CORE PHYSICIANS

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Core Physicians is a community based, multi-specialty group practice based in Exeter, NH. In response to CMS request for provider feedback, we are presenting our rationale in support of CMS coverage of Preventative Lung Cancer Screening with Low Dose Computed Tomography.

We formally align ourselves with the U. S. Preventative Services Task Force (USPSTF) announcement of its formal recommendation for yearly preventative lung cancer screening with low dose CT on high–risk individuals.

While the costs of screenings and rate of false positives appear to be of great concern, the consideration related to lives saved with earlier detection, costs saved due to earlier detection ethically must be given the greatest focus. The ultimate goal being detection before a patient presents with symptoms.

The compelling research and statistics provided in support of approval of this preventative tool are numerous. The strength of this positive motion forward is offered below:

- Peter B. Bach, Director for The Center for Health Policy and Outcomes, Department of Medicine at Memorial Sloan-Kettering Cancer Center, offered 54 publications cited that support of this next step.
- The American Lung Association directs the need for a national screening trial along with the specific use of low-dose computed tomography.
- Our National Library of Medicine at the National Institutes of Health provided a qualitative analysis that considered the thought processes behind physicians already ordering this testing and made recommendations in December 2011 that further studies follow up their formative data. This has now been completed. The data compels forward motion for implementing preventative screening coverage for our high risk patient population.
- Within the archives of the National Library of Medicine is the published article "Lung Cancer Screening: One Step Forward" {Cleve Clin J Med. 2012). It appropriately states that we are entering a new era in which lung cancer screening may be considered a standard of care. This article goes on to cite that the New England Journal of Medicine 2011 publication also supports this approach in the high-risk population.

We feel that high-risk patients are clearly defined in the CMS release as well as the appropriate approach using low dose computed tomography and stand in agreement with those specific requirements.

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Considering the data, research, the health of our community, and the practice of ethical medicine, we formally offer our support for the proposed NCD establishing CMS coverage of annual Lung Cancer Screening with low dose computed tomography to high-risk Medicare patients.

Respectfully submitted,

Ashley Lamb MD

IHM Peter IHM, MD

Gregory Davidson MD

Eric Anderson, MD

Jerrice Peelman, MD

Taraneh Azar, MD.

Elizabeth Matsumoto

Daniel Kuor DO

Darren Guy DO

Nicola Vogel MD

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Respectfully submitted,

Jessica Sutherland, MD

Vanessa Preble

Steve Coffey, MD

William Berndt, MD

Greg Goodkin, MD

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Respectfully submitted,

Kathleen Kelly MD, CWSP — KATHLEEN KELLY, MD

Patricia Pangan MD — PATRICIA PANGAN, MD

Nancy Braese DO — NANCY BRAESE, D.O.

Cynthia Tolbert MD — CYNTHIA TOLBERT, M.D.

Kim King APRN

Melanie Lanier DO — MELANIE LANIER, DO

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Respectfully submitted,

Schaffer Mike Schaffer, MD

Johnson, MD E. William Johnson, MD

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Respectfully submitted,

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Respectfully submitted,

ARNP

MD

MIKE PANGAN, MD

CORE PHYSICIANS

an exeter health resource | The Art of Wellness

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Respectfully submitted,

Tim Keenan MD

TIMOTHY KEENAN, MD

Advertisement

Jan 26 2014

US Gov't pronounces lung cancer screening the standard of care

Clinic and Consults, Policy, Ethics, Education, Radiology & Imaging Add comments

It's official: the U.S. Preventive Services Task Force (USPSTF) announced its formal recommendation for yearly low-dose chest CT screening for lung cancer in high-risk individuals on December 30, 2013.

The final **grade B recommendation** ("Suggestion: offer or provide this service") was virtually unchanged from the draft recommendations the USPSTF made in July 2013. It advises adults 55 to 79 years old with at least a 30 pack-year history of smoking who have quit for less than 15 years to get annual chest CTs for up to 26 years. Those with significant illnesses limiting life expectancy, or who would not be able to undergo curative surgery, should not be screened, the panel advised.

By making lung cancer screening the standard of care for the 9 million eligible Americans, the final recommendation by the USPSTF will have far ranging effects on physicians in primary care, pulmonary and radiology.

Since the publication of the National Lung Screening Trial in 2011, lung cancer screening programs have rapidly proliferated across the U.S., as medical centers compete for the leading-edge, and also for potentially lucrative patients. Otis Brawley of the American Cance

Society estimated that each of the 95% false positive lung cancer screening CTs would cost about $45,000 (or generate $45,000 in revenue, depending on your point of view).

The new grade B recommendation should markedly accelerate the trend, since the Affordab Care Act requires private insurers to cover services the task force grants an "A" or a "B" recommendation without copay or deductible – in other words, free. Medicare will not be required by law to cover lung cancer screening (but could still decide to). Since primary car and other physicians will be responsible for missed lung cancer diagnoses if they do not offe screening, low dose CT screening should soon achieve "reflex" status, like mammography and colon cancer screening.

That could save up to 12,000 lives yearly from the #1 cancer killer in the U.S. (201,144 diagnoses, 158,248 deaths in 2010), for which medical treatments have been poorly effective. But industrial-scale screening of 9 million qualifying patients will also come with some growing pains: overdiagnosis of harmless lung cancers and new professional demands on primary care physicians, pulmonologists, radiologists, and thoracic surgeons.

The reasons can be summed up in a simple phrase: false positives. About 35% of patients i the NLST had at least one false positive scan in 3 years, requiring further follow-up CTs and occasionally, biopsy or surgery, for lesions that were not cancer. Since 95% of all the nodules and other lesions seen were false positives, nationwide screening can be expected t generate a massive new data feed of hundreds of thousands of new CT scans and follow-up which most centers' systems are not currently prepared to handle. Screening people for as long as 26 years should be expected to produce even more false positive CT scans per patient than seen in the NLST.

The lower the risk in the group of patients tested, the higher the false positive rate will be. Although adults in the NLST all had a heavy smoking history, that similarity masked important differences between them that resulted in a dramatic variation in risk, and in the rate of false positive scans.

