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Agency for Healthcare Research and Quality
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Subject: USPSTF Recommendation Statement Screening for Lung Cancer; Comments of GO2 for Lung Cancer, the American College of Radiology, and The Society of Thoracic Surgeons – Update Request

Dear Dr. Nicholson:

The GO2 for Lung Cancer [1], the American College of Radiology® (ACR)[2], and The Society of Thoracic Surgeons [3], formally request an update of the existing United States Preventive Services Task Force (USPSTF) recommendation statement for Screening Lung Cancer with Low-dose Computed Tomography (LDCT), and revise with the evidence-based guidelines published by the American Cancer Society (ACS) and the National Comprehensive Care Network (NCCN). **Our joint societies ask for the removal of both the 15 years since quitting smoking criterion and the upper age limit to screening in response to the current body of evidence which has been incorporated into the updated ACS and NCCN evidence-based guidelines**.[4,5]

[1] The GO2 for Lung Cancer is a national non-profit organization, founded by patients and survivors, dedicated to saving, extending, and improving the lives of those vulnerable, at risk, and diagnosed with lung cancer.
[2] The ACR is a professional organization representing 40,000 radiologists, radiation radiologists, nuclear medicine physicians, and medical physicists, committed to advancing the science and quality of radiological care for patients.
[3] The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,600 surgeons, researchers, and allied healthcare professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.
[4] Andrew, Oeffinger, K. C., Shih, T., Walter, L. C., Church, T. R., Elizabeth T.H. Fontham, Elkin, E. B., Etzioni, R., Guerra, C. E., Perkins, R. B., Kondo, K., Kratzer, T. B., Manassaram-Baptiste, D., Dahut, W. L., & Smith, R. A. (2023). Screening for lung cancer: 2023 guideline update from the American Cancer Society. *CA: A Cancer Journal for Clinicians*. https://doi.org/10.3322/caac.21811
[5] NCCN. (2023, October 18). NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening [Review of NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening]. https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

Both the ACS and NCCN screening guidelines expanded the screening eligibility criteria and are estimated to capture five million additional lives at higher risk for lung cancer. Given the recent evidence, the magnitude of impact, and the number of lives at risk, we urge the USPSTF to **prioritize and expedite** the *review and update* process for low-dose CT lung cancer screening with a focus on the following key areas:

- Remove the 15 years since quitting smoking history eligibility criterion for annual screening;
- Remove the upper age limit for annual screening; and
- Relevance, Usefulness, and Medical Benefits of Lung Cancer Screening

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I. **Our joint societies strongly urge the USPSTF to expeditiously remove the *15 years since quitting* smoking criterion currently required for annual screening.**

Kondo et al. completed an independent systematic review requested by the ACS Guideline Development Group and looked at lung cancer diagnosis and mortality beyond 15 years since quitting (YSQ) smoking in individuals with a 20+ pack-year history. Their findings show the risk of lung cancer not only persisted beyond 15 years after quitting smoking but actually elevated the risk of those who have not smoked in 15 or more years for two or three decades.[6]

Landy et al. quantified the counteracting effects of years since quitting smoking and concomitant aging on lung cancer risk, including exceeding the 15 YSQ smoking, and concluded that because of aging, absolute lung cancer risk increases beyond 15 YSQ, which does not support exemption from screening or curtailing screening once it has been initiated. They further concluded that compared with relaxing the USPSTF quit-year criterion, augmentation using the Life Years From Screening – CT prediction model could prevent most of the deaths at substantially superior efficiency while also preventing deaths among individuals who currently smoke with low intensity or long duration.[7]

Meza et al. addressed the impact of increasing lung cancer screening eligibility by relaxing the maximum years since quitting smoking threshold with a simulation modeling study. They found that *expanding screening to persons who formerly smoked and have greater than 15 YSQ would result in considerable increases in deaths averted and life-years gained*.[8]

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[6] Kondo, K., Rahman, B., Ayers, C., Relevo, R., Griffin, J., & Halpern, M. T. (2023). Lung cancer diagnosis and mortality beyond 15 years since quit in individuals with a 20+ pack-year history: A systematic review. *CA: A Cancer Journal for Clinicians*. https://doi.org/10.3322/caac.21808

