

August 3, 2020

US Preventive Services Task Force 5600 Fishers Lane Mail Stop 06E53A Rockville, MD 20857

Re: Draft Recommendation Statement on Screening for Lung Cancer

Dear US Preventive Services Task Force,

On behalf of LUNGevity Foundation, the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the approximately 230,000 Americans diagnosed with lung cancer each year and the estimated 558,250 Americans living with the disease,¹ we are writing in response to the US Preventive Services Task Force (USPSTF) draft Recommendation Statement on screening for lung cancer that was released for review on July 7, 2020. LUNGevity applauds the expanded eligibility criteria in the draft guidelines so that more individuals are eligible for lung cancer screening and in particular, that this expanded eligibility criteria may help to reduce both gender and racial disparities. Based on the evidence presented in the draft Recommendation Statement LUNGevity believes that guidelines could be strengthened further and provides the comments below for consideration.

Concerns over B Rating

The draft Recommendation Statement currently has a B recommendation.. We commend the USPSTF for expanding the age and smoking history limit for lung cancer screening and understand that with this expansion has come the need to evaluate the risk-benefit ratio of low-dose computed tomography (LDCT) in those individuals who are younger and have a lighter pack year history of smoking. **We recommend a two-tiered recommendation for lung cancer screening for different populations.**

- 50 to 54 with a lighter history of smoking receiving a grade B recommendation
- 55 and above with a heavier history of smoking receiving an A recommendation

The American Association for Family Physicians does not endorse lung cancer screening, citing the main reason as "evidence was insufficient to recommend for or against annual



low-dose computed tomography in this population".² We feel that the use of a B recommendation would continue to be a huge barrier to the uptake of lung cancer screening.

Use of Risk-Stratification Such as Lung-RADS and Volumetric Assessments

Indication for screening and indication for nodule evaluation (tools for nodule management) are inextricably linked. While the guidelines focus primarily on indications for screening, we request the USPSTF to consider inclusion of some discussion around nodule management, which determines both adherence and success of a screening program.

It would be helpful for the report to include a nodule management analysis using a risk stratification system such as Lung-RADs to determine annual adherence, rate of detection of false positives and false negatives, and rate of invasive procedures avoided. Retrospective application of Lung-RADS to the NLST made LDCT more specific, albeit with smaller corresponding reductions in sensitivity.³ We recommend that the USPSTF analyze Lung-RADS data prospectively captured through the American College of Radiology registry. This would help in understanding whether the small loss in sensitivity impacts the overall impact on lives saves through LDCT. It is also worth noting that the NELSON trial used volumetric assessments of the LDCT scans, which seemed to significantly decrease the harms of LDCT without risk stratification.⁴

This suggests that LDCT technology may be refined with both two-dimensional (Lung-RADS) and three-dimensional (volumetric) assessments, which in turn will help mitigate harms such as invasive follow-ups for benign nodules. It would be helpful for the readers of the recommendation statement to be aware of these refinements.

In addition to the specific comments above, we would also like to highlight implementation issues that may arise with the expansion of the guidelines. There is unequivocal evidence that lung cancer screening by LDCT can save lives and this benefit is determined by both patient-specific factors (age and smoking history) and equally importantly, physician perception.⁵ Relaxing LDCT screening criteria provides the possibility to positively impact on health disparities given the potential increased eligibility of women and African Americans who have a lighter pack year history of smoking. However:

1) *Shared decision-making may be a bottleneck to uptake of new guidelines* - SDM is an excellent opportunity for patient-centered care.⁶ Currently, CMS mandates a shared decision-making engagement with all lung cancer screening-eligible



beneficiaries. Decreasing the age limit of screening-eligible individuals will increase the volume of individuals requiring shared decision-making (SDM). We see this being unsustainable even under the current circumstances. While the SDM mandate is not a requirement by the USPSTF guidelines per se, we feel that the updated guidelines would benefit from a nuanced discussion on the use of SDM in the context of the updated guidelines. **Specifically, we recommend** SDM for the younger age group 50-54 where a discussion of risk-benefit is still to be determined in this population at large. Our suggestion stems from the fact that younger individuals will more likely require a candid discussion of riskbenefits of LCS and proactive nodule management, given that the chances of a nodule being benign in the younger population may be higher.⁷ Furthermore, while at first glance it may seem that given the anticipated increase in volume of individuals screened using the expanded guidelines, primary care physicians (PCPs) may be the most suited for carrying out the SDM component of lung **cancer screening**. PCPs are well-positioned to deliver patient-centered care and use SDM as a teachable moment not just for risk-benefit discussions but also the importance of tobacco cessation. However, it is important to ensure that PCPs are equipped to conduct SDM in a patient-centric and effective way,8 as incorrect SDM may itself deter individuals from engaging in lung cancer screening⁹. In summary, a more nuanced discussion on the impact of SDM on lung cancer screening uptake would be a positive step towards circumventing this implementation challenge proactively.

