### Initial Results of a Lung Cancer Screening Demonstration Project: A Local Program Evaluation

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ung cancer is the leading cause of cancer morbidity and mortality in the United States.¹ Given the high disease burden and aggressive nature of lung cancer, considerable effort has been directed at early detection and treatment through lung cancer screening (LCS) trials. The National Lung Screening Trial (NLST) reported a 20% relative reduction in lung cancer mortality with low-dose computed tomography (LDCT) compared with chest x-rays.² The primary principle of LCS is detection and surveillance of small lung nodules over time for changes that are suspicious for malignancy.

The NLST served as the primary basis for the recent United States Preventive Services Task Force recommendation for annual LCS with LDCT for high-risk individuals. Several professional societies have also endorsed annual LDCT for high-risk individuals, and in 2015, CMS added LCS as a reimbursable preventive service. Despite the benefits of LDCT for LCS on both lung cancer and all-cause mortality, there are concerns about high costs and potential associated harms, including false-positive results, overdiagnosis, lo.11 radiation exposure, and psychological distress, particularly for patients who receive an indeterminate result. 13,14

To gain information about the feasibility of implementing these recommendations, the Veterans Health Administration (VHA) completed a National Demonstration Project. The Minneapolis Veterans Affairs Health Care System (MVAHCS) was 1 of 8 demonstration sites. We report the initial results of LCS at the MVAHCS to provide more detailed information than was collected in the National VHA Demonstration Project regarding tobacco pack-year (TPY) information, patient uptake rates of LCS in response to different invitation approaches, characteristics of lung nodules detected on LDCT, and the clinical significance of incidental findings on LDCTs that are unrelated to LCS.

#### **ABSTRACT**

**OBJECTIVES:** To describe participation rates, results, and lessons learned from a lung cancer screening (LCS) demonstration project.

**STUDY DESIGN:** Prospective observational study at 1 of 8 centers participating in a national Veterans Health Administration LCS demonstration project.

METHODS: An electronic health record (EHR) algorithm and tobacco pack-year (TPY) information prompt identified patients potentially eligible for LCS. LCS invitation was planned to consist of shared decision-making materials, an invitation letter to call the LCS manager, a reminder letter, and an outreach phone call for nonresponders. The outreach call was subsequently dropped due to time constraints on the LCS manager. Lung nodules and incidental findings on LCS low-dose computed tomography (LDCT) were recorded in templated radiology reports and tracked with EHR notes.

**RESULTS:** Of 6133 potentially eligible patients, we identified 1388 patients with eligible TPY information: 918 were invited for LCS and 178 (19%) completed LCS. LCS completion was more likely in patients in the mailing-plus-call outreach group (phase I) compared with the mail-only group (phase II) (22% vs 9%; P <.001). Among those completing an LDCT, 61% had lung nodules requiring follow-up: 43% of the nodules were less than 4 mm in diameter, 12 patients required further diagnostic evaluation, and 2 had lung malignancies. There were 179 incidental LDCT findings in 116 patients, and 20% were clinically significant.

conclusions: Important considerations in LCS are accurate identification of eligible patients, balancing invitation approaches with resource constraints, and establishing standardized methods for tracking numerous small lung nodules and incidental findings detected by LDCT.

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#### **METHODS**

#### **Setting and Patient Eligibility**

Initial LCS results at the MVAHCS between January 1, 2014, and May 22, 2015, were analyzed. We employed a national VHA electronic

health record (EHR) algorithmic program to identify potential eligible patients who met the preliminary LCS criteria at the time of an appointment with their primary care provider (PCP). The criteria were: being aged 55 to 80 years; having no diagnosis codes in the EHR for hospice care or lung, esophageal, pancreatic, or liver cancer; having no chest CT in the previous year; and not being previously coded in the EHR as not expected to live more

than 6 months. If a patient met all of these criteria, the algorithm activated an EHR prompt for the appointment check-in nurse to collect TPY information (ie, current cigarette smoking status, years smoked, and average lifetime packs per day).