Among the highest-risk cohort in the NLST, the number needed to screen to prevent a deat from lung cancer was only 161, but in the lowest-risk cohort (all of whom still had 30 pack year histories, remember), **5,276** people needed to be screened to save a life. The 20% of heavy smokers in the lowest-risk category had a 99.98% chance of having no benefit from screening. This is partly why lung cancer screening only got a grade B recommendation, wit "moderate certainty of a moderate net benefit."

Is there radiation risk from lung cancer screening? Low-dose chest CT delivers about 2 mSv (each year); atomic bomb survivors' mean dose was 40 mSv. The risk of getting cancer fro a 1-10 mSv radiation dose has been estimated to be 1 in 10,000. Most estimates

conservatively assume the risk from serial CT scans is additive (so 20 years of CT scanning one atomic bomb exposure), however, cellular DNA repair between low-dose scans may mitigate this risk.

Researchers are working on prospectively validating lung cancer risk calculators (the ones that produced some of the above data) to better stratify the risk of patients with heavy smoking histories. Deployed systematically, these would allow the most rational and productive use of lung cancer screening CT, saving lives while reducing harm to cancer-free patients. You can play with the not-ready-for-production tools yourself.

As the headlines dissolve into workaday health care policy, practical implementation of lung cancer screening will fall to physicians and the systems we work in. There was no standardized follow-up protocol for abnormal lung scans in the NLST, so to some extent, thi is an open field. Many primary care physicians, radiologists and pulmonologists will try to just add this new item to the long list of stuff they already need to do. My suspicion is the frequency and volume of follow-up CTs needed for the deluge of false-positive tests will quickly become unmanageable using such an ad hoc approach. Referral to medical centers with established lung cancer screening programs, potentially with remote/telemedicine consultations for underserved areas, may be more likely to approach the 20% mortality reduction in the NLST.

Lung cancer screening with low dose chest CT is a crude but effective tool that should evolv and improve over time. In large part, that evolution will be determined by physicians implementing the recommendation. So what are you waiting for — fire up those scanners, print out those Fleischner guidelines, and start saving some lives. (Every 320 scans, you ca score yourself one.)

USPSTF website, "Screening for Lung Cancer: Current Recommendation," Decemb 2013.

Frank C. Detterbeck and Michael Unger. Screening for Lung Cancer: Moving Into a New Era, *Ann Intern Med.* Published online 31 December 2013.

Bach PB. Raising the Bar for the U.S. Preventive Services Task Force. Ann Intern Med 2013 Dec 31. doi: 10.7326/M13-2926.

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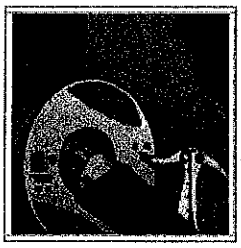
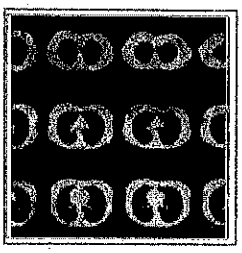


Overdiagnosis rate with lung cancer screening CT is 18% (JAMA Int Med)



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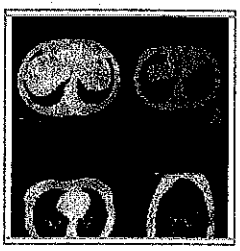
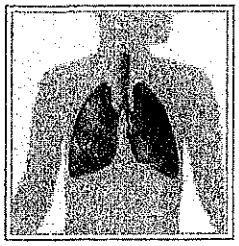
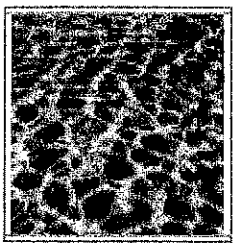


How to ration lung cancer screening CTs, rationally (NEJM)



New lung cancer prediction tool promises better use of screening CT (NEJM)



ACCP, ATS only weakly recommend lung cancer CT screening, warn of harms (JAMA)

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September 9, 2013

Louis B. Jacques, MD
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore MD 21244

Formal Request for a National Coverage Determination on Lung Cancer Screening with Low Dose Computed Tomography

Dear Dr. Jacques,

I am writing to submit a formal Track # 1 request for a National Coverage Determination (NCD) on whether the use of Low Dose Computed Tomography (LDCT) is reasonable and necessary for the early detection of lung cancer (i.e. lung cancer screening) in beneficiaries at high risk of developing the disease. The probable Medicare Benefit Category for lung cancer screening with LDCT is Preventive and Screening Services described by section 1861(s)(2)(BB) of the Social Security Act. Coverage is allowable for Medicare if the United States Preventive Services Task Force (USPSTF) endorses LDCT screening with an "A" or "B" recommendation. The procedure currently has an "I" grade from the USPSTF, but an update is in progress and the Task Force released a draft recommendation on July 30th, 2013 with a "B" grade, roughly aligning the task force recommendations with those of many organizations.[1-6]

In line with the findings and recommendations of the medical literature related to this screening test I am requesting that the Centers for Medicare and Medicaid Services (CMS) determine that screening for lung cancer with LDCT when conducted in centers with appropriate expertise and staffing is reasonable and necessary for those beneficiaries who are between 55 and 74 years of age, are current smokers (or have quit smoking within the last 15 years) and have a smoking history of at least 30 pack years (defined as number of packs smoked per day multiplied by number of years smoked). It should be covered under Coverage with Evidence Development using a patient specific registry designed to ask several important unanswered questions about screening and its impact on beneficiaries that I detail in my request, and it should only be covered for beneficiaries who elect to receive the service after a data driven decision making discussion with their physician.

The following pages and attachments contain the necessary supporting documentation for this NCD request as specified by CMS in the Federal Register (Vol. 68, No. 187, page 55637). Thank you for taking the time to review and consider this request.

Sincerely,

Peter B. Bach
Director, Center for Health Policy and Outcomes
Department of Epidemiology and Biostatistics
Department of Medicine
Memorial Sloan-Kettering Cancer Center
New York, NY

Supporting Documentation

I. A full and complete description of the item or service in question

Computed tomography (CT or CAT scan) is a radiologic imaging procedure which produces cross sectional pictures of the body, providing a detailed of view of organs, bones and other tissues. Low dose computed tomography (LDCT) is a version of a CT scan that aims to minimize the patient's exposure to radiation from the procedure. LDCT has been seen as a potential advance in lung cancer screening due to its advantages in accuracy and radiation minimization when compared to CXR and regular dose CT, respectively.[7] Computed tomography has been approved as a class II medical device by the United States Food and Drug Administration for diagnostic uses, but not for screening.