[7] Landy, R., Cheung, L. C., Young, C. D., Chaturvedi, A. K., & Katki, H. A. (2023). Absolute lung cancer risk increases among individuals with >15 quit-years: Analyses to inform the update of the American Cancer Society lung cancer screening guidelines. Cancer. https://doi.org/10.1002/cncr.34758

[8] Meza, R., Cao, P., de Nijs, K., Jeon, J., Smith, R. A., Ten Haaf, K., & de Koning, H. (2024). Assessing the impact of increasing lung screening eligibility by relaxing the maximum years-since-quit threshold: A simulation modeling study. Cancer, 130(2), 244–255. https://doi.org/10.1002/cncr.34925

Dr. Tammemagi published an article titled "Time to quit using *quit time* as a lung cancer screening eligibility criterion" that evaluates the historical and current body of evidence, including a comprehensive discussion regarding the USPSTF and CMS lung cancer recommendation and coverage, timeliness barriers with their processes and cycles, contrasted by the NCCN guideline review cycle and completed annually at minimum, and how USPSTF and CMS rate to today's swiftly advancing world of science in lung cancer. This author points to the ACS guideline and its careful review of the evidence, their removal of the 15 YSQ, and encourages the USPSTF, CMS, and other organizations to expeditiously remove the YSQ limitations, as hundreds of thousands of high-risk individuals currently do not have access to screening because of this existing quit-years eligibility rule. He further states that *it can be considered unethical to delay correction of the currently flawed screening criteria, depriving thousands of former smoking individuals of the lifesaving benefits of LCS.*[9]

Based on the ACS findings and recent publications (Kondo/Landy/Meza/Tammemagi), if the 15 years since quitting criterion is removed and if all eligible individuals followed the updated ACS guideline, there would be an increase in lung cancer screening eligible individuals from 14.2 million to 19.2 million, with 21% more lives saved and 19% more life years gained. These studies clearly indicate the benefits of screening after 15 years of having stopped smoking and, therefore, **the 15 years since *quit time* as a lung cancer screening eligibility criterion should be removed as evidenced by both the NCCN guideline and recently updated ACS guideline**. People should not be excluded from screening who stopped smoking more than 15 years ago, as this is a population that has lasting and rising risk due to aging and smoking history.[10,11,12,13]

II. **Our joint societies strongly urge USPSTF to remove the upper age limit criterion currently recommended for screening eligibility.**

There is an inconsistency between the USPSTF and CMS with the upper age limit to initiate or continue low dose CT lung cancer screening (80 vs 77 years). The upper age limit for annual screening was previously imposed due to a perceived lack of evidence and as a legacy of the inclusion criteria of the National Lung Screening Trial, which has imprinted into policies and coverage decisions. The screening criteria are sometimes reiterated by guidelines to educate providers and patients on covered benefits and eligibility imposed by the USPSTF, CMS, etc. Additionally, in the recent ACS guideline, the upper age limit for screening was expanded to 80 years, and the NCCN guideline removed the upper age limit altogether, as it is well-established that medical

[9] Martin Carl Tammemägi. (2023). Time to quit using quit time as a lung cancer screening eligibility criterion. Cancer, 130(2), 182–185. https://doi.org/10.1002/cncr.34999

[10] Kondo, K., Rahman, B., Ayers, C., Relevo, R., Griffin, J., & Halpern, M. T. (2023). Lung cancer diagnosis and mortality beyond 15 years since quit in individuals with a 20+ pack-year history: A systematic review. CA: A Cancer Journal for Clinicians. https://doi.org/10.3322/caac.21808

[11] Meza, R., Cao, P., de Nijs, K., Jeon, J., Smith, R. A., Ten Haaf, K., & de Koning, H. (2024). Assessing the impact of increasing lung screening eligibility by relaxing the maximum years-since-quit threshold: A simulation modeling study. Cancer, 130(2), 244–255. https://doi.org/10.1002/cncr.34925