To provide equitable access and prevent exceeding the initial screening capacity for LCS, the National VHA Demonstration Project recommended gradual local implementation by a random rolling activation of EHR prompts per individual PCPs. At our site, providers opted out of this approach because of an existing program of a manager-driven lung nodule tracking system. We therefore elected to randomly choose patients with eligible TPY information (≥30 pack-years and either currently smoking or quit <15 years ago) for invitation to LCS using a 2:1 ratio (2 patients selected for LCS invitation for every 1 usual care patient), by the LCS program manager, an MPH with training in health education and extensive clinical experience. The MVAHCS Internal Review Board determined that patient-level randomization for invitation to the Demonstration Project was not considered research, but rather a quality improvement and feasibility evaluation method. Randomization was implemented in blocks, with groups assigned using random number generator-based software algorithms.

All MVAHCS patients had access to a comprehensive Tobacco Cessation Program, which includes assessment of smoking status via an annual EHR prompt, patient education materials, individual and group behavioral therapy, and pharmacotherapy.

#### **LCS Invitation**

Eligible patients were mailed shared decision-making (SDM) materials developed by the VHA National Center for Health Promotion and Disease Prevention<sup>15</sup> (eAppendix [available at ajmc.com]) and a letter inviting them to call the LCS program to discuss LCS and schedule an LDCT. A second letter was mailed a week later. At the outset of the local demonstration project, the program manager attempted to complete phone contact with all invitation nonrespondents. During an LCS call, the patient and program manager would review the SDM material and discuss any LCS-related questions. Patients were encouraged to quit smoking, and the program manager offered to place a consult to the tobacco cessation team (phase I). Patients were encouraged to contact their PCP with any additional personal questions regarding LCS. After 9 months, in response to resource

#### **TAKEAWAY POINTS**

- Lung cancer screening (LCS) is a complex process that is best supported by a managed system approach in order to accurately identify eligible patients, provide consistent shared decision making (SDM), ensure standardized low-dose computed tomography interpretation, and track results over time.
- > Optimal approaches to patient invitation for LCS and SDM are unclear.
- ➤ A better understanding of the clinical significance of small (<4 mm diameter) lung nodules and incidental findings is needed.

constraints, we converted to LCS invitation by mailing only (SDM material, plus 2 letters; phase II).

#### **LDCT Procedure**

LCS LDCT appointments were scheduled for eligible patients requesting screening after the SDM mailing. LDCTs were performed with multidetector helical technique in a single breath-hold during a suspended state of full inspiration. Axial images were obtained from the lung apices to the costophrenic sulci, with a 0.8-mm slice thickness. Multiplanar reconstructions were obtained at a 1.0-mm interval for interpretation. Maximum intensity projection reconstructions were also performed. <sup>16</sup> No veterans had an LDCT outside the VHA system.

Radiologists utilized a National Demonstration Project LCS LDCT report template that included a standardized description of the lung nodules of greatest concern for malignancy. Reports contained specific lung nodule codes captured by an electronic tool provided by the National VHA Demonstration Project. LCS program managers accessed the tracking tool, documented the nodule of greatest concern, and entered the guideline-based follow-up plan<sup>17,18</sup> in the EHR template that interfaced with the tracking tool. Any incidental findings noted in the impression were recorded in the EHR template, which the PCP was asked to digitally sign as notification of findings. If there were significant incidental findings, defined as findings in the impression for which the radiologist had recommended follow-up action, the manager completed an additional significant incidental finding EHR template that the PCP was asked to sign. All LCS patients were mailed standardized LCS LDCT result letters and educational leaflets, including information about lung nodules and LCS, along with reiteration of smoking cessation recommendations.