II. A specific detailed description of the proposed use of the item or service, including the target Medicare population and the medical condition(s) for which it can be used

The target population includes beneficiaries between the ages of 55 and 74, who are either current smokers or have quit smoking within the last fifteen years and have a smoking history of at least thirty pack years. Beneficiaries with any of the following characteristics should not be included in the target population: history of aerodigestive cancer; individuals undergoing active treatment for any cancer; history of removal of any portion of the lung, excluding small tissue biopsies via needle or bronchoscopic biopsy; requirement for home oxygen supplementation; unexplained weight loss of more than 15 pounds in the 12 months prior; recent hemoptysis; pneumonia or acute respiratory infection treated with antibiotics in the 12 weeks prior to eligibility assessment; chest CT examination in the 18 months prior; individuals with a life expectancy of less than 5 years.[7] Beneficiaries with a past history of lung cancer should not be eligible for the service as imaging of the chest in these individuals constitutes use of the CT scanner as a diagnostic service under a different benefit category that is already covered for Medicare beneficiaries when conducted appropriately.

Note that pack years are defined as the duration of smoking history (years) multiplied by the intensity of smoking history (packs smoked per day). Some example smoking histories that equate to 30 pack years include smoking one pack per day for 30 years and smoking 2 packs per day for 15 years.

III. An explanation of the design, purpose and method of using the item or equipment, including whether the item is for use by health care practitioners or patients

The service is for the use of qualified health practitioners to proactively search for lung cancer in patients who are asymptomatic but at high risk of developing the disease (screening). It is not intended to screen for or diagnose other diseases or disorders although related incidental findings are occasionally uncovered.

IV. A description of any clinical trials currently underway that might be relevant to a decision regarding coverage of the item or service

There are several ongoing randomized trials, and several that are completed but for which some important analyses are pending, including a planned cost-effectiveness analysis of data derived from the NLST trial. The USPSTF is also currently in the process of updating their recommendations on the topic (for updated information see: http://www.uspreventiveservicestaskforce.org/uspstf/topicsprog.htm). This review will determine if

the service earns an A or a B recommendation which would provide statutory authority for CMS to include this screening service in the benefit for Medicare enrollees (the currently available "draft" recommendations have issued a "B" grade). The ongoing studies are described in detail within the table located at the end of this document.

V. A compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service

A list of the peer-reviewed publications relevant to the medical benefits of screening for lung cancer with LDCT is located at the end of this document. These publications are described below in section VI and a full text version of each of the articles is included in an attachment.

VI. Statement from the requestor regarding the evidence for lung cancer screening with LDCT

A. An Explanation of the relevance of the evidence selected

With this request I am submitting a comprehensive set of published studies on lung cancer CT screening derived from a recent systematic review published in the Journal of the American Medical Association, as well as relevant studies published since that review was published. The key inclusions are the review itself regarding the benefits and harms of lung cancer screening using LDCT,[2] the three randomized controlled trials (RCTs) comparing the benefit of screening with LDCT to that of screening with chest x-ray (CXR),[7-12] six RCTs comparing the benefit of screening with LDCT to that of no screening,[13-22] one RCT comparing the benefit of screening with CXR to no screening,[23] thirteen observational cohort studies which evaluate LDCT screening[24-43] and five sets of clinical practice guidelines on the use of LDCT for lung cancer screening.[1-4,6] The studies not included in the review include a more recently published RCT,[13] the USPSTF's draft updated recommendation statement, evidence report and modeling report,[5,44,45] a risk prediction model based on NLST data[46] and an editorial discussing the variation in benefit likely to be seen across eligible patients who differ in their baseline risk of developing lung cancer.[47] Note that several of the RCTs and cohort studies have multiple publications. All of the selected RCTs and cohort studies are limited to individuals at high risk of developing lung cancer due to age and significant smoking histories among other factors, although the eligibility criteria due differ along with other aspects of the intervention.

B. Rationale for how the evidence selected demonstrates the medical benefits for the target Medicare population

Cancer screening tests necessarily involve tradeoffs. Numerous individuals who will never suffer from the condition being screened for are subjected to the test and many have findings on the test that lead to follow-up evaluations which carry risks and costs. Yet a few individuals who undergo effective screening tests benefit due to the early detection of a condition that can have its outcome altered through early intervention. The systematic review of the evidence regarding the benefits and harms of LDCT screening outlines these respective potential harms and benefits and forms the basis for many of the current practice guidelines for lung cancer screening. The guidelines are listed below in the table. The review, and all of the clinical practice guidelines concluded that LDCT screening for lung cancer may benefit a specific target population of Medicare beneficiaries (current smokers, or former smokers who have quit within the last 15 years, are between the ages of 55-74 and have a smoking history of at least 30 py) and recommended that the test be offered to those patients by their clinicians. Two sets of guidelines (from NCCN and AATS), as well as the draft update to the USPSTF's recommendation

statement, also proposed screening some other individuals whose risk of lung cancer was (in the guideline writers judgment) sufficiently high.[3-5]

All the guidelines share a cautious tone regarding the harms of screening and the expertise that is necessary to perform screening in the least harmful and most beneficial way possible. The guidelines from ASCO, ACCP and ATS note the importance of screening individuals only in settings that are able to deliver comprehensive care similar to that received by NLST participants.[2] These screening recommendations came with several other caveats including the following: counseling should include a complete description of potential benefits and harms so the individual can decided whether to undergo LDCT screening; screening should be conducted in a center similar to those where the NLST was conducted, with multidisciplinary coordinated care and a comprehensive process for screening, image interpretation, management of findings, and evaluation and treatment of potential cancers. The USPSTF's draft recommendation statement and the AATS guidelines also acknowledge that limiting screening to settings with capabilities similar to those of the NLST sites could be beneficial.[5]

The guidelines released by ASCO, ACCP and the ATS also recommended what is generally agreed upon within the evidence based community concerned with lung cancer screening, which is that a registry is needed to determine if LDCT screening conducted in individuals not in the clinical studies yields the same findings and measures of harm that were seen in the NLST study. Concerns about external validity of the NLST results stem from unanswered questions about the technical, structural and clinical components of LDCT screening. On the technical = and structural sides there are the demographic makeup of NLST participants compared to the NLST-eligible population nationwide, the previously mentioned issues related to the atypical nature of the NLST sites and the associated individual radiologists and other health professionals, as well as issues related to the equipment used, such as collimation settings and scan quality of the CT scanners.

