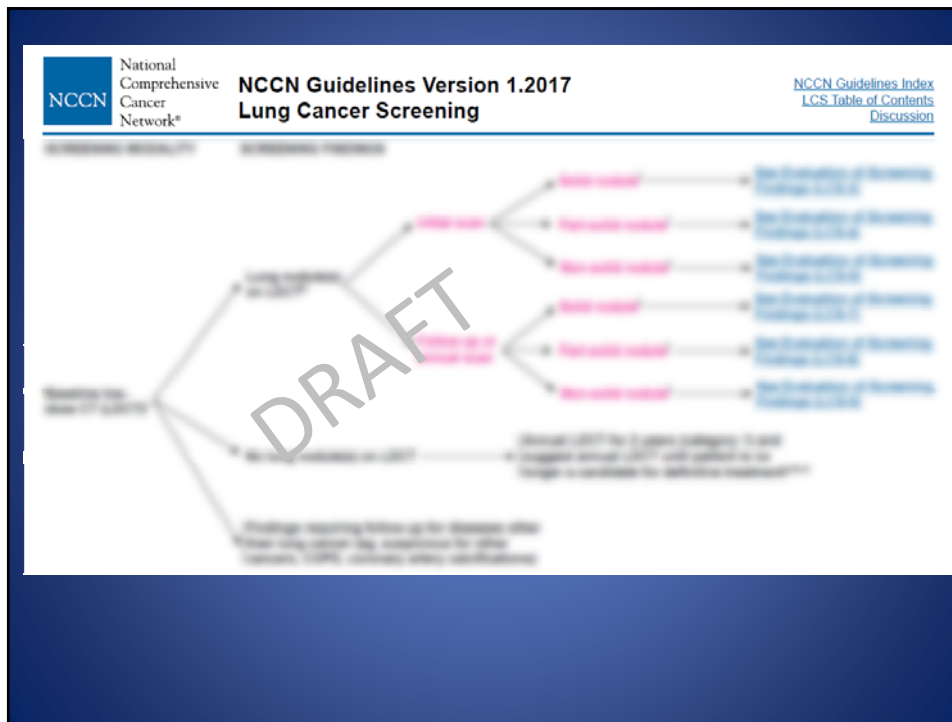
A Retrospective Assessment

Paul F. Pinsky, PhD; David S. Gierada, MD; William Black, MD; Reginald Munden, MD; Hrudaya Nath, MD; Denise Aberle, MD; and Ella Kazerooni, MD

False-positive rate

	NLST	LungRADS	Improvement w/LungRADS
Baseline	26.6%	12.8%	52%
After baseline	21.8%	5.3%	76%

Ann Intern Med. 2015;162:485-491.



Issues Debated in Lung Cancer Screening

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Counseling High Risk Patients About CT Screening

What are the risks:

Radiation risk:¹

LDCT 0.61 to 1.5 millisieverts (mSv)*

Routine CT - 5 to 8 mSv

Naturally occurring radiation exposure at sea level is 3mSv/year

Mammography 0.4 mSv Head CT 2 mSv

Anxiety risk due to:

Uncertainty of a positive screening test

Discovery of an significant incidental finding

Complication risk²:

From diagnostic procedure for a positive screening test: 1.4%

Financial risk:

Cost of an uncovered screening CT scan (\$300)

*1 in 100,000 to 1 in 10,000 additional risk of fatal cancer from 1 screening CT scan.

¹ <http://www.radiologyinfo.org>

² NEJM 2011;365(2):158

CMS requires Shared Decision Making counseling for LCS



The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to add a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, annual screening for lung cancer with low dose computed tomography (LDCT), as an additional preventive service benefit under the Medicare program if all of the following criteria are met:

Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N) February 5, 2015

Shared Decision Making Aid

American Thoracic Society

DECISION AID
For Lung Cancer Screening with Computerized
Tomography (CT)

PATIENT EDUCATION



<http://www.thoracic.org/patients/patient-resources/resources/decision-aid-lcs.pdf>

Shared Decision Making Aid



Lung Cancer Screening Saves Lives

Should you be screened for lung cancer?

