

August 3, 2020

Alex H. Krist, MD MPH c/o U.S. Preventive Services Task Force Agency for Healthcare Research and Quality 540 Gaither Road Rockville, MD 20850

Subject: USPSTF DRAFT Recommendation Statement Screening for Lung Cancer; Comments of the American College of Radiology

Dear Members of the U.S. Preventive Services Task Force:

On behalf of the American College of Radiology (ACR)—a professional organization representing over 40,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—we appreciate the opportunity to submit comments regarding the July 7, 2020 draft recommendation statement of the Agency for Healthcare Research and Quality's (AHRQ) U.S. Preventive Services Task Force (USPSTF) on screening for lung cancer. The ACR strongly supports the USPSTF proposal to lower the starting age for screening from 55 to 50 and the smoking history requirements from 30 pack-years to 20 pack-years. The ACR encourages efforts to expand screening — particularly among minorities and women. In addition, the ACR seeks clarification from the USPSTF regarding its continuation of a grade B recommendation. Several recently published studies demonstrate the mortality benefit is substantial and meets the criteria for a grade A recommendation. A grade A recommendation will encourage providers to recommend this screening test and foster wide-spread adoption.

Annual lung cancer screening with LDCT in high-risk patients significantly reduces lung cancer deaths.¹ This screening can identify cancers at an early, treatable and curable stage. Given that the American Cancer Society predicts 135,720 lung cancer deaths this year, more-widespread

¹ https://www.radiologyinfo.org/en/info.cfm?pg=screening-lung

screening could save 30,000–60,000 lives in the United States each year.² To ensure this lifesaving screening is broadly available and utilized by an expanded pool of at-risk patients, the ACR respectfully recommends the following:

Screening Eligibility

The USPSTF proposal to lower the starting age for screening from age 55 to age 50 and adjust smoking history requirements from 30 pack-years to 20 pack-years are positive changes for lung cancer screening (LCS) and will especially help reduce the disparity in eligibility criteria for African Americans. These new limits are well substantiated by NELSON results and by the NCCN Group 2 screening results. However, the ACR believes the screening eligibility requirements should be further adjusted to capture a broader pool of individuals at high risk for lung cancer based on factors beyond age and smoking history. For example, individuals with a family history of lung cancer have a two to threefold increased risk of developing the disease and occupational exposures and presence of emphysema (or other underlying lung disease) are known risk factors for lung cancer—yet these points are not specifically addressed in the draft USPSTF eligibility criteria. To address these omissions and broaden the eligibility pool for lung cancer screening, the ACR urges the USPSTF to further adjust the eligibility requirements by adding various occupational exposures to known carcinogens, as well as including criteria associated with a strong family history of lung cancer ^{3,4,5,6}. Adoption of these broader metrics for screening eligibility will ensure a robust population of high-risk individuals have access to this life-saving screening.

Extension/Removal of Quit-Years Requirements

The ACR strongly recommends LDCT as a screening tool for individuals at high risk for lung cancer and urges the USPSTF to refrain from utilizing arbitrary cessation cut off dates as a metric for eligibility.^{7,8} Many individuals with heavy pack-year smoking histories who quit more than 15 years ago are still at high risk, yet would not meet the eligibility requirements for screening as currently proposed within the USPSTF draft recommendations for lung cancer

⁷ Reexamining Rates of Decline in Lung Cancer Risk After Smoking Cessation: A Meta-Analysis.

² https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html

³ Risk Perceptions and Family History of Lung Cancer: Differences by Smoking Status. Chen LS, Kaphingst KA. Public Health Genomics. 2010 Dec; 14(1): 26-34,

⁴ Ramsey SD, Yoon P, Moonesinghe R, Khoury MJ. Population-based study of the prevalence of family history of Cancer: Implications for Cancer Screening and Prevention. Genet Med. 2006; 8: 571-575

⁵ Natadori, J, et al "Association Between Lung Cancer Incidence and Family History of Lung Cancer: Data from Large-Scale Population-Based Cohort Study, the JPHC Study" CHEST 2006; 130: 968-975.

⁶ Schwartz, AG "Lung Cancer: Family History Matters" CHEST 2006; 130: 936-937,

https://pubmed.ncbi.nlm.nih.gov/32603182/

⁸ Lifetime Smoking History and Risk of Lung Cancer: Results From the Framingham Heart Study. Hilary A. Tindle, Meredith Stevenson Duncan, Robert A. Greevy, Ramachandran S. Vasan, Suman Kundu, Pierre P. Massion, Matthew S. Freiberg. JNCI J Natl Cancer Inst (2018) 110(11): djy041

screening.⁹ To simplify eligibility requirements and further promote screening, the ACR strongly urges the USPSTF to remove the 15-year smoking cessation quit date. In the absence of removing the cessation requirement in its entirety, the date should be extended to *at least* 20 years.