The NLST was conducted in # sites throughout the US. 76% of these sites were NCI designated comprehensive cancer centers.[2] The significance of this designation is evident in the fact that it is received by only 41 of the 5,000+ hospitals in the country. Further, 82% of NLST sites were large academic medical centers with more than 400 beds. The population screened in the NLST was also different, in important ways, from the NLST-eligible population nationwide. In comparison to the population of individuals in the US who meet the NLST eligibility criteria for age and smoking history, the NLST study subjects were more highly educated (31.5% vs 14.4% with a college degree or higher), younger (73% vs 65% under 65 years of age) and less likely to be current smokers (48% vs 57%). These characteristics suggest that the NLST population was healthier than the typical NLST-eligible individual, which would bias the NLST results towards greater benefits and fewer harms.[9]

Clinically, reported rates of false positives of LDCT screening have been extremely variable, varying by study from less than 5% to nearly 50%.[2] Similarly, reported rates of followup surgical procedures varied from less than 1% to nearly 6%.[2] The 60 day mortality rate following lung resection in the NLST was only 1 percent (meaning 30 day and in-hospital mortality were lower than this figure).[8] Meanwhile, an analysis of the Nationwide Inpatient Sample suggests that in 2010 the average in-hospital mortality rate following lobectomy was 1.9%.[48] Important questions about the effects of LDCT screening on smoking behavior also remain unanswered. Differences in the prevalence and intensity of smoking, as well as rates of cessation and recidivism, between the population eligible for screening under Medicare and the NLST population could limit the effectiveness of screening. These sources of uncertainty surrounding the external validity of the NLST results could be addressed through the use of a well designed patient registry including, among other items, data on nodule detection and

characteristics, follow-up testing, radiation exposure, patient experience, and smoking behavior. Screening quality metrics that could be assessed through this registry should also be developed.

Three additional sets of clinical practice guidelines (or similar documents) released by the National Comprehensive Cancer Network, the American Association of Thoracic Surgeons and American Lung Association came to similar conclusions and made similar recommendations, although the former two societies recommended screening some additional populations.[1,3,4]

Table: Summary of Recommendations on Lung Cancer Screening Completed by US-based Professional Societies and Government Agencies

Recommend screening NLST eligible groups[1]	AATS, ACCP, ACS, ALA, ASCO, ATS, NCCN, USPSTF(draft)[2]	
Also recommend screening other groups	AATS	Screen up to age 79. Screening may begin at age 50 with 20 pack years if 5 year risk of lung cancer is >5%.
	NCCN	Screening may begin at age 50 with 20 pack years if one additional risk factor is present.[3]
	USPSTF(draft)[1]	Screen up to age 79.

1: Individuals between 55 and 74 years of age, who are current smokers (or have quit smoking within the last 15 years) and have a smoking history of at least 30 pack years (defined as number of packs smoked per day multiplied by number of years smoked).
2: The USPSTF is currently in the process of completing their updated recommendation on lung cancer screening. The recommendations referred to in this table are currently in 'draft' form. Information on the status of the USPSTF recommendation is available at: http://www.uspreventiveservicestaskforce.org/uspstf/topicsprog.htm
3: Relevant additional risk factors according to NCCN include cancer history, lung disease history, family history of lung cancer, radon exposure and occupational exposure to asbestos or another carcinogen.[4]

C. Information that examines the magnitude of the medical benefit

Four RCTs, the National Lung Screening Trial (NLST)[8], the Detection and Screening of Early Lung Cancer by Novel Imaging Technology and Molecular Essays Trial (DANTE),[15] the Danish Lung Cancer Screening Trial (DLCST),[19] and the Multicentric Italian Lung Detection Study (MILD)[13] have reported results on the effect of LDCT screening for lung cancer on mortality. All four trials reported data on all cause and lung cancer specific mortality, as well as (indirectly or directly) mortality from all causes other than lung cancer. The NLST found that 3 annual rounds of screening with LDCT resulted in a 20% relative decrease in deaths from lung cancer vs CXR over a median of 6.5 years of follow-up (P=.004).[8] In absolute terms, the chance of dying from lung cancer was 0.33% less over the study period in the LDCT group. The smaller DANTE, DLCST and MILD studies each compared a planned 5 annual rounds of screening to usual care and, after 34, 58 and 53 months of followup, respectively, found no statistically significant difference in lung cancer mortality between screened and unscreened groups (figure).[15,19] No study found a significant difference in deaths not due to lung cancer resulting from screening either individually or combined.[8]

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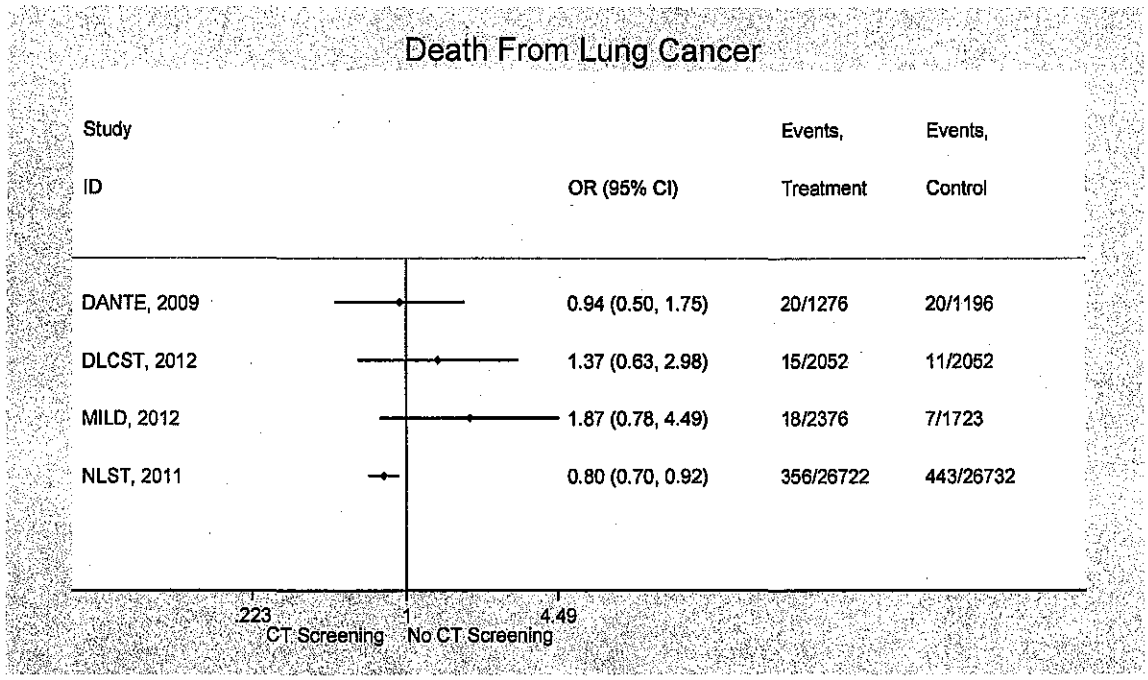

