The State of Lung Cancer Screening:
The Current Science and Practice

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Report Information

Title: The State of Lung Cancer Screening: the Current Science and Practice

Description: This report provides a summary of the current state of lung cancer screening – status of the science and current practice to share with the Missouri Cancer Consortium and other partners to encourage promotion of and engagement in lung cancer screening.

Audience: This report is intended for use by the general public as well as state and local policy makers, researchers, local public health agencies, health care personnel, voluntary organizations and others interested in lung cancer screening.

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I. Background

Lung cancer survival has not substantially improved in the past 30 years, although during the same time period, significant progress has been made in the survival of many other cancers such as breast, colorectal and prostate. Such progress might be connected to the introduction and widespread adoption of efficient and effective screening tests for these cancers.

Lung cancer may be a disease for which screening could have a great impact.\textsuperscript{1} In the 1970s, trials were conducted evaluating chest roentgenograms with and without sputum cytology as lung cancer screening modalities, but no reduction in lung cancer mortality was shown. There have been several studies in which low-dose computed tomography (LDCT) detected tumors at an earlier stage than chest radiography (x-ray).\textsuperscript{1,2,3,4} Although these studies showed promising results with respect to the sensitivity of computed tomography, many were non-randomized cohort studies. Mortality reduction is the real benefit of screening and it needs to be demonstrated through randomized trials. Consequently, the National Cancer Institute (NCI) funded the National Lung Screening Trial (NLST), a randomized trial which enrolled participants during 2002 to 2004 and collected data through 2009 to determine whether screening with LDCT, as compared with chest radiography, would reduce mortality from lung cancer among high-risk persons.\textsuperscript{2,5,6,7} The NLST involved 53,454 healthy males and females aged at least 55 years who were deemed at high risk for lung cancer because of their smoking history.\textsuperscript{8} The result of the NLST demonstrated a 20 percent mortality reduction in the LDCT group compared to radiography group.\textsuperscript{1,8} Researchers continue to seek new methods of screening such as autofluorescence bronchoscopy, advanced techniques of sputum analysis, and molecular biology to identify alterations for early diagnosis and prognostic biomarkers.\textsuperscript{1,9,10}

II. Lung Cancer Screening

In December 2013, the United States Preventive Services Task Force (USPSTF), based on the landmark NLST study, recommended annual screening for lung cancer with LDCT in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy, or the ability or willingness to have curative lung surgery.\textsuperscript{11,12,13} A 30 pack-year history is the equivalent of smoking one pack of 20 cigarettes a day for 30 years, or 2 packs per day for 15 years,\textsuperscript{14} or one-half pack daily for 60 years.\textsuperscript{12} The USPSTF gave a positive recommendation with a B grade for lung cancer screening with LDCT which indicates that there is a high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. The suggestion for practice is to offer or provide this service.\textsuperscript{15}

Both policy-level and clinical decision making about LDCT must consider the potential benefits of screening (reduced mortality from lung cancer) and possible harms.\textsuperscript{16} Although LDCT screening may benefit individuals at an increased risk for lung cancer,\textsuperscript{17} the benefits of screening
must be reconciled with its potential harms which are primarily related to radiation-induced carcinogenesis, high false-positive rates, and the potential for over-diagnosis.\textsuperscript{18,19}

LDCT screening exposes individuals to excess radiation, not only at the time of screening, but also in the course of downstream follow-up and likely at consecutive intervals given that screening would be performed on a periodic basis.\textsuperscript{18} Although individual risk may be acceptable, the large number of individuals who might be exposed could translate into a measurable population,\textsuperscript{18} and further increase the risk for developing lung or other cancers.