#### **Data Collection and Measures**

We obtained baseline information for age, gender, race/ethnicity, smoking status, TPY information, and LCS LDCT completion dates from the EHR. When analyzing the uptake rate, we compared uptake at 219 days (minimum number of days of follow-up post randomization and mailing of the invitation for all participants) to allow for equal opportunity for follow-up. Additional information collected from the EHR and tracking tool included LDCT results. The National VHA

#### **CLINICAL**

**TABLE 1.** Baseline Patient Characteristics

Characteristics	N = 926			
Smoking status (%)				
Current	53.7			
Former	46.3			
TPYs, mean ± SD	55.2 ± 25.8			
Age, years, mean ± SD	64.6 ± 5.6			
Male (%)	94.9			
Race (%)				
Caucasian	77.3			
African American	5.3			
American Indian/Native Alaskan	1.4			
Pacific Islander/Native Hawaiian	0.2			
Unknown/declined/missing	15.8			
Ethnicity (%)				
Hispanic or Latino	0.7			
Not Hispanic or Latino	92.4			
Unknown/declined/missing	6.9			

TPY indicates tobacco pack-year.

Demonstration Project classified any lung nodule with a diameter of 2 mm or greater as requiring follow-up LDCT. LDCT results were categorized as: (1) no nodule to be tracked; (2) nodule not known to be benign, requiring tracking to establish stability over time (solid nodules without suspicious features ≤8 mm, ground-glass nodules >5 mm, or mixed-density nodules with a solid component <5 mm); (3) diagnostic evaluation needed for possible malignancy (any nodule with suspicious features, known to be new, or growing based on prior imaging); or (4) lung cancer diagnosis as a result of the initial LDCT followed by pathologic confirmation or by multidisciplinary conference consensus when tissue could not be obtained. We defined an incidental LDCT finding as any finding other than pulmonary nodules that was recorded in the report impression. We defined a significant incidental finding as any finding in the impression that required further follow-up in the opinion of an independent internist and the LCS staff pulmonologist who reviewed the EHRs.

#### **Statistical Analyses**

We report demographic and smoking characteristics of eligible patients invited for LCS in the demonstration project. To identify factors potentially associated with LCS uptake among invitation participants, we compared demographic and smoking characteristics by LDCT screening completion status within the follow-up period using Pearson's  $\chi^2$  or Fisher's exact tests for categorical measures and Wilcoxon 2-sample rank-sum tests for continuous measures. We compared LCS uptake between phases I and II using a Pearson's  $\chi^2$  test. We summarize initial screening results for patients who completed any LDCT screening through May 22, 2015.

#### **RESULTS**

The preliminary EHR eligibility algorithm identified 6133 unique patients with primary care visits from January 2, 2014, through August 15, 2014. There were 4745 patients (77%) excluded from invitation to LCS for the following reasons: 3248 with incomplete TPY information (53%), 89 out of age range (1%), 2 smokers who quit more than 15 years ago or had fewer than 30 pack-years (<1%), 1394 never-smokers (23%), and 12 patients who declined to provide TPY information (<1%).

A total of 1388 patients were eligible for LCS invitation. Of these, 926 were invited for LCS and 462 were not invited but had opportunity for referral outside of the demonstration project. Eight of the 926 patients were noted to be ineligible upon chart review by the program manager prior to invitation and were excluded from further analysis, leaving 918 patients invited for LCS. Twenty-seven patients died before being able to complete screening. Baseline characteristics of patients invited for LCS are described in **Table 1**.

The LCS program manager completed calls to 280 patients invited for LCS; the remaining 638 patients received SDM materials and invitation letters only. Patients received LCS within 1 month of accepting screening or per patient preference.

Of 918 patients invited for LCS, 178 (19%) completed an LDCT. Of the 766 invited participants in phase I, 165 (22%) had an LDCT. Of the 152 phase II patients who did not receive an outreach phone call, 13 (9%) had an LDCT. The difference between the 9% and 22% uptake rates was statistically significant (*P* <.001). Due to resource constraints, planned calls could not be made for 486 of the 766. Of the remaining 280 with complete phone status, 165 (59%) had an LDCT. The rate of LCS uptake, with follow-up time fixed to 219 days, was highest for the first cohort of eligible veterans but then remained steady during the rest of phase I. The rate of LCS declined during phase II. Increased awareness by PCPs was not a source of bias given their low rate of referral. We found no significant differences in demographic or smoking characteristics between those who completed an LDCT and those who did not (**Table 2**).