Get Started

<http://lungcancerscreeningsaveslives.org/>

Shared Decision Making Aid

LUNG CANCER SCREENING DECISION AID HOME ABOUT LUNG CANCER & SCREENING CALCULATE MY LUNG CANCER RISK

<http://www.shouldiscreen.com>

YOUR LUNG CANCER RISK

Fill in the information below to find out whether you are in the group where screening is recommended by the US Preventive Services Task Force. The calculator will also indicate how much you stand to benefit from getting screened. This will help you better determine whether your potential benefit from screening outweighs the harms.

* INDICATES REQUIRED FIELDS

1. How old are you?*

2. What is your current smoking status?*

- Smoker
 Former Smoker
 Never Smoker

3. For how many years total have you smoked cigarettes?*

4. On average, how many cigarettes did you smoke per day?*

5. What is your gender?

6. What is the highest grade or year of school you completed?

7. How would you describe your race/ ethnicity?

8. How tall are you?

 Feet Inches

9. How much do you weigh? (lbs.)

10. Have you ever been told by a doctor that you have cancer?

Yes No

11. Does your family have a history of lung cancer?

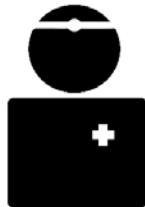
Yes No

12. Have you ever been told by your doctor that you have chronic pulmonary disease also known as COPD (chronic bronchitis or emphysema)?

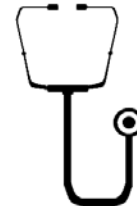
Yes No

Submit

Shared Decision Making Aid Lung Cancer Screening SHOULD I DO IT?



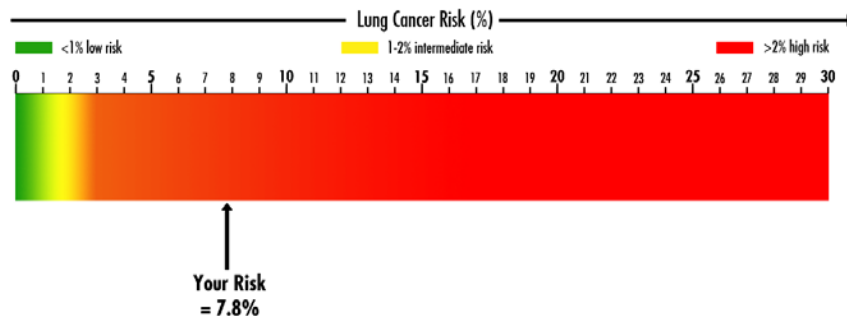
Given your age and smoking history,
you are **eligible** for screening
according to the US Preventive Services
Task Force criteria.



<http://www.shouldiscreen.com/>

Shared Decision Making Aid

The chance of you developing lung cancer in the next 6 years is 7.8%. Talk to your doctor about the option to screen or not to screen as s/he will understand your situation best.



<http://www.shouldiscreen.com/>

Issues Debated in Lung Cancer Screening

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Screening Efficiency Number Needed to Screen

Screening mammography ^{1,2}	780 - 2000
Screening colonoscopy ²	1250
Screening LDCT (in NLST)	320

1. Gøtzsche PC, Nielsen M. Screening for breast cancer with mammography. *Cochrane Database Syst Rev.* 2011;(1):CD001877
2. *J Med Screen* 2001;8:125–127

Applying the National Lung Screening Trial eligibility criteria to the US population: what percent of the population and of incident lung cancers would be covered?

Paul F Pinsky and Christine D Berg

SEER (Surveillance, Epidemiology and End Results)
United States Census
National Health Interview Survey
Two statistical models of lung cancer risk

Proportion of those diagnosed with lung cancer that would be covered by the NLST-based eligibility criteria.

27%

J Med Screen 2012;19:154–156



Annual Number of Lung Cancer Deaths Potentially Avertable by Screening in the United States

Jiemin Ma, PhD, MHS¹; Elizabeth M. Ward, PhD²; Robert Smith, PhD³; and Ahmedin Jemal, DVM, PhD¹

8.6 million Americans eligible for screening
Annual number of lung cancer deaths averted – 12,250

Experience With a CT Screening Program for Individuals at High Risk for Developing Lung Cancer

NCCN Group 2 adds 2 million eligible for screening
Additional estimate of averted lung cancer deaths ≈ 3000

Cancer 2013;119:1381-5

J Am Coll Radiol 2015;12:192-197.