It should be noted that the results presented in the above forest plot, taken from the systematic review by Bach et. al., differ slightly from those in the USPSTF's evidence report. Using reported person months of followup (instead of the median as in Bach et. al.) the USPSTF evidence report found RRs for lung cancer mortality of 0.83 (95% CI: 0.45 – 1.54) in the DANTE trial and 1.99 (95% CI: 0.8 – 4.96) in the MILD trial.[45]

A fifth RCT, the Prostate, Lung, Colorectal and Ovarian Randomized Trial (PLCO), found no mortality difference between CXR screening and usual care among individuals who would have been eligible for the NLST, allowing the control populations in the NLST, DANTE, MILD and DLCST trials to be considered reasonably comparable, even though the NLST used CXR screening rather than usual care as the control intervention.[23] It is important to note that although all of these studies restricted eligibility to individuals at high risk of lung cancer, the NLST, which was the only study to find a mortality benefit from LDCT screening, used the most restrictive eligibility criteria and appears as a result to have screened a population at higher risk of developing lung cancer than the DANTE, DLCST and MILD trials.

Potential harms of LDCT screening for lung cancer include false positive results, complications resulting from diagnostic procedures (following either true positive or false positive results), overdiagnosed cancers, exposure to radiation, and detriments to quality of life. As detailed by Bach et al most of the RCT and cohort studies evaluating LDCT screening report on the frequency of false positive results and unnecessary diagnostic procedures as well as the complications resulting from both necessary and unnecessary diagnostic procedures.[2] However, there is substantial heterogeneity in the manner in which these results are reported and in the results themselves. Across studies approximately 20% in each round of screening had a positive result requiring some degree of followup, while approximately 1% had lung cancer.[2] Regarding the risks of radiation exposure, models estimate that the radiation risks associated with LDCT screening are outweighed by the benefits for NLST eligible individuals, although this is not necessarily the case for individuals at lower risk of developing lung

cancer.[2] The evidence available on overdiagnosis (detection of cancers that would not affect the patient's life if left untreated) and quality of life issues related to LDCT screening for lung cancer is very limited and more evidence is needed to draw conclusions in these areas.[2]

As previously mentioned, LDCT screening could potentially have benefits (or harms) related to smoking behavior if there are differences in the prevalence and intensity of smoking, as well as rates of cessation and recidivism, between populations who receive LDCT screening and those who do not. The evidence on these outcomes in studies of LDCT screening is limited and mixed. According to the USPSTF's evidence report multiple trials found no difference in smoking behavior between treatment and control groups, although one of the two showed increased smoking abstinence among those with abnormal findings.[45] Results from cohort studies were also varied.[45]

There is substantial variation between patients in the benefits that can be expected from lung cancer screening based on their underlying risk factors. Within the NLST eligible population the estimated number of lung cancer deaths averted with LDCT screening varies fifteen fold, as shown in the table below.[47] At the same time, the variety of harms associated with LDCT screening described above, such as false positive screening results and their associated effects on quality of life, may affect individuals in different and personal ways.

Table. Projected Likelihood Over 6 Years of Lung Cancer Death With or Without Screening per 1000 Persons Screened*

Participant	Risk Factors	Deaths From Lung Cancer (Without Screening) per 1000 Persons, *n*	Deaths From Lung Cancer (With Screening) per 1000 Persons, *n*	Lung Cancer Deaths Averted per 1000 Persons, *n*	Persons Needed to Be Screened Annually for 3 y to Prevent 1 Death From Lung Cancer Over 6 y, *n*
"Typical" participant in the NLST	62-year-old male current 1.5-PPD smoker for 35 y	19.5	15.6	3.9	256
Minimum eligible participant in the NLST	55-year-old female former 1-PPD smoker for 30 y who just quit	4.0	3.2	0.8	1236
High-risk participant eligible for the NLST	70-year-old current 2-PPD smoker for 55 y	60.9	48.7	12.2	82
Minimum eligible participant by NCCN guidelines	50-year-old male former 1-PPD smoker for 20 y who quit 10 y ago with an occupational asbestos exposure history	1.6	1.3	0.3	3180
Low-risk eligible participant for Sequoia Hospital lung screening program	40-year-old female former 1-PPD smoker for 10 y who quit 15 y ago	0.10	0.08	0.02	35 186

NCCN = National Comprehensive Cancer Network; NLST = National Lung Screening Trial; PPD = packs per day.
* Assuming the program includes 3 y of annual screening.

For these reasons lung cancer screening is an example of a health care decision in which there is a reasonable likelihood that a patient's preferences would affect the probability for an approach to be considered optimal. Therefore, screening for lung cancer is a clear example of a situation in which Informed or Shared Decision Making (SDM) should be applied. SDM is a collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences. The utilization of well established SDM methods should play a role in Medicare's coverage of LDCT screening for lung cancer. Several validated prediction models are available which could form the basis of tools that will facilitate a SDM process. These models have been shown to produce similar estimates and have been used in the development of multiple publicly available electronic risk prediction tools (images).[46,49-52]

Image: Screenshot of the MSKCC Lung Cancer Risk Prediction Tool

Lung Cancer Screening Decision Tool

TEXT SIZE

Our lung cancer screening decision tool helps clinicians and patients determine the chance that screening will be beneficial based on a patient's age and smoking history.