Of the 178 patients who completed an initial LDCT during the follow-up interval, 39% either had clinically benign nodules that did not require further follow-up or had no nodules. Sixty-one percent had a nodule requiring follow-up; of these, 43% had a nodule <4 mm, 20% had a nodule ≥4 mm to <5 mm, 7% had a nodule ≥5 mm to 6 mm, 18% had a nodule >6 mm to 8 mm, and 12% had a nodule >8 mm in diameter. Twelve patients required diagnostic evaluation, and 2 had malignant nodules. The time from LDCT to lung cancer diagnosis ranged from 14 to 76 days. A total of 179 incidental findings were reported in 116 patients; 65% of patients had at least 1 incidental finding. Twenty percent of the incidental findings were considered clinically significant, most commonly abdominal abnormalities such as renal masses.

Despite EHR prompts to check-in nurses, complete TPY information was not captured in the national data tracking tool for most patients during the demonstration project. We retrospectively determined that this was mainly due to inaccurate initial TPY information entry by check-in nurses into restrictive EHR data fields. We retrospectively reanalyzed the TPY data to obtain more accurate estimates of the number of potentially LCS-eligible patients at our institution. Among the 6099 patients with complete TPY reminders after reanalysis, 76% did not meet LDCT eligibility criteria. Of those, 30% never smoked, 16% had fewer than 30 pack-years, and 54% quit more than 15 years ago. Of the 24% who met criteria for further LCS consideration, 46% were former smokers and 54% were current smokers.

#### **DISCUSSION**

Our initial local experience demonstrates the importance of a well-designed, systematic approach to the complex process of LCS. EHRs must be designed to capture accurate, complete TPY data to determine LCS eligibility. Patient participation may vary by invitation method, with potentially higher uptake rates following more direct patient outreach. Reliable LCS tracking tools that interface with the EHR are useful to efficiently manage large numbers of patients with lung nodules, many of which have a very low probability of malignancy yet require complex, prolonged surveillance. LCS systems should be designed to address numerous incidental findings of varying clinical significance.

LCS uptake by patients seemed dependent on the invitation approach. Uptake was higher when a phone call was added to SDM and letters. This uptake was comparable with the National VHA Demonstration Program results.15 Person-to-person SDM, although desirable, is resource intensive and time consuming. Given the large number of potentially eligible patients, initially adopting a less aggressive invitation method, such as provision of written SDM materials followed by mailings only, may allow healthcare institutions to offer equitable screening access for all interested patients. However, LCS uptake at our facility was lower with this approach. Although PCPs at our institution opted out of the demonstration project, their participation in LCS SDM is of potential value to patients, given the unique insights they may have regarding their patients. Conversely, restricting SDM to PCPs might subject patients to possible provider bias for or against LCS. In addition to phone counseling, new LCS programs might consider alternative strategies, such as online interactions on MyHealtheVet, screening "drop-in" clinics, or lung health fairs or other community events, to reach patients.

We found a higher rate of patients with lung nodules than was reported in the NLST (59% vs 27%), although our results were similar to the overall rate detected in the National VHA Demonstration Project.<sup>15</sup> One possible explanation for the higher rate in our

**TABLE 2.** Participant Characteristics by LDCT LCS Uptake After LCS Invitation

LCS Invitation					
	Uptake (				
Characteristics	Yes (n = 178)	No (n = 740)	P		
Smoking status (%)			.141		
Current	48.9	55.0			
Former	51.1	45.0			
TPYs, mean ± SD	54.3 ± 23.7	55.3 ± 26.3	.571		
Age, years, mean ± SD	64.2 ± 5.2	64.8± 5.6	.264		
Male (%)	96.1	94.6	.423		
Race (%)			.248		
Caucasian	76.4	77.8			
African American	7.9	4.6			
American Indian/ Native Alaskan	1.1	1.2			
Pacific Islander/ Native Hawaiian	0.6	0.1			
Unknown/declined/missing	14.0	16.2			
Ethnicity (%)			.538		
Hispanic or Latino	0.0	0.8			
Not Hispanic or Latino	94.4	92.2			
Unknown/declined/missing	5.6	7.0			