A second major harm of LDCT in the NLST was a high screen positivity rate, particularly a high false-positive rate.\textsuperscript{18} A positive screening result was obtained in 24.2 percent of LDCT screens and 6.9 percent of chest X-ray screens. Across the three rounds of screenings, 96.4 percent of the LDCT tests and 94.5 percent of the chest X-ray exams were found to be false positives, meaning that the observed finding was not due to lung cancer. The fact that these false-positive results were not cancer was usually confirmed noninvasively by the lack of change in the finding on follow-up LDCTs.\textsuperscript{20} Although the NLST targeted high-risk individuals based on older age and significant smoking history, (defined by pack-years of smoking), a number of other variables influence the risk of lung cancer among ever-smokers including underlying chronic obstructive lung disease, occupational exposure to asbestos or other carcinogens, history of lung cancer in a first-degree relative, and a personal prior history of lung (or other smoke-related) cancer.

Screening test performance is also influenced by the interpretation criteria. The interpretation algorithm used in the NLST was dichotomous.\textsuperscript{18} The Dutch-Belgian randomized lung cancer screening trial (Nederlands-Leuven Longkanker Screenings Onderzoek [NELSON]) used a two-step interpretation strategy based on nodule size to classify the screen as positive or negative.\textsuperscript{18} Although the reduction in cancer mortality results of the NELSON screening trial are not yet available, the investigators have reported the performance characteristic of their interpretation strategy which appropriately conveys the notion that lung cancer screening is a process over time rather than a single examination.

A final potential harm of LDCT screening is over diagnosis, meaning the diagnosis of a cancer that would not go on to cause symptoms or death.\textsuperscript{18} Over-diagnosis in lung cancer may result from one of the following two scenarios: the cancer is so biologically indolent that it will not result in the death of the individual, or the cancer is treated or progresses sufficiently slowly that the individual dies of competing conditions such as cardiovascular or respiratory disease. Autopsy studies have provided compelling evidence of over diagnosis by observing clinically silent cancers of the lung, prostate, and thyroid in individuals who have died of other causes. Estimates from randomized trials also suggest that a proportion of screen-detected cancers represent over diagnosis. Strong evidence shows that LDCT screening can reduce lung cancer and all-cause mortality. However, the harms associated with screening must be balanced with the benefits.\textsuperscript{21}
III. The Debate

Population-based Screening

The NSLT provided evidence about the efficacy of screening but did not answer questions about effectiveness when implemented in everyday clinical practice. Consequently, the recommendation left some critical issues unaddressed. The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) concluded that there was inadequate evidence to recommend national coverage for lung cancer screening. This conclusion highlights the controversy over what constitutes sufficient evidence to support widespread implementation of a new technology. It also heightened the tension between advocates who were eager to see wide deployment of lung cancer screening quickly and others who were concerned about the ability of health care systems to provide LDCT screening to the potentially large number of patients meeting the criteria while still minimizing harms. Another concern was that a new intervention that works in randomized trials does not guarantee that it would work as well when delivered in real-world practice, nor that the benefits in the community would justify the possible harms and costs. The big question is, should these unresolved issues delay the implementation of lung cancer screening pending further study, or do the potential benefits compel the early adoption.

A middle ground approach between early adoption and waiting years for more conclusive evidence was to carefully plan and evaluate a comprehensive approach to lung cancer screening, including a staged and limited implementation and evaluation program before broader implementation. This prompted the Veterans Health Administration (VHA), the nation’s largest health care system, to develop a 2-year clinical demonstration project involving eight VHA medical centers that serve more than 500,000 veterans. This decision was based on some of the uncertainties, as outlined by the MEDCAC, as well as questions about the effect of screening on their patients, staff and health care system. At the same time, the compelling results of the NSLT and high burden of smoking and lung cancer among veterans argued against a “wait-and-see” approach. The VHA hopes that the data from their project will help assess whether the predominantly older male VHA population with several chronic conditions has different outcomes with screening from those of the younger, healthier NLST population. They understand that their quality improvement project, designed to assess implementation, would not be able to determine the effect of screening on mortality.

The VHA study is still going on; however, despite objections from the advisory committee, in November 2014, Medicare decided to cover annual screening for current and former smokers until age 75. Starting February 2015, Medicare decided to cover annual screening for current and former smokers meeting certain criteria: have smoked an average of one pack per day for the last 30 years, have no symptoms or signs of lung cancer, receive the chest scan at a qualified radiology facility, and 55 to 77 years of age. The coverage includes a counseling session offered before screening to explain the exam, its benefits and risks, and what it may reveal.
Experts suggest that counseling might be more effective if offered by an individual’s primary care physicians when they receive screening results.