Screening Guidelines, Shared Decision Making, and Health Equity

Given USPSTF's expanded eligibility recommendations, healthcare providers must become more familiar with lung cancer screening guidelines and prescribe these exams for high-risk patients. Despite the 7 years since the original USPSTF recommendations, recent research indicates that fewer than 4 percent of eligible patients take advantage of lung cancer screening exams, largely due to a lack of awareness of the benefits.¹⁰ Although there are several factors contributing to low LCS utilization, the complexities associated with the eligibility requirements and inconsistencies associated with Shared Decision Making (SDM) are often cited as significant barriers.¹¹ To increase LCS utilization, screening programs and the accompanying steps for enrollment should embrace patient-centric models that streamline processes and increase patient compliance.¹² For example, while SDM is an important component of enrollment in a lung cancer screening program, consideration should be made for providing opportunities for the SDM appointment or consultation to occur in conjunction with the actual screening exam. In this type of scenario, a patient can be referred by a PCP or healthcare provider to a radiology department or center that performs LCS—a center that is well-versed in the SDM process and content that needs to be discussed, has standardized information associated with the pros/cons of screening (false-positive, false-negative, over diagnosis rates, and radiation exposure)—and can provide succinct and accurate information to potential LCS patients, including requisite pre-authorizations prior to the exam taking place during the same visit. Streamlining these processes will help patients avoid unnecessary delays in the screening process and will also offload the burdensome SDM requirements from busy providers who are sometimes uncomfortable with the SDM process and/or present inconsistent or inaccurate information to potential LCS patients.

In addition, collective efforts must be made to eliminate persistent health and racial inequities associated with lung cancer screening. In the United States, lung cancer mortality rates are highest in African Americans compared with other races and the magnitude of the disparity in

⁹ Yang JO, Wang Y, Wampfler JA, et al. Trends in Subpopulations at High Risk for Lung Cancer. J Thorac Oncol 2016; 11:194-202

¹⁰ Jemal A, Fedewa SA. Lung cancer screening with low-dose computed tomography in the United States-2010 to 2015. JAMA Oncol . 2017;39:1278–1281

¹¹ National Academies of Sciences, Engineering, and Medicine. 2017.

Implementation of lung cancer screening: Proceedings of a workshop. Washington, DC: The National Academies Press. doi: https://doi.org/10.172216/23680.

¹² Kanodra NM, Pope C, Halbert CH, Silvestri GA, Rice LJ, Tanner NT. Primary Care Provider and Patient Perspectives on Lung Cancer Screening. A Qualitative Study. Ann Am Thorac Soc 2016 Nov; 13(11): 1977-1982

mortality has been widening over the last four decades.¹³ Beyond race, a recent study published in the New England Journal of Medicine also confirmed higher lung cancer rates in white and Hispanic women in comparison to men, including increases rates of lung cancer in women with no smoking history.¹⁴ Given that lung cancer remains the leading cancer death in every racial and ethnic subgroup and is the leading cancer killer of women, a responsible and ethical expanded screening recommendation is needed for these additional at-risk populations.¹⁵

The ACR urges the USPSTF to include real-world evidence, Post Market Surveillance data, as well as other well-designed research approaches as to refine their recommendation. Doing so would improve health and racial equity of low dose CT screening across disparate populations including the underserved, African Americans, and minorities, as well as women.

The ACR appreciates the opportunity to provide comments on the USPSTF draft recommendations for lung cancer screening. Moving forward, the ACR also welcomes continued dialogue with AHRQ and the USPSTF on all topics related to radiology. If you have any questions related to the aforementioned comments and/or would like additional information, please contact Gloria Romanelli, ACR Senior Director of Legislative and Regulatory Relations, at <u>gromanelli@acr.org</u> or Megan Marcinko, ACR Director of Government Relations, at <u>mmarcinko@acr.org</u>.

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William T. Thorwarth, Jr., MD, FACR American College of Radiology

 ¹³ Pasquinelli MM, Kovitz KL, Koshy M, et al. Outcomes From a Minority-Based Lung Cancer Screening Program vs the National Lung Screening Trial. JAMA Oncol. 2018;4(9):1291–1293. doi:10.1001/jamaoncol.2018.2823
¹⁴ Jemal, Ahmedin; Miller, Kimberly D.;Ma, Jiemin; Siegel, Rebecca L.; Fedewa, Stacey A.;Islami, Farhad; Devesa, Susan S.; Thun, Michael J. "Higher Lung Cancer Incidence in Young Women Than Young Men in the United States." 2018/05/23. New England Journal of Medicine. 1999-2009.

https://www.nejm.org/doi/full/10.1056/NEJMoa1715907

¹⁵ The Patient Perspective on Lung Cancer Screening and Health Disparities. A Borondy Kitts. J Am Coll Radiol 2019;16:601-606.