[12] Landy, R., Cheung, L. C., Young, C. D., Chaturvedi, A. K., & Katki, H. A. (2023). Absolute lung cancer risk increases among individuals with >15 quit-years: Analyses to inform the update of the American Cancer Society lung cancer screening guidelines. Cancer. https://doi.org/10.1002/cncr.34758

[13] Martin Carl Tammemägi. (2023). Time to quit using quit time as a lung cancer screening eligibility criterion. Cancer, 130(2), 182–185. https://doi.org/10.1002/cncr.34999

appropriateness of lung cancer screening and treatment is subject to physiologic status, comorbidities, and the ability to undergo curative intent therapy. The evidence-based benefit of screening these individuals beyond 77 and 80 years is far greater than previously published risks as included in these guidelines.[14,15]

Varlotto et al. investigated whether screening for lung cancer might benefit individuals 75-84 years because of the increasing life expectancy of the American population. They concluded that screening for lung cancer may benefit individuals at increased risk of lung cancer in that upper age group. More specifically, they found that the survival benefits of aggressive therapy are similar in females between 55–74 and 75–84 years old.[16]

It is essential to recognize that cancer risk continues to increase with advancing age and does not decrease at age 77 or 80. Many of these individuals continue to be eligible for curative intent treatment with good outcomes and a favorable prognosis.[17] Well-established data from institutional reports and registry analyses document the favorable patient outcomes from the surgical management of early-stage lung cancer. Objective assessments of surgical efficacy should use contemporary results, including screening studies [e.g., International Early Lung Cancer Action Program (I-ELCAP)].[18] In addition, other advances in other therapeutic modalities, including stereotactic body radiation therapy (SBRT), standard radiation therapy (RT), chemotherapy, and immunotherapy have dramatically increased survival beyond 77 years of age.[19,20,21,22]

A person-centered approach is critical when addressing risks and benefits. While age and smoking history are used for risk assessment, other potential risk factors for lung cancer can be identified during the informed *patient-provider* discussion, including the overall health of the individual and comorbidities and their healthcare values regarding ongoing screening. Both the ACS and NCCN guidelines endorse shared decision making (i.e.,

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[14] Andrew, Oeffinger, K. C., Shih, T., Walter, L. C., Church, T. R., Elizabeth T.H. Fontham, Elkin, E. B., Etzioni, R., Guerra, C. E., Perkins, R. B., Kondo, K., Kratzer, T. B., Manassaram-Baptiste, D., Dahut, W. L., & Smith, R. A. (2023). Screening for lung cancer: 2023 guideline update from the American Cancer Society. CA: A Cancer Journal for Clinicians. https://doi.org/10.3322/caac.21811

[15] NCCN. (2023, October 18). NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening [Review of NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening]. https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

[16] Varlotto, J. M., DeCamp, M. M., Flickinger, J. C., Lake, J., Recht, A., Belani, C. P., Reed, M. F., Toth, J. W., Mackley, H. B., Sciamanna, C. N., Lipton, A., Ali, S. M., Richkesvar P. M. Mahraj, Gilbert, C. R., & Yao, N. (2014). Would Screening for Lung Cancer Benefit 75- to 84-Year-Old Residents of the United States? Frontiers in Oncology, 4. https://doi.org/10.3389/fonc.2014.00037

[17] NCCN. (2023, October 18). NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening [Review of NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening]. https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

[18] I-ELCAP Publications – I-ELCAP – IELCART. (n.d.). Retrieved June 14, 2024, from https://www.ielcap.org/home/ielcap/research/ielcap-publications/

[19] Shu, Z., Dong, B., Shi, L., Shen, W., Hang, Q., Wang, J., & Chen, Y. (2020). Stereotactic body radiotherapy for elderly patients (≥ 75 years) with early-stage non-small cell lung cancer. Journal of Cancer Research and Clinical Oncology, 146(5), 1263–1271. https://doi.org/10.1007/s00432-020-03154-5

[20] Watanabe, K., Katsui, K., Sugiyama, S., Yoshio, K., Kuroda, M., Hiraki, T., Kiura, K., Maeda, Y., Toyooka, S., & Kanazawa, S. (2021). Lung stereotactic body radiation therapy for elderly patients aged ≥ 80 years with pathologically proven early-stage non-small cell lung cancer: a retrospective cohort study. Radiation Oncology, 16(1). https://doi.org/10.1186/s13014-021-01769-7