**Screening versus Smoking Cessation**

In an interview, Dr. Russell P. Harris, a preventive medicine specialist at the University of North Carolina at Chapel Hill said, “Screening is being perceived by people as an alternative to stopping smoking. But stopping smoking would have huge benefits for the individual and society way beyond people not dying from lung cancer,” which causes almost 160,000 deaths a year, 90 percent of them caused by smoking. Dr. Harris suggested that it would be better to spend money used for screening on smoking cessation and prevention by providing free stop-smoking aids, sponsoring antismoking advertising, raising taxes on tobacco products, and raising the age at which people are allowed to buy tobacco products. Furthermore, smoking causes many other cancers. The latest Surgeon General report on smoking finds that active smoking is now causally associated with age-related macular degeneration, diabetes, colorectal cancer, liver cancer, adverse health outcomes in cancer patients and survivors, tuberculosis, erectile dysfunction, orofacial clefts in infants, ectopic pregnancy, rheumatoid arthritis, inflammation, and impaired immune function. In addition, exposure to secondhand smoke has now been causally associated with an increased risk for stroke. Whiteman states that although screening for lung cancer is beneficial, it should not be seen as an alternative to giving up or stopping smoking.

**Screening Interval, Risk, and Individuals Not Meeting Guidelines**

Dr. Peter Mazzone, a lung expert at the Cleveland Clinic, is concerned that request for LDCT screening from smokers slightly outside the new guidelines will be an issue to face. In addition, although LDCT is a useful tool for assisting in diagnostics, it is a source of ionizing radiation and can cause cancer. The NCI advises patients to discuss the risks and benefits of LDCT with their doctors. Annual screening may not be a good idea if radiation from LDCT can cause cancer. Fortunately several studies are looking into how these concerns might be addressed to make LDCT screening more beneficial to participants. In the NELSON trial, screening of 7,915 participants at baseline, 1 year, 2 years and 2.5 years indicated that a 2.5 year interval is less effective in identifying cancer at an early stage than screening annually.

**IV. Addressing Risk**

Recent studies have shown that for LDCT examinations such as cardiac examination and lung cancer screening, using optimization techniques such as CT localizer radiographs (LRs) may result in a significant dose reduction and thereby in a substantial reduction of total radiation dose. The American College of Radiology Lung Imaging Reporting and Data System (Lung-RADS) designed to standardize reporting of LDCT and to decrease the false positive rates without significantly compromising on the sensitivity reported that Lung-RADS does not have a specific reporting category for patients with isolated hilar and mediastinal adenopathy or pleural
infusion in the absence of lung nodules. They stated that Lung-RADS has never been studied in a prospective fashion and suggested that it needs to be revised in its new version.28

Early stages of lung cancer are often manifested as pulmonary nodules, although the occurrences of small nodules which are predominantly benign are responsible for the high percentage of false positive in screening studies.29 Scientists have discovered that quantitative analyses (radiomics) of LDCT lung cancer screening images at baseline can be used to assess risk for development of cancer. Radiomics is a process for high-throughput extraction of quantitative features that result in the conversion of images into mineable data and the subsequent analysis of these data for decision support.30 This is in contrast to the traditional practice of treating medical images as pictures intended solely for visual interpretation. Radiomic data contain first-, second-, and higher-order statistics. These data are combined with other patient data and are mined with sophisticated bioinformatics tools to develop models that may potentially improve diagnostic, prognostic, and predictive accuracy. Because radiomics analyses are intended to be conducted with standard of care images, it is conceivable that conversion of digital images to mineable data will eventually become routine practice. Radiomics out preformed Lung-RADS and volume.31