World Health Organization

centre Publications Countries Programmes Governance About WHO

Health systems

Equity

Equity is the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically. *Health inequities* therefore involve more than inequality with respect to health determinants, access to the resources needed to improve and maintain health or health outcomes. They also entail a failure to avoid or overcome inequalities that infringe on fairness and human rights norms.

THE OFFICIAL SPONSOR OF BIRTHDAYS: 

Cancer Facts & Figures 2014

Cancer Disparities

An overarching objective of the American Cancer Society's 2015 challenge goals is to eliminate disparities in the cancer burden among different segments of the US population, defined in terms of socioeconomic status (income, education, insurance status, etc.), race/ethnicity, geographic location, sex, and sexual orientation.

Lung cancer patient disparities:

- Older – 68% Medicare population
- Higher mortality amongst African-Americans
- Lower socioeconomic groups mortality 4-5 times greater
- Rural access to screening and treatment

THE JOURNAL OF
**THORACIC AND
CARDIOVASCULAR SURGERY**

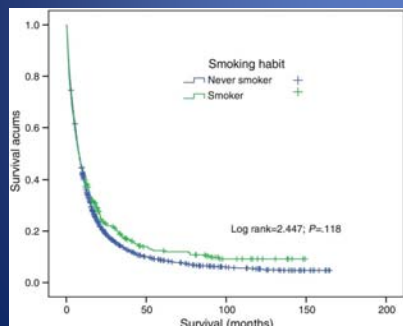
Flores et al

General Thoracic Surgery

Balancing curability and unnecessary surgery in the context of computed tomography screening for lung cancer

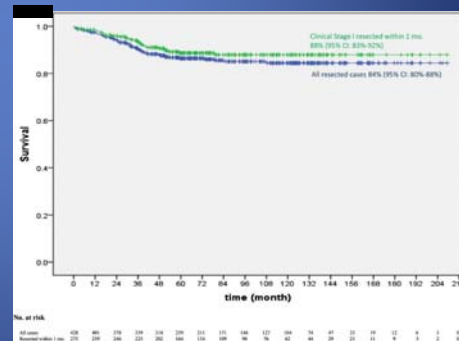
Lung Cancer Survival

Current Lung Cancer Survival



Lamelas, IP, et al. Arch Bronconeumol.2014;50:62-6

I-ELCAP



J Thorac Cardiovasc Surg 2014; 147:1619-1626.

Lung Cancer Screening Summary

Lung cancer screening reduces mortality in a high risk population
Randomized trial data, and USPSTF eligibility, do not consider risk factors other than age and smoking

Non-randomized data exists to validate other risk factors

Rigid adherence to NLST inclusion criteria

 Ignores important data regarding lung cancer risk

 Disenfranchises patients at legitimate risk

 Lost opportunity of maximizing benefit of lung cancer screening

 Violates principles of equity and elimination of health care disparities

Data supports NCCN Group 2 as having similar risk to NLST

Policy should extend screening to patients similar to NCCN Group 2

Screening risk minimized by algorithmic management and multidisciplinary expertise

Shared decision making important to balance risks and benefits

Q&A SESSION

Please use the Q&A feature on the right-hand portion of your screen to submit clinical questions to the speakers.

- An e-mail will be sent within 5-7 business days with instructions on how to login to complete post-test and evaluation. These must be completed in order to receive a CE certificate. Contact education@nccn.org should you not receive this e-mail within 5 business days.
- If you participated with a group of peers, a list of everyone who attended in your group must be submitted to education@nccn.org within the next two weeks.
- If you have not individually registered, please register at: <http://www.cvent.com/d/dfqty3>.
- For notification of upcoming NCCN educational events:

 Visit NCCN.org/events

 Join our group on LinkedIn: [NCCN Conferences and Meetings Group](#)

 Follow us on Twitter: [@NCCNMeetings](#) and [@NCCNnews](#) and [@JNCCN](#)

 Like our page on Facebook: [National Comprehensive Cancer Network](#)

UPCOMING WEBINAR

- **Treatment of Older Adult Patients with Non-Small Cell Lung Cancer**
Tuesday, July 26 at 1:30 PM [EDT]
Neelesh Sharma, MD, PhD, *Case Comprehensive Cancer Center/University Hospitals Seidman Cancer Center and Cleveland Clinic Taussig Cancer Institute*

Register at NCCN.org/events

Thank you for your participation in today's program!

NCCN Member Institutions



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