[21] Gridelli, C., Peters, S., Velcheti, V., Attili, I., & de Marinis, F. (2023). Immunotherapy in the first-line treatment of elderly patients with advanced non-small-cell lung cancer: results of an International Experts Panel Meeting by the Italian Association of Thoracic Oncology (AIOT). ESMO Open, 8(2), 101192. https://doi.org/10.1016/j.esmoop.2023.101192

[22] Tsukita, Y., Tozuka, T., Kushiro, K., Hosokawa, S., Sumi, T., Uematsu, M., Honjo, O., Yamaguchi, O., Asao, T., Sugisaka, J., Saito, G., Shiihara, J., Morita, R., Katakura, S., Yasuda, T., Hisakane, K., Miyauchi, E., Morita, S., Kobayashi, K., & Asahina, H. (2024). Immunotherapy or Chemoimmunotherapy in Older Adults With Advanced Non–Small Cell Lung Cancer. JAMA Oncology. https://doi.org/10.1001/jamaoncol.2023.6277

informed discussion) and recommend extending lung cancer screening for individuals who are likely to benefit the most.[23,24] **Our organizations strongly believe the existing shared decision making discussion is sufficient to offer this life-saving benefit to those that are 77 and beyond.**

III. Relevance, Usefulness, and Medical Benefits of Low Dose CT Lung Cancer Screening

Low dose chest CT, as the only proven tool for the early detection of lung cancer to reduce lung cancer mortality, is a reasonable and necessary, noninvasive, CT exam that is straightforward and easy to perform with minimal patient effort required. In addition, CT systems are authorized by the Food and Drug Administration (FDA) with indications for low-dose lung cancer screening. We request that the USPSTF work in concert with CMS to update lung cancer screening policies simultaneously and expeditiously for the expanded at-risk population, based on the updated ACS and NCCN guidelines, the impact and projected number of lives saved, and current body of evidence.

The effectiveness of low-dose CT lung cancer screening is remarkable, and current and emerging literature continue to provide further evidence of this lifesaving benefit. Henschke et al., in a November 2023 *Radiology* publication, concluded that the 10-year and 20-year lung cancer survival rate of 80% is sustained within the International-Early Lung Cancer Action Program (I-ELCAP) cohorts.[25] Further, cancer epidemiology demonstrates a substantial reduction in lung cancer mortality since the initiation of lung cancer screening which has been the primary driver of record-breaking annual reductions in overall cancer mortality in the United States.[26]

In addition, Flores et al. found that stage shift from later to earlier stage disease over the last decade was associated with improved mortality among people with lung cancer.[27] Yang et al., looked at the association between improved survival and low dose CT screening and the diagnostic shift from late to early-stage of lung cancer, highlighting the importance of early detection.[28] Ganti et al. evaluated the incidence, prevalence, survival, and initial treatment in patients with non-small cell lung cancer in the US and concluded that the increased incidence of stage I at diagnosis likely reflects improved evaluation of incidental nodules.[29] Hendrick et al., found that the lung cancer screening benefits far outweigh the risks of future harms associated with

[23] Andrew, Oeffinger, K. C., Shih, T., Walter, L. C., Church, T. R., Elizabeth T.H. Fontham, Elkin, E. B., Etzioni, R., Guerra, C. E., Perkins, R. B., Kondo, K., Kratzer, T. B., Manassaram-Baptiste, D., Dahut, W. L., & Smith, R. A. (2023). Screening for lung cancer: 2023 guideline update from the American Cancer Society. CA: A Cancer Journal for Clinicians. https://doi.org/10.3322/caac.21811

[24] NCCN. (2023, October 18). NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening [Review of NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening]. https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

[25] Henschke, C. I., Yip, R., Shaham, D., Markowitz, S., Cervera Deval, J., Zulueta, J. J., Seijo, L. M., Aylesworth, C., Klingler, K., Andaz, S., Chin, C., Smith, J. P., Taioli, E., Altorki, N., Flores, R. M., Yankelevitz, D. F., & International Early Lung Cancer Action Program Investigators. (2023). A 20-year Follow-up of the International Early Lung Cancer Action Program (I-ELCAP). Radiology, 309(2), e231988. https://doi.org/10.1148/radiol.231988