V. Future Directions

Although nodule size may not be thought of as a conventional biomarker, it is perhaps the oldest and most frequent used non tissue-based means of estimating likelihood of lung malignancy.32 Size of a pulmonary nodule and likelihood of malignancy are positively correlated, and 80 percent of benign incidental nodules are less than two centimeters in largest diameter. In basic terms, there are calcified nodules and non-calcified nodules.33 Calcified nodules contain deposits of calcium which are visible on imaging scans. This can happen when the body responds to infections such as tuberculosis and usually means a nodule is not cancer. Non-calcified nodules are classified as ground glass opacities, partially solid or solid nodules. Ground glass opacities (GGO) look like a hazy (not clear) area on a CT scan, like ground glass. This may be the result of inflammation caused by infection or other lung damage, but could also be a sign of a type of lung cancer that is slow-growing.33 Pulmonary nodules are smaller than three centimeters (about 1.5 inches) in diameter or less.34,35 If an abnormality is seen on an x-ray of the lungs that are larger than three centimeters, it is considered a “lung mass” instead of a nodule and is more likely to be cancerous.34,35 Lung nodules need to be at least one centimeter in size before they can be seen on a chest x-ray.35 In contrast to a solitary pulmonary nodule, multiple lung nodules may occur when two or more nodules are found within the lungs.35

Ground-glass Opacity (GGO) nodules

Future direction in lung cancer screening involves a systematic approach to ensure correct diagnosis and optimal management of ground-glass opacity (GGO) nodules including noninvasive approaches to diagnosis, further research to develop and validate effective smoking cessation interventions (SCIs) in the LDCT setting, and looking for ways to recruit hard to reach
populations. The advent of computed tomography (CT) screening for lung cancer will increase the incidence of GGO nodules detected and referred for diagnostic evaluation and management.\textsuperscript{36} GGO nodules are defined radiologically as focal areas of slightly increased CT attenuation through which the normal lung parenchyma structures, airways, and vessels are visually preserved. In fact, airways are often recognized more clearly because of the increased contrast between intraluminal air, which appears very black, and the surrounding abnormal lung parenchyma, which has increased density. Increased lung opacity occurs when the amount of air in the airspaces and in the lumen of the airways is decreased and when the soft-tissue structures increase in size and/or amount. Thus, a reduction in the volume of the airspaces, as well as a partial or total replacement of the air in the airspaces by cells or fluid, will result in increased opacity. In GGO nodules, airspace volume reduction is only partial, and the alveolar lumen is only moderately filled with cells and fluid, to a degree where complete consolidation of lung parenchyma does not occur.

GGO nodules, also referred to as subsolid nodules, are radiologically divided into two categories: 1) pure GGO nodule (p-GGO), which contains no solid component and 2) part-solid GGO nodules, which contain both pure GGO region and a consolidated region. The part-solid nodules are also called mixed GGO nodules. In malignant part-solid GGO nodules, the solid part historically represents invasion, whereas the pure GGO areas are considered adenocarcinoma in situ (AIS). Solid transformation of GGO nodules is thus considered a strong indicator of malignancy.\textsuperscript{37} A study showed that, based on the proportion of the solid component, called the consolidation/tumor (C/T) ratio, it may be possible to differentiate between invasive and noninvasive malignant disease.\textsuperscript{38} However, GGO nodules are often slow-growing, and if malignant transformation from carcinoma in situ does occur, the process may take years, and the reason a longer follow-up time is necessary. The optimal length of follow-up for stable GGO nodules and the optimal curative-intent therapy remain uncertain.\textsuperscript{36}

Although the detection of pure ground-glass opacity nodules on high-resolution chest computed tomography (HRCT) often implies a diagnosis of lung adenocarcinoma, the management of p-GGO nodules remains under discussion. Careful observation and decision making with respect to the timing on intervention in cases of p-GGO nodules are warranted.\textsuperscript{39} The logic in observing a ground-glass nodule over time to assess for morphologic changes relies on the predictability of a relatively linear growth model. However, in some instances, these lesions persist for years without significant evolution and then become aggressive with invasive or metastatic potential. This behavior may result from acquisition of one critical molecular abnormality that changes the biology of cancer from indolent to aggressive. Unfortunately, there are no current mechanisms by which to distinguish the timing of this transformation.\textsuperscript{40}