2) *Health disparities may in fact be exacerbated* – While lowering the eligibility criteria may increase the number of African Americans who can benefit, it does not necessary translate into actual increases in number. The NLST and NELSON trials were conducted in academic institutions and the trial participants were more educated than the community who may benefit from screening. Therefore, relaxation of eligibility criteria needs to be complemented with large scale awareness programs as well as presence of high-quality screening facilities to truly realize the public health benefit of expanded eligibility. Currently, there is a huge disparity in the distribution of lung cancer screening facilities in the United States with various areas of high need lacking appropriate screening facilities.¹⁰

We appreciate that the purpose of the guidelines is not to address implementation challenges. However, as the leading lung cancer patient advocacy group in the United States, we feel it is important to have a proactive discussion on how these challenges can be addressed, such that the true population-level benefit of LDCT for lung cancer screening can be achieved.



LUNGevity is grateful for the opportunity to comment on the USPSTF draft Recommendation Statement on Screening for Lung Cancer. The comments outlined above can be discussed with me, my staff, and LUNGevity's Scientific Advisory Board, which is made up of some of the world's leading experts in lung cancer biology, practice management, access to innovative medicines, and overall patient care. I can be reached at 240-454-3100 or <u>aeferris@lungevity.org</u> if you have any questions or would like to engage in further dialogue.

Thank you for your attention to this important matter.

Sincerely,

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Andrea Stern Ferris President and Chief Executive Officer LUNGevity Foundation

ABOUT LUNGEVITY:

LUNGevity's mission is to improve outcomes for people diagnosed with lung cancer. Our goals are three-fold: (1) to accelerate research to patients that is meaningful to them; (2) to empower patients to be active participants in their care and care decisions; and (3) to help remove barriers to access to high quality care. We have the largest lung cancer survivor network in the country and actively engage with them to identify, understand, and address unmet patient needs. We also have a world class Scientific Advisory Board that guides the programs and initiatives of the organization. Additionally, we collaborate with other lung cancer patient advocacy groups and organizations, such as the American Lung Association and CHEST, who serve the lung cancer community.

REFERENCES:

 SEER. Cancer Stat Facts: Lung and Bronchus Cancer. <u>https://seer.cancer.gov/statfacts/html/lungb.html</u>. Published 2020. Accessed August 1, 2020.



- 2. Croke LM. Cancer Screening: ACS Releases Annual Summary of Recommendations. *Am Fam Physician*. 2019;99(11):719-722.
- 3. Pinsky PF, Gierada DS, Black W, et al. Performance of Lung-RADS in the National Lung Screening Trial: a retrospective assessment. *Ann Intern Med.* 2015;162(7):485-491.
- 4. de Koning HJ, van der Aalst CM, de Jong PA, et al. Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial. *The New England journal of medicine*. 2020;382(6):503-513.
- 5. Wang GX, Baggett TP, Pandharipande PV, et al. Barriers to Lung Cancer Screening Engagement from the Patient and Provider Perspective. *Radiology*. 2019;290(2):278-287.
- 6. Tanner NT, Silvestri GA. Shared Decision-making and Lung Cancer Screening: Let's Get the Conversation Started. *Chest.* 2019;155(1):21-24.
- McWilliams A, Tammemagi MC, Mayo JR, et al. Probability of cancer in pulmonary nodules detected on first screening CT. *The New England journal of medicine*. 2013;369(10):910-919.
- Carter-Harris L, Gould MK. Multilevel Barriers to the Successful Implementation of Lung Cancer Screening: Why Does It Have to Be So Hard? *Ann Am Thorac Soc.* 2017;14(8):1261-1265.
- 9. Goodwin JS, Nishi S, Zhou J, Kuo YF. Use of the Shared Decision-Making Visit for Lung Cancer Screening Among Medicare Enrollees. *JAMA Intern Med.* 2019;179(5):716-718.
- 10. Kale MS, Wisnivesky J, Taioli E, Liu B. The Landscape of US Lung Cancer Screening Services. *Chest.* 2019;155(5):900-907.