Enter Your Information — Clear — Calculate ▸

Age 55 (50 to 75 years)

Gender Male

Number of years you have smoked cigarettes 25 (25 to 55 years)
You must have smoked between 25 and 55 years to use this model.

During your years as a smoker, how many cigarettes per day did you smoke, on average? 24 (10 to 60 cigarettes)
You must have smoked between 10 and 60 cigarettes per day to use this model.

Have you quit smoking? ◉ YES ○ NO

How many years ago did you quit smoking? 15 (0 to 20 years)
You must have quit smoking between 0 and 20 years ago to use this model.

Have you been exposed to asbestos at work? ○ YES ◉ NO

Your Results

Learn more about your results below

Lung screening cases saved for 1,000 people like you over the next 5 years

Out of 1,000 people like you who are NOT screened, number who will be diagnosed with and die from lung cancer	3.4
Out of 1,000 people like you who ARE screened, number who will die from lung cancer	2.7
Out of 1,000 people like you who ARE screened, the number of lives that will be saved	0.7
Number of people like you that would need to be screened in order for ONE of you to benefit	1486

Image: MD Anderson Lung Cancer Risk Prediction Tool

Quit smoking
Please specify age that you quit smoking.
40

Family History
Have more than 2 of your immediate family (parent, sibling or child) members been diagnosed with a cancer (not including non-melanoma skin cancer)?
No

Dust Exposure
In your work or hobbies, have you ever been exposed to dusts (including saw dusts, wood dusts, sand, but not ordinary house dust) for more than 8 hours a week for at least a year?
No

Hay Fever
Has a doctor ever told you that you have hay fever?
No

Emphysema
Has a doctor ever told you that you have emphysema or Chronic Obstructive Pulmonary Disease?
No

Given your set of risk factors

*** former smoker**

your risk of lung cancer is **1.45 higher** compared to a man of similar age without any risk factors. This risk is considered **Low Risk**.

D. Reasoning for how coverage of the item or service will help improve the medical benefit to the target population

Coverage of the screening test will improve the medical benefit by enabling access to a procedure that has been found to reduce lung cancer mortality in individuals at substantially elevated risk of lung cancer in the setting of a large federally funded study with a high degree of oversight conducted at large highly experienced centers. It is now recommended by seven separate medical professional organizations based in the United States and the USPSTF has issued a "B" grade in the form of draft recommendations. To maximize the benefit and minimize the harms of the procedure, coverage should be limited to centers of excellence that are able to provide the comprehensive level of care that was made available to NLST participants. Characteristics of these centers should be defined by the agency in collaboration with experts in the field. A screening registry should be mandated using coverage with evidence development process to ensure that benefits, harms, and processes are continually monitored when beneficiaries are being screened and their findings are being further evaluated. The registry would be used to address unanswered questions regarding the external validity of the NLST mortality results, rates of false positives and related followup procedures, and the effects of LDCT screening on smoking behavior. The use of shared decision making is vitally important and LDCT screening should only be covered if the patient chooses to be screened after being informed of the benefits and harms of screening in a data driven discussion, through the use of SDM methods, with their physician.

List of publications (full text versions of each article are included in a separate attachment)

1. Providing Guidance on Lung Cancer Screening to Patients and Physicians. 2012. (Accessed 1/25/2013, at http://www.lung.org/lung-disease/lung-cancer/lung-cancer-screening-guidelines/lung-cancer-screening.pdf.)
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Trials Currently in Progress for Lung Cancer Screening with LDCT

Study	Number of Participants			Screening with LDCT			Study Duration		Number of Screens			Participant Characteristics			
	Randomized (total)	% Screened or Followed at Baseline by Trial Arm		Collimation (mm)	Nodule Size (mm) Warranting Work-up (Imaging, Diagnostic Tests)	Is a Diagnostic Protocol in Place?	Years of Accrual	Planned Years of Follow-up (from Baseline)	Planned	Completed (at last report)	Conducted Annually?	Male	Age Range	Smoking History Eligibility (current or former)	
		LDCT	Control											Pack-Years[a]	Years since quit
LDCT versus Usual Care (no screening)															
NELSON[20]	15,822[b]	95%	100%	0.75	≥ 4.6 / > 9.8	Yes[c]	2004-NR	10	3	2	No[d]	84%	50-75	> 15	≤ 10
DLCST[18]	4,104	100%	100%	0.75[e]	≥ 5 / > 15	Yes	2004-06	10	5	1	Yes	55%	50-70	> 20	< 10[f]
ITALUNG[17]	3,206	87%	100%	1-1.25	≥ 5 / ≥ 8[g]	Yes	-	-	4	1	Yes	65%	55-69	≥ 20	< 10
UKLS[53]	32,000 (planned)	TBA	TBA	0.5-0.625	≥ 15	Yes	TBA	10	1	0	NA	TBA	50-75	NA[i]	
LUSI[54]	4,052	TBA	TBA	NR	≥ 5	Yes	2007-2011	NR	5	4	Yes	TBA	50-69	≥ 15	< 10
LDCT versus Chest X-Ray															
NLST[j]	53,454	98%	97%	≤ 2.5	≥ 4	Yes	2002-04	> 7	3	3	Yes	59%	55-74	≥ 30	≤ 15

Note: NR = Not Reported, The column heading Nodule Size (mm) Warranting Work-up indicates first the largest size nodule warranting additional imaging, and second the largest size nodule warranting diagnostic testing

[a] Pack-years is defined as the number of cigarettes packs (20 cigarettes per pack) smoked per day multiplied by the number of years smoked.

[b] Randomization is ongoing with a target accrual of 16000 participants.

[c] A protocol was reported, however specific details on adherence or deviation from the protocol or actual procedures used were not reported.

[d] Planned screening at years 1,2, and 4.

[e] Collimation = 16 x 0.75 mm

[f] Former smokers had to have quit after the age of 50 years and less than 10 years ago.

[g] Diagnostic workup was referral to a positron emission tomography scan.

[h] The median follow-up was 33.7 months and only 161 (6.5%) participants had 5 or more years of follow-up. Baseline data are mainly reported

[i] Based on the LLP risk prediction model, participants with a 5% 5-year risk (or greater) of developing lung cancer were eligible.

[j] The NLST trial is completed. However, an cost effectiveness analysis of screening with LDCT based on the NLST data is planned.

AMERICAN LUNG ASSOCIATION.
Fighting for Air

LUNG CANCER CT SCREENING:

SHOULD MY PATIENT BE SCREENED?