The management of screen-detected nodules, which must include methods for distinguishing between malignant and benign nodules, is crucial to the success of a screening program.\textsuperscript{36}
In addition, it is important to keep in mind that GGO is a rather unspecific radiologic feature seen in a number of clinical conditions involving different pathologic processes. Knowledge of these pathologies, along with a patient history and observation via repeat scans, is therefore necessary in the diagnostic work up of GGO nodules.\textsuperscript{36} GGO nodules remain a diagnostic challenge and therefore a more systematic approach with particular emphasis on patient education and shared decision-making, is clearly warranted and can help optimize outcomes.\textsuperscript{36}

While surgical resection, specifically lobectomy, is currently the standard of care for early-stage lung cancer,\textsuperscript{36,44} it is not clear that this is necessarily the optimal approach for patients with GGO nodules who are ultimately diagnosed with lung cancer, in whom the tumor biology may be different from that of patients with historically diagnosed lung cancer. However, the role of more limited surgical resection is being explored and alternative treatment strategies such as stereotactic ablative body radiation as also being considered.\textsuperscript{36}

GGO - dominant clinical stage IA lung adenocarcinoma (pure GGO group) showed an excellent prognosis. Wedge resection should be carefully considered for patients with mixed GGO nodules (C/T ratio > 0.25) because of the high recurrence rate. Radiologic noninvasiveness (C/T \leq 0.25) might be a good indicator for candidates for sub-lobar resection in cases of early stage lung adenocarcinoma.\textsuperscript{41}

**Smoking Cessation Interventions**

Although LDCT for lung cancer screening remains an opportunity with high potential, the potential for additional risk reduction via smoking cessation interventions (SCIs) has not been fully realized; therefore, conducting research to develop and validate effective SCIs in the LDCT setting is still a critical need.\textsuperscript{42}

SCIs are very cost effective ways of reducing the risk of developing lung cancer among smokers.\textsuperscript{43,44} Smoking cessation is known to be greater when an individual experiences a significant health event. LDCT may represent one such significant health event and there is evidence that all trial participants were inclined to stop smoking more than average, suggesting that screening is a teachable moment to improve smoking behavior.\textsuperscript{45} Thus the building in smoking cessation, targeted or tailored to screening participants, is an important adjunct that is likely to increase cost effectiveness and potentially decrease all-cause mortality.\textsuperscript{44}

A review of the USPTF recommended that a program that annually screens adults aged 55 to 80 who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years should receive SCIs to prevent continued tobacco use.\textsuperscript{19} In fact, this review states that smoking cessation is the most important intervention to prevent early-stage non-small cell lung
cancer (NSCLC) which LDCT has greater sensitivity for detecting than chest radiography. It suggested that screening with LDCT be viewed as an adjunct to tobacco cessation intervention.

LDCT screening may prevent lung cancer deaths for both former and current smokers, but the opportunity for smoking cessation provides an added benefit for screening participants who continue to smoke. Lung cancer screening alone without cessation advice could provide unjustified relief to smokers, reducing their likelihood of quitting smoking.42

Considering that lung cancer incidence is progressively greater in individuals with lower socioeconomic status, (groups that are hard to engage in healthcare interventions), it is important to explore ways to maximize their participation rates in lung cancer screening.44 One such program under way in the United Kingdom is looking at novel ways to recruit people by using mobile LDCT scanners.46

VI. Resources

Patients

Is lung cancer screening right for me?

There is a decision aid for people considering lung cancer screening using LDCT with instruction on how to make that decision. Information on the following topics is provided: facts about lung cancer, definition of lung cancer, possible signs and symptoms of lung cancer, who should be screened for lung cancer, possible benefits and harms of lung cancer screening with LDCT, explanation of lung cancer screening with LDCT, and what is important when deciding about screening for lung cancer, to help prepare them to talk with their health care professions about whether lung cancer screening is right for them.

