HHS Public Access

Author manuscript

JAMA Oncol. Author manuscript; available in PMC 2022 May 01.

Published in final edited form as:

JAMA Oncol. 2021 May 01; 7(5): 684–686. doi:10.1001/jamaoncol.2020.8376.

The 2021 US Preventive Services Task Force Recommendation on Lung Cancer Screening:

The More Things Stay the Same…

Mayuko Ito Fukunaga, MD[#], **Renda Soylemez Wiener, MD, MPH**[#], **Christopher G. Slatore, MD, MS**[#]

Division of Pulmonary, Allergy, and Critical Care Medicine, Department of Medicine, University of Massachusetts Medical School, Worcester (Ito Fukunaga); Division of Health Informatics and Implementation Science, Department of Population and Quantitative Health Sciences, University of Massachusetts Medical School, Worcester (Ito Fukunaga); Meyers Primary Care Institute, University of Massachusetts Medical School, Worcester (Ito Fukunaga); Center for Healthcare Organization and Implementation Research, VA Boston Healthcare System, Boston, Massachusetts (Wiener); Pulmonary Center, Boston University School of Medicine, Boston, Massachusetts (Wiener); Center to Improve Veteran Involvement in Care, VA Portland Health Care System, Portland, Oregon (Slatore); Division of Pulmonary and Critical Care Medicine, Department of Medicine, Oregon Health & Science University, Portland (Slatore); Section of Pulmonary and Critical Care Medicine, VA Portland Health Care System, Portland, Oregon (Slatore).

[#] These authors contributed equally to this work.

The United States Preventive Services Task Force (USPSTF) recently updated its recommendation statement regarding lung cancer screening (LCS) using low-dose computed tomography (LDCT).[1] This update was based on a systematic evidence synthesis,[2] including review of more than 220 publications, and informed by extensive decision analysis modeling by the Cancer Intervention and Surveillance Modeling Network CISNET) Lung Cancer Working Group.[3] As with its 2013 statement,[4] the USPSTF gave LCS a B recommendation, meaning its consensus was that there is moderate certainty that annual screening for lung cancer with LDCT is of moderate net benefit.[1] Key changes from the 2013 statement include expansion of the recommended eligibility criteria to begin screening at age 50 years instead of 55 years and requiring 20 rather than 30 pack-years total first-hand cigarette smoke exposure. There was no change in the remaining recommendations, such as the modality and frequency of screening or when to discontinue LCS, and the USPSTF kept risk-factor eligibility criteria rather than switching to criteria determined by risk model.

This update is timely because many more studies regarding LCS have been published, and a host of questions about LCS have risen since the 2013 recommendation.[5] The Dutch–Belgian lung cancer screening trial Nederlands–Leuvens Longkanker Screenings Onderzoek

Corresponding Author: Christopher G. Slatore, MD, MS, VA Portland Health Care System (R&D66), 3710 SW US Veterans Hospital Rd, Portland, OR 97239 (christopher.slatore@va.gov).

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(NELSON),[6] the second largest randomized clinical trial assessing lung cancer screening, was published in 2020 and confirmed the primary benefit found in the National Lung Screening Trial (NLST)[7] that LCS with LDCT reduced lung cancer mortality. Lung-RADS (Lung CT Screening Reporting and Data System[8]) has been widely adopted to improve protocol-based follow-up of screening-identified nodules, but the NELSON trial raised new questions about the optimal frequency of screening and when to stop, as well as the role of volumetric assessment in evaluating screen-detected nodules. Concerns have been raised that the 2013 USPSTF eligibility criteria for LCS would exacerbate health disparities given that they do not account for important risk factors such as Black race, chronic obstructive pulmonary disease, family history, and occupational exposures.[9] There has been growing interest in the use of models of lung cancer risk or life-years gained models to improve the LCS efficiency and mitigate disparities in eligibility. Finally, for the first time, the Centers for Medicare & Medicaid Services mandated a formalized shared decision-making encounter prior to LCS.[10] This decision created debate over issues such as how to support shared decision-making during time-constrained primary care visits, whether a nurse navigator should provide shared decision-making instead of primary care providers or other independent health care providers, and most importantly, whether shared decision-making for LCS should be mandated considering it is not required for other cancer screenings.

The USPSTF recommended LCS based on the evidence review[2] that indicates use of regular LDCT scans leads to a significant reduction in lung cancer mortality. This is supported by the NLST and NELSON trials, the only 2 studies with sufficient power to answer this question, although only the NLST found an overall mortality benefit. This sizable benefit should be compared with the harms of LCS, which include: (1) the risk of radiation-induced cancers (CISNET models estimate 1 radiation-induced lung cancer death for every 13 lung cancer deaths averted by LCS), (2) short-term distress among some individuals with screen-detected findings (studies suggest no long-term increase in distress or anxiety related to LCS), (3) physical complications related to invasive procedures to evaluate screen-detected findings (complications are rare at <1% of screened individuals but vary across studies depending on both frequency of procedures and complication rates), and (4) over-diagnosis (estimated by CISNET models at 6% of lung cancers detected through LCS per the updated USPSTF criteria). Studies have not found positive nor negative effects of LCS with smoking cessation, so it is important that active smoking cessation interventions be integrated with LCS.