Screening for cancer means testing for cancer *before* there are any symptoms. Screening for some types of cancer has reduced deaths by early detection and treatment. Now there is a test that *can* reduce death from lung cancer through early detection. The test is not recommended for everyone and it has risks as well as benefits. Here are key points you may want to use in discussion with your patients who may be at risk for lung cancer or are worried about their risk for lung cancer.

The best way to prevent lung cancer is to never smoke or stop smoking now. If your patients are still smoking, talk to them about ways you can help them quit smoking.

Q: Who is a good candidate for lung cancer screening?

A: The National Lung Screening Trial (NLST) criteria are:

- a ***current or former smoker*** (former smokers having quit within the past 15 years)
- and in the age group from ***55 to 74 years***
- and with a ***smoking history of at least 30 pack-years*** (1 pack/day for 30 years, 2 packs per day for 15 years, etc.)
- and no history of lung cancer

There is no evidence at this time that other high-risk groups should be screened. Patients with lung disease, particularly COPD should be evaluated by a pulmonologist regarding the advisability of CT screening in the context of the severity of their disease.

At this time, ***only Low Dose CT scans*** are recommended for screening. ***Chest X-rays are not recommended for screening***.

Q: What should I discuss with my patient who may be a candidate for a CT scan to screen for lung cancer?

A: CT scan screening is a complicated process that requires you first:

- Take a complete health history
- Determine possible co-morbidities (conduct spirometry if indicated)
- Educate about symptoms of lung disease and lung cancer
- Discuss the benefits, risks and possible procedures associated with the screening process
- Discuss the costs of screening, including financial, personal and time costs
- Advise current smokers to quit smoking, offering to help them with appropriate pharmacologic and behavioral options.

Q: Where should I refer a patient for a CT scan to screen for lung cancer?

A: Refer your patient to institutions that have experience in conducting ***Low Dose CT scans***, as well as, using the latest CT technology.

- Make sure that the facility uses "best practices" for lung cancer screening
- There should be a link to an expert multidisciplinary team that can provide follow- up for evaluation of nodules. If the facility does not have that expertise on site, they should be able to make referrals to appropriate institutions.
- They should also discuss the results and how they will follow up with you and your patient after the screening.

Q: What does it cost to have a CT scan for lung cancer?

A: Because the (NLST) results are recent, health insurance companies and Medicare may not cover the cost for a CT scan to screen for lung cancer at this time. That means that your patient may have to pay for the procedure out of their own pocket. Be sure to advise your patient to check with their insurance plan for the screening scan and to see what is covered if the results of the CT scan show that they should have additional procedures. ***Ask the referral facility doing the CT scan to carefully and clearly explain to your patient all the costs that they may possibly incur and not just the cost of the CT scan alone.***

Q: What do the results mean?

A: A ***"positive"*** or ***"suspicious"*** result means that the CT scan shows something is abnormal. This could mean lung cancer or some other serious condition. It could also mean there is no serious condition and thus is a ***"false positive"***. Your patient may need to have additional procedures, and those procedures may carry additional risks. If your patient does have lung cancer or some other serious condition, you and the team of experts should discuss all possible treatment options with the patient, including clinical trials and palliative care.

A ***"negative"*** result means that there were no abnormal findings at this time and on this CT scan. It does not mean that your patient absolutely does not have lung cancer. It also does not mean that they will never get lung cancer. You should discuss when and if they should be tested again.

There may also be an ***"indeterminate"*** result and you and the expert team will recommend watchful follow-up and further imaging at a later time.

Whatever the result: if your patient is still smoking, talk to them about ways to help them quit smoking.

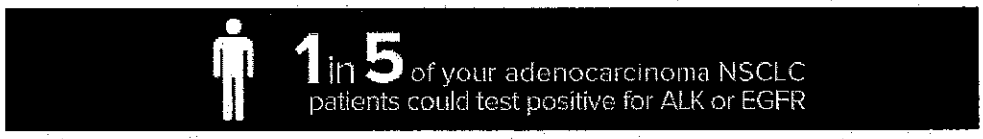
Q: Where can I get more information about lung cancer and lung cancer screening?

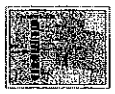
A: The American Lung Association assembled an expert committee to review the results of the NLST and offer recommendations for the best possible guidance to physicians, their patients and the general public regarding Low Dose CT scans to screen for lung cancer. The full report may be found at: Lung.org/lung-cancer-screen

You and your patients can contact the American Lung Association to find out more about lung cancer and lung cancer screening.

Remember: The best way to prevent lung cancer is to never smoke or stop smoking now. If your patients are still smoking, talk to them about ways you can help them quit smoking.

Go to: www.Lung.org
Call: 1-800 LUNG USA (1-800-586-4872)

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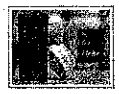
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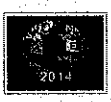

Prevention Is Crucial to Stem 'Tidal Wave of Cancer'

Medscape Medical News > Oncology

USPSTF Finalizes Recommendations for Lung Cancer Screening

Roxanne Nelson

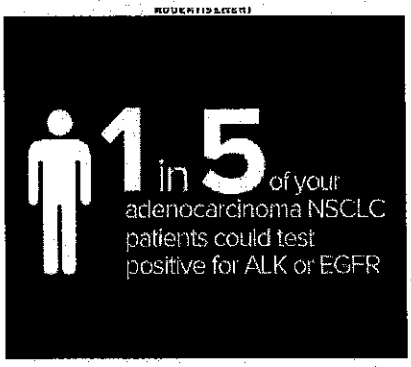
December 30, 2013

13 comments Print

EDITORS' RECOMMENDATIONS

USPSTF Finds 'Moderate Benefit' From Lung Cancer Screening

The US Preventive Services Task Force (USPSTF) has now issued its final recommendation on lung cancer screening, published December 31 in the *Annals of Internal Medicine*.



Lung Cancer News & Perspectives

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DRUG & REFERENCE INFORMATION

Non-Small Cell Lung Cancer

Extrapulmonary Small Cell Carcinoma

Globe Retraction

The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) for adults between the ages of 55 to 80 years who have a 30 pack-year smoking history and who currently smoke or have quit within the last 15 years.

