JAMA Network Open

Editorial

Expanded Access to Lung Cancer Screening—Implementing Wisely to Optimize Health

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Lung cancer remains the number one cause of cancer deaths in the US, with smoking accounting for approximately 90% of cases. Although smoking rates have declined to historic lows, millions of people in the US remain at elevated risk owing to a lifetime of accumulated tobacco exposure. Lung cancer screening (LCS) with annual low-dose computed tomography (LDCT) aims to reduce cancer mortality through increased lung cancer detection at a curable stage. Randomized clinical trial results, such as the National Lung Screening Trial (NLST),[1] led the US Preventive Services Task Force (USPSTF) in 2014 to recommend LCS for adults in generally good health and at high lung cancer risk based on age and smoking history.[2] New data led the USPSTF to commission an updated evidence review and modeling report to inform revised recommendations to better optimize population benefits.[3-5] The USPSTF now recommends expanding LCS to younger and less intensive smokers, defined as adults aged 50 to 80 years with 20 or more pack-years of smoking history who currently smoke or, as previously, have quit smoking within the past 15 years (B recommendation, moderate certainty of moderate net benefit).[3-5] The USPSTF concluded that new recommendations could lead to important gains, such as an estimated increase 122 averted lung cancer deaths per 100 000 adults in the population (381 estimated averted deaths per 100 000 adults in the population with the old recommendations vs 503 estimated averted deaths per 100 000 adults in the population with the new recommendations) and 2035 life-years gained (4882 estimated life-years gained with the old recommendations vs 6918 estimated life-years gained with the new recommendations).[2-5] However, these benefits could come at the expense of increased harms, including deaths associated with radiation exposure, false-positive screening results, overdiagnosed cancers, and incidental findings requiring evaluation.

The new guideline expands LCS to hundreds of thousands more individuals. The eligibility criteria originally recommended by the USPSTF[2] closely mirrored NLST eligibility.[1] Although the NLST was one of the largest randomized clinical trials conducted by the National Institutes of Health, to our knowledge, it was also the only adequately powered LCS study. Therefore, a relative paucity of direct evidence informed initial modeling studies and recommendations. While NLST criteria captured many high-risk smokers, other high-risk individuals were left out.[6] For example, Black men have the highest lung cancer death rates but are often lighter smokers than their White counterparts, and 91% of NLST enrollees were White.[1] Even at the point of lung cancer diagnosis, two-thirds of Black men with lung cancer have a pack-year history that previously would render them ineligible for LCS.[7] Questions remained as to preferred start and stop ages and screening intervals. Younger individuals are at lower lung cancer risk but can often better tolerate surgical treatment. Modeling studies suggest they have more life-years to gain and lower overdiagnosis risk if lung cancer is detected.[5] Biennial vs annual screening reduces harms but may also reduce benefits. Other important and identifiable lung cancer risk factors were not considered in the USPSTF recommendation statement from 2014.[2] Risk calculators can extend LCS to individuals not meeting current criteria but who have high calculated risk when including other factors. The 2021 USPSTF systematic review[4] addresses risk-based screening, in which risk calculators with thresholds are used to determine eligibility. This strategy contrasts with current criteria-based screening that considers fewer factors (ie, age, smoking) with set cutoffs. The USPSTF selected criteria-based screening owing

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to increased complexity of implementation coupled with inconsistent evidence of added net benefit with risk-based screening.[3-5]

The change in eligibility is welcome and has the potential to reduce lung cancer morbidity and decrease disparities in LCS access by increasing eligibility among smokers of racial/ethnic minority groups, such as Black individuals. However, an eligibility expansion alone is inadequate to increase LCS rates and resolve disparities. Currently, LCS is poorly implemented. Almost 5 years after the Centers for Medicare & Medicaid Services (CMS) endorsement,[8] only a small proportion (approximately 2%-16%) of eligible patients were being screened.[9] In comparison, breast and colon cancer screening rates approach 70% despite combined annual death rates less than two-thirds that of lung cancer.[3-5] Despite CMS coverage and high lung cancer deaths among individuals with low socioeconomic status, adults with low socioeconomic status are underrepresented among LCS recipients.[10]

Why has LCS been so difficult to implement? The reasons are many and can be traced back to key differences between LCS and other cancer screenings.[11] While the USPSTF issued a B recommendation, they did so with more nuanced language than other B recommendations.[3-5] The USPSTF emphasizes that net benefits are dependent on screening programs closely matching trial performance metrics regarding individual's life expectancy, cancer risk, willingness to undergo lung surgery, accuracy of image interpretation, and ability to resolve false positive tests without invasive procedures. We agree; but this is a tall order with important implications for implementation and net benefits.