It is important to note that the CISNET decision analysis models[3] helped the USPSTF identify evidence-based criteria for eligibility and LDCT frequency, not the recommendation itself.[1] It was determined that CISNET models were important to consider because the randomized trials had different eligibility criteria and LDCT frequency, relatively short-term follow-up, and a much smaller number of surveillance rounds than will occur in routine clinical practice. It is beyond our scope and expertise to provide an in-depth review of the CISNET methodologies. However, we will point out some important differences and strengths from its 2014 study, limitations, and how these results should affect decision-making around LCS eligibility criteria.[11]

Compared to its 2014 study,[11] the CISNET altered some of the assumptions, scenarios, and implications for its models. Lung-RADS was used to model nodule management (3 of the 4 groups), included modified risk model–based strategies in addition to risk factor–based strategies, included a sensitivity analysis based on 5-year life expectancy, and provided a description of how different strategies may affect different racial and ethnic groups.[3] These changes will make the results more relevant to current populations and address some of the important concerns in the field. Notably, the CISNET group did not incorporate the results of the NELSON trial into its models.

The CISNET modeling study[3] is quite thorough but still has some acknowledged limitations. The models assumed that 100% of eligible people would participate in LCS and that they would be 100% adherent—an assumption that has not been borne out in practice, where uptake of LCS hovers at 5% and reported adherence varies between 12% and 91%.[12,13] Moreover, uptake and adherence are very unlikely to be equally distributed across all groups. In fact, national data from the Veterans Health Administration suggests that marginalized groups, such as Black veterans and those with mental health comorbidities, are less likely to receive recommended follow-up after initial screening in a timely fashion.[14] Thus, these real-world issues will drastically reduce the benefits predicted by the model as well as the expected benefits and harms for different groups. As another important limitation, the CISNET group[3] evaluated modified risk models that did not include risk factors besides age and cigarette smoke exposure variables. Accordingly, the CISNET models do not inform decisions about the use of all of the inputs to common risk models.

It is important to consider how these modelling results will affect the determination of eligibility and implementation criteria. We recognize the necessity for the USPSTF and payers to select hard cut points for determining eligibility. However, as the CISNET results dramatically illustrate,[3] the benefits and harms of LCS exist along a spectrum. The models can help guide decisions away from inefficient scenarios, but they cannot by themselves determine the “right” criteria because each choice involves trade-offs between harms and benefits. For example, who is to say that an estimated number needed to screen to prevent 1 lung cancer death of 37 (NLST-like estimate) is really better than 45 (2021 USPSTF recommendation[1]), both with wide confidence intervals? Or that increasing the estimated lung cancer mortality reduction from 9.8% to 13.0% is worth an additional 192 000 LDCT scans per 100 000 persons? Or that using risk factor–based criteria, which tend to select younger patients with less risk of dying from lung cancer and thus have less lung cancer deaths averted but longer life-years gained, are better than risk model–based criteria that have the opposite effect? We encourage stakeholders from across the LCS continuum to vigorously debate the inherent trade-offs in selecting eligibility criteria.

The CISNET investigators[3] point out that their estimated numbers needed to screen to prevent 1 lung cancer death are much lower than those estimated from medium-term trials with a limited number of screening rounds. Current shared decision-making approaches have favored presenting the results of trials. However, it may be time to change that approach and present the estimated values based on models since those results may be less precise but are more applicable to receiving an annual LDCT scan for many years, which a patient should consider when opting for screening.

Since the NLST was published in 2011,[7] there have been many questions and challenges regarding how to implement a high-quality LCS program in real-world clinical settings. Lung cancer screening is not just an imaging study. It is a complex process. Indeed, the American College of Chest Physicians and American Thoracic Society identified 9 core elements necessary for high-quality LCS and provided guidance on how to implement these elements.[5] While these policy efforts are critical to ensuring that the benefits of LCS outweigh the harms at the population level, they may exacerbate disparities in lung cancer outcomes if only highly resourced settings have the ability to implement comprehensive, high-quality LCS programs, making screening inaccessible to individuals with higher lung cancer risk, such as socioeconomically disadvantaged individuals and rural populations.

Despite recommendations from professional societies and coverage by the Centers for Medicare & Medicaid Services, the uptake of LCS has been low and slow.[12] With this update of the USPSTF recommendation,[1] the population eligible for LCS will increase from an estimated 14.1% to 22.6%. Increasing the number eligible without increasing the means to do so will very likely perpetuate the problem of limited implementation. It is more necessary than ever, and indeed the USPSTF calls for more research, to identify effective strategies to reach and engage the target population and ensure implementation of each core element for high-quality LCS. We hope that by the next iteration of the USPSTF statement on LCS, there will be enough evidence to include recommendations on effective implementation strategies to disseminate high-quality LCS to all who may benefit.

Acknowledgments

Conflict of Interest Disclosures: Dr Ito Fukunaga is supported by a grant from the National Heart, Lung, and Blood Institute (1K12HK138049-01). Dr Wiener reports support through the VA Boston Healthcare System, receiving personal fees from the American Thoracic Society by serving as associate documents editor, serving as an unpaid peer reviewer for the evidence review conducted by the RTI International-University of North Carolina at Chapel Hill Evidence-based Practice Center in support of the United States Preventive Services Task Force statement on lung cancer screening, and serving as the co-chair of the VA New England Lung Cancer Screening Council but does not receive additional compensation for this role. Dr Slatore reports support through the VA Portland Health Care System, receiving grants from the American Cancer Society and the US Department of Veterans Affairs outside of the submitted work, and serving as codirector of the lung cancer screening program at the VA Portland Health Care System but does not receive additional compensation for this role.

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