Talking with a health care professional about lung cancer screening

Patients are advised to talk to their health care providers about screening to make a decision based on what is right for them. They are reminded that making a decision to screen for lung cancer is personal. Patients are provided with some questions to think about, keeping in mind the possible benefits and harms that are most important to them. They are also advised to find out about insurance coverage of the screening.

Information for Consumers

- Understanding Lung Cancer (National Cancer Institute)
- Screening for Lung Cancer: Consumer Guide (U.S. Preventive Services Task Force)
- Find an Approved Screening Facility (Centers for Medicare & Medicaid Services)
For detailed information on patient decision aids go to https://effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/lung-cancer-screening/patient/

**Clinicians**

There is a summary guide for primary care clinicians regarding lung cancer screening with LDCT. For more detail on this summary, go to https://effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/lung-cancer-screening/clinician-summary/.

In addition there is a clinician’s checklist to help the clinician determine the patient’s eligibility. For more information, go to https://effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/lung-cancer-screening/clinicians-checklist/.

**Patients and their Health Care Providers:  Shared Decision-making**

For information on tools to facilitate discussions between health care professionals and their patients about lung cancer screening with LDCT and for decision making tools for patients and their health care providers go to: https://effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/lung-cancer-screening/

**VII. Summary**

Lung cancer seems to be a disease for which screening could have great impact. Several studies showed that LDCT detected many tumors at an earlier stage than chest radiography. However, many of those studies were non-randomized trials and could not demonstrate a reduction in mortality. The NLST, a randomized trial using LDCT demonstrated a 20 percent mortality reduction. Although the NLST provided evidence about the efficacy of screening, it did not answer questions about effectiveness when implemented in everyday clinical practice nor address some of the concerns about risks.

The MEDCAC concluded that there was inadequate evidence to recommend national coverage for lung cancer screening using LDCT. This conclusion highlights the controversy over what constitutes sufficient evidence to support wide spread implementation of this new technology. In addition, there were several other concerns regarding using LDCT for lung cancer screening such as:

- The ability of health care system to provide a LDCT screening program to a potentially large number of patients meeting the criteria while still minimizing ionizing radiation and the possibility of over diagnosis and high false positives rates.

- A new intervention that works in randomized trials does not guarantee that it would work as well when delivered in real-world practice, nor benefits in the community would justify the possible harms and costs.
However, the big question was, should these unresolved issues delay the implementation of lung cancer screening pending further study, or do the potential benefits compel the early adoption. A middle ground approach between early adoption and waiting years for more conclusive evidence was to carefully plan and evaluate a comprehensive approach to lung cancer screening, including a staged and limited implementation and evaluation program before broader implementation.

The USPSTF based on the landmark NSLT study gave a positive recommendation with a B grade for lung cancer screening with LDCT and recommended annual screening for lung cancer with LDCT in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. This led to another concern that request for LDCT screening from smokers slightly outside the new guidelines will be an issue to face. Fortunately several studies have looked into how these concerns might be addressed to make LDCT lung cancer screening useful to participants and came up with the following:

- Screening annually decreases the proportion of advanced disease compared to screening at 2-year and 2.5-year intervals, and therefore annual screening enhances the effectiveness or efficacy of screening.

- Using optimizing techniques such as CT localizer radiographs (LRs) for LDCT lung cancer screening may result in a significant radiation dose reduction and thereby in a substantial reduction of a total dose.

- Quantitative analyses (radionmics) of LDCT lung cancer screening images at baseline can be used to assess risk for development of cancer.

- It has been suggested that lung cancer screening using LDCT reduces lung cancer specific and overall mortality in high risk patients.

The Agency for Healthcare Research and Quality has developed tools to facilitate discussion between health care professionals and their patients about lung cancer screening with LDCT.

**VIII. Conclusion**

Based on the current science and practice, the current state of lung cancer screening is annual screening using LDCT with clients who meet the USPSTF criteria. Combining systematic screening practice with smoking cessation programs may offer benefits beyond screening alone.
IX. References


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