When it comes to identifying eligible patients, LCS is one of the first cancer screenings to target a high-risk group or behavior. Accurate information on smoking history is key, but it can be difficult to accurately ascertain in many electronic health records (EHRs). This is particularly true for former smokers, who will not be flagged by simple yes-or-no tobacco use queries. Without EHR support, clinicians are left to remember to repeatedly and accurately apply the criteria. This may systematically fail to identify appropriate candidates or lead to screening ineligible patients. Additionally, stigma against smokers may also decrease clinicians' LCS enthusiasm.[12]

The characteristics of LCS also increase screening complexity. Many patients will have small pulmonary nodules, nearly all of which will be false positives.[1] Nevertheless, these nodules require longitudinal tracking, can provoke anxiety in patients, and may require subspecialist evaluation or additional diagnostic testing. Many patients will live with uncertainty as to whether the nodule is benign for a year or longer. Improved LDCT resolution combined with better algorithms for characterizing nodules, such as Lung-RADS (American College of Radiology), could result in fewer false positives than the algorithms used in initial trials.[13] Unlike other cancer screenings, LCS commonly detects incidental findings in other organ systems, such as the kidneys, thyroid, and heart. So-called *incidentalomas* often require additional evaluation and interventions with unclear net benefits. Harms due to overdiagnosis, while low for LCS, may be higher for incidental findings. While LDCT is usually fully covered by insurance, the additional tests, clinic visits, and treatments generated may not be. All of these factors increase LCS complexity, cost, and burden.

Because of these nuances, in the first of its kind among cancer screening recommendations, the CMS decision memo[8] for LCS requires documented shared decision-making (SDM) before LCS can be ordered and reimbursed. Given potential downstream consequences, this is a reasonable step to help patients understand what they are agreeing to. The CMS memo[8] also mandates that clinicians address smoking cessation at the time of referral. As useful as it may be, the SDM visit can also be a barrier. Clinicians performing SDM must be educated about LCS, have access to appropriate decision aids, know local referral processes, and efficiently implement this in a busy clinic while addressing other potentially greater health concerns. If the patient is instead referred to a centralized screening program for SDM, they may be charged another copay or decide the process is too burdensome to complete.

For LCS to be optimally effective, implementation guides stress the importance of formal programs, including eligibility confirmation, effective patient tracking, adherence to structured nodule reporting and evaluation, and access to a multidisciplinary committee of clinical specialists.[14]

These subspecialists may be in short supply in lower-resource settings but are necessary to minimize unnecessary invasive testing and to promptly diagnose and treat identified cancers. It is not surprising that rural patients, for example, have disparities in LCS access.[15] To scale LCS to even more eligible individuals under the new guidelines[3-5] would require considerable investment in CT scanners, radiologists, LCS coordinators, EHR updates—all the many components required to make this intervention effective and efficient.

These barriers are not insurmountable. Clinicians and patients should be educated that estimated harms and benefits, if implemented as outlined by the USPSTF,[3-5] compare favorably with other widely recommended cancer screening strategies, including breast, colon, and cervical cancer. Currently, LCS participation varies considerably by state and is not well matched to the local lung cancer incidence. A notable exception is Kentucky, where the screening rate is nearly 4-fold the rates of neighboring states.[16] Kentucky's high LCS rate may be largely attributable to the Kentucky Lung Cancer Education Awareness Detection and Survivorship (LEADS) program, which has applied evidence-based implementation strategies on a statewide level to increase LCS uptake.[17] The LEADS program invested in clinician education, patient-facing resources, and billing information to help boost primary care referrals. In the future, establishment of LCS quality metrics and performance measures may promote uptake among health systems not yet providing this service on a broad scale.

Future research should focus on streamlining LCS and further matching of eligibility to the population with the greatest benefits, while better addressing ongoing smoking, stigma, and disparities.[3-5] Annual LCS is intensive. Less frequent biennial screening, as successfully used in a 2020 study by de Koning et al,[18] is an attractive alternative that may preserve benefits, reduce harms and burdens for many, and enhance implementation. A better definition of what constitutes an adequate health status could help match LCS to participants able to undergo surgical lung cancer treatment and most likely to gain from cancer screening.

The revised USPSTF recommendation[3-5] reflects a move toward encouraging greater and more equitable access to this proven screening strategy. To achieve the net benefits determined by the USPSTF would require successful implementation dependent on systemwide reductions in physician and patient barriers. This includes creation of efficient and effective SDM tools and ensuring appropriate LCS eligibility, imaging, and nodule evaluations and enhanced smoking cessation support. Attention to these issues could help the new USPSTF LCS recommendations[3-5] achieve their intended goal of improving population health and well-being.

ARTICLE INFORMATION

Published: March 9, 2021. doi:10.1001/jamanetworkopen.2021.0275

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Conflict of Interest Disclosures: None reported.

Funding/Support: Drs Melzer and Wilt are supported by resources from the Minneapolis VA Health Care System.

Role of the Funder/Sponsor: The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the US government. This work was supported by resources from the Minneapolis VA Health Care System.

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