In addition, they note that screening should be discontinued once a person has not smoked for 15 years or has developed a health condition that will substantially limit life expectancy or the ability or willingness to undergo curative lung surgery.

"It's clear that the longer and the more a person smokes, the greater their risk is for developing lung cancer," says the co-vice chair of the USPSTF Michael LeFevre, MD, MSPH, in a statement. "When clinicians are determining who would most benefit from screening, they need to look at a person's age, overall health, how much the person has smoked, and whether the person is still smoking or how many years it has been since the person quit."

The final recommendation follows closely the wording of the draft recommendation that the USPSTF issued July 2013, after which there was a time for comments. Both the draft and the final document concluded that there was a "moderate certainty" that annual screening is of "moderate net benefit" for individuals with a smoking history. This was a step forward from the recommendation it issued back in 2004, when it concluded there was insufficient evidence to recommend screening.

As previously reported by *Medscape Medical News*, this new recommendation is in line with those issued by several other bodies, including the American Cancer Society, the American College of Chest Physicians, and the National Comprehensive Cancer Network, which, in November 2011, was the first to issue a guideline for lung cancer screening.

Evidence and Harms

The USPSTF emphasizes that lung cancer screening is not an alternative to smoking cessation and that screening cannot prevent most deaths that are directly related to lung cancer. However, they found there was "adequate evidence that annual screening for lung cancer with LDCT in a defined population of high-risk persons" could prevent a substantial amount of disease-related mortality. The magnitude of individual benefit of screening also largely depends on a person's risk for developing lung cancer, as those facing the highest risk are the most likely to reap the benefits.

Harms have been associated with LDCT screening, including false-negative and false-positive results, incidental findings, overdiagnosis, and radiation exposure. A substantial proportion of individuals undergoing screening are affected by false-positives, notes the USPSTF, and the vast majority (95%) of all positive results do not lead to a cancer diagnosis. Although further imaging can resolve most false-positive results, some patients will undergo more invasive follow-up.

The USPSTF reports they found "insufficient evidence" on the harms associated with incidental findings, and although overdiagnosis of lung cancer does occur, the "precise magnitude is uncertain." The results of a modeling study that was conducted for the USPSTF estimated that 10% to 12% of screen-detected cancer cases are overdiagnosed.

Important Questions Remain

In an accompanying editorial, Frank C. Detterbeck, MD, from Yale University School of Medicine, New Haven, Connecticut, and Michael Unger, MD, from the Fox Chase Cancer Center, Philadelphia, Pennsylvania, emphasize that the USPSTF is recommending a structured and comprehensive screening process, and not just a scan.

However, this report does not address many of the practical aspects of implementing lung cancer screening, they say. For example, they note that "[D]isproportionate screening attracts individuals who have great anxiety about developing lung cancer even though their risk is actually not so high. These people need reassurance, with discussion of their risk for lung cancer and the issues associated with screening as they apply to them."

Another issue is patient selection and how it will actually occur in a real world setting, as "ample evidence shows underuse of cancer screening in populations for which it is indicated and overuse in those for which it is not," they write. "It is one thing to have strict criteria for entry into a study and no data that lung cancer screening works; it is another to argue that we should be screening and then expect that individuals with concerns can be excluded by simply drawing a line."

For a lung cancer screening program to be effective, it really needs to reach those at high risk, they comment. However, studies indicate that individuals at the highest risk seem less interested in being screened despite recognizing that they are at risk. The USPSTF also does not address who will evaluate people who are interested in or should consider CT screening for lung cancer, the editorialists write.

Many fundamental questions also remain, such as what the natural history of screen-detected cancer cases is, and are there criteria for whom and when to treat, Dr. Detterbeck and Dr. Unger point out.

"This is a dynamic field, and refinements in screening models could become available quickly," they write. "We should learn from differences among the randomized lung cancer screening trials.... If we stray too far from what we confidently know, we risk facing the difficult task of undoing mistakes. We need to implement screening given the evidence that we have, but we should proceed in a stepwise fashion."

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J Community Health. 2011 Dec;36(6):949-56. doi: 10.1007/s10900-011-9394-2.

A qualitative analysis of lung cancer screening practices by primary care physicians.

Henderson S, DeGroff A, Richards TB, Kish-Doto J, Soloe C, Heminger C, Rohan E.

Author information

Abstract

Lung cancer is the leading cause of cancer death in the United States, but no scientific organization currently recommends screening because of limited evidence for its effectiveness. Despite this, physicians often order screening tests such as chest X-rays and computerized tomography scans for their patients. Limited information is available about how physicians decide when to order these tests. To identify factors that affect whether physicians' screen patients for lung cancer, we conducted five 75-min telephone-based focus groups with 28 US primary care physicians and used inductive qualitative research methods to analyze their responses. We identified seven factors that influenced these physicians' decisions about screening patients for lung cancer: (1) their perception of a screening test's effectiveness, (2) their attitude toward recommended screening guidelines, (3) their practice experience, (4) their perception of a patient's risk for lung cancer, (5) reimbursement and payment for screening, (6) their concern about litigation, and (7) whether a patient requested screening. Because these factors may have conflicting effects on physicians' decisions to order screening tests, physicians may struggle in determining when screening for lung cancer is appropriate. We recommend (1) more clinician education, beginning in medical school, about the existing evidence related to lung cancer screening, with emphasis on the benefit of and training in tobacco use prevention and cessation, (2) more patient education about the benefits and limitations of screening, (3) further studies about the effect of patients' requests to be screened on physicians' decisions to order screening tests, and (4) larger, quantitative studies to follow up on our formative data.

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Cleve Clin J Med. 2012 May;79(5):337-45. doi: 10.3949/ccjm.79a.12018.

The rationale for, and design of, a lung cancer screening program.

Mazzone P.

Author information

Abstract

We are entering a new era in which lung cancer screening may be considered the standard of care. The National Lung Screening Trial (NLST) has shown that the number of deaths due to lung cancer can be reduced through screening with low-dose computed tomography (CT) in a high-risk population (N Engl J Med 2011; 365:395-409). Key issues--such as how to manage lung nodules, how to improve cost-effectiveness, and how to minimize radiation exposure--need to be addressed when designing a lung cancer screening program. Time and further technical advances will help to optimize the programs that are developed.

Comment in

Lung cancer screening: one step forward. [Cleve Clin J Med. 2012]

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