[26] Lung Cancer Statistics | How Common is Lung Cancer? (2023, January 12). Www.cancer.org. https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html#:~:text=The%20American%20Cancer%20Society

[27] Flores, R., Patel, P., Alpert, N., Pyenson, B., & Taioli, E. (2021). Association of Stage Shift and Population Mortality Among Patients With Non–Small Cell Lung Cancer. JAMA Network Open, 4(12), e2137508. https://doi.org/10.1001/jamanetworkopen.2021.37508

[28] Yang, C.-Y., Lin, Y.-T., Lin, L.-J., Chang, Y.-H., Chen, H.-Y., Wang, Y.-P., Shih, J.-Y., Yu, C.-J., & Yang, P.-C. (2023). Stage Shift Improves Lung Cancer Survival: Real-World Evidence. Journal of Thoracic Oncology, 18(1), 47–56. https://doi.org/10.1016/j.jtho.2022.09.005

[29] Ganti, A. K., Klein, A. B., Cotarla, I., Seal, B., & Chou, E. (2021). Update of Incidence, Prevalence, Survival, and Initial Treatment in Patients With Non–Small Cell Lung Cancer in the US. JAMA Oncology, 7(12), 1824. https://doi.org/10.1001/jamaoncol.2021.4932

exposure to radiation during screening and diagnostic follow-up tests.[30] Low-dose CT lung cancer screening has progressed, is proven effective, and programs have been successfully implemented across settings, including community hospitals.[31]

Summary

Lung cancer is the leading cause of cancer death and accounts for about 1 in 5 of all cancer deaths. The ACS estimates over 125k lung cancer deaths in 2024 in the United States, a figure that is greater than the mortality rates of colon, breast, and prostate cancers combined. Every year, a staggering number of Americans die from a disease that is preventable, treatable, and even curable.[32] Screening uptake is slowly increasing but remains low. In a recent study, the 2022 LCS prevalence was 16.4% and 19.6% using 2021 and 2013 USPSTF criteria.[33] **It is important that the USPSTF and other government agencies quickly act to remove artificial barriers for individuals who would benefit from screening.**

Our joint societies applaud the USPSTF for expanding the lung cancer screening eligibility criteria in 2021. We strongly recommend and support an expedited and prioritized update to the USPSTF recommendation statement to **remove specific screening eligibility criteria that remain a barrier to individuals at high risk for lung cancer. These changes would align with the current and compelling evidence-based guidelines from the ACS and NCCN. Specifically, we advocate removing the 15 years since quitting smoking and upper age criteria.**

Thank you for this opportunity to help save millions of lives by expanding lung cancer screening.

Sincerely,

Laurie Fenton Ambrose
Co-Founder, President and CEO
GO2 for Lung Cancer

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

Jennifer C. Romano, MD, MS
President
The Society of Thoracic Surgeons

cc: Scientific Leadership Board

[30] R. Edward Hendrick, & Smith, R. A. (2023). Benefit-to-radiation-risk of low-dose computed tomography lung cancer screening. Cancer, 130(2), 216–223. https://doi.org/10.1002/cncr.34855
[31] Copeland, A., Criswell, A., Ciupek, A., & King, J. C. (2019). Effectiveness of Lung Cancer Screening Implementation in the Community Setting in the United States. Journal of Oncology Practice, 15(7), e607–e615. https://doi.org/10.1200/jop.18.00788
[32] American cancer society. (2023, January 12). Lung Cancer Statistics | How Common is Lung Cancer? Www.cancer.org. https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html
[33] Henderson, L. M., Su, I-Hsuan., M. Patricia Rivera, Pak, J., Chen, X., Reuland, D. S., & Lund, J. L. (2024). Prevalence of Lung Cancer Screening in the US, 2022. JAMA Network Open, 7(3), e243190–e243190. https://doi.org/10.1001/jamanetworkopen.2024.3190