LCS indicates lung cancer screening; LDCT, low-dose computed tomography; TPY, tobacco pack-year.

program is that LDCT technology and protocols have advanced since the NLST, including thinner reconstruction intervals and use of maximum intensity projection reconstruction. 19,20 Interreader variability among radiologists can also account for differences in nodule detection sensitivity and false-positive rates.21 However, the most likely explanation is a difference in the definition of a lung nodule: Based on existing guidelines at the time,17 the National VHA Demonstration Project defined a nodule 2 mm or greater in diameter as requiring follow-up compared with 4 mm or greater in NLST.<sup>2</sup> By the NLST definition, 33% of our patients had a nodule requiring follow-up, similar to the frequency reported in the NLST. More recently, the American College of Radiology provided guidelines for tracking lung nodules detected during LCS.<sup>22</sup> These guidelines consider solid lung nodules less than 6 mm or new solid lung nodules less than 4 mm to have a very low likelihood of malignancy, thus their recommendation to continue annual LCS. This assumes that all such patients will remain eligible for LCS, although some will not be, due to age or other changing eligibility criteria. It also does not address issues of liability if no follow-up LDCT is recommended or performed or how to engage in SDM with patients who might make different decisions about future LDCT dependent on its purpose. Would decisions differ if the LDCT was

<sup>&</sup>lt;sup>a</sup>Eight patients were found ineligible prior to screening and were not contacted.

#### **CLINICAL**

a screening scan (ie, no known disease) versus a scan to follow up on a small, albeit very low-risk, lung nodule? Until further evidence and guidance is provided regarding tracking sub-4 mm nodules, tracking nodules 2 mm or greater in diameter for at least 1 year continues to be common practice.

Increased detection of small lung nodules with a very low likelihood of malignancy, as well as other incidental findings, may have potential adverse consequences. Patients with nodules requiring follow-up may experience anxiety while awaiting the next LDCT. 14,23 The extent to which indeterminate nodules and incidental findings affect patient psychological well-being remains uncertain; however, an analysis of the NLST results found no increase in anxiety in patients with a false-positive nodule (requiring only serial LDCT surveillance) or a significant incidental finding on screening compared with patients with a negative LDCT. 24 Increased detection of small lung nodules increases resource utilization with uncertain clinical benefit 25 and may result in additional diagnostic evaluations with associated costs and complications.

We detected more clinically significant incidental findings than the NLST.<sup>2</sup> It is unclear whether our definitions and methods of determining clinical significance were comparable with those of the NLST, and the consequences of detecting clinically significant incidental findings have not been systematically characterized.

#### Limitations

Our study had several limitations. This was a single-site evaluation, utilizing a VHA EHR with potentially more complete data capture and patient tracking than may be available in other healthcare systems. However, efficient and accurate data capture is also a strength of our study, as it is an essential requirement for successful LCS implementation. The high rate of TPY information capture error during the demonstration project limited the selection sample to patients with complete initial TPY information. Because of the change from calling nonrespondents in phase I to mailing outreach only in phase II of this demonstration project, we were given an opportunity to estimate the screening rates between 2 direct invite methods, albeit with limitations. First, there was no random invitation assignment. Second, there could be temporal or other reasons for the observed decrease in screening rate that we are unable to account for in this study. Third, due to this unplanned change, systems were not in place to completely capture which invite method the patient received. Due to that limitation, we are unsure if the completed calls from phase I were perhaps from patients very motivated to be screened who called in early or if they were initially nonrespondents who received an outreach call. We estimated that if one does not call initial nonrespondents (phase II), the screening rate would be 9%, which estimates the proportion of motivated patients willing to call in to seek early screening. The significant difference in screening rates between phase I and phase II warrants further investigation to better assess

the difference an outreach call to nonresponders can make to LCS uptake rates. The number of lung malignancies we detected on initial LCS LDCT was lower than that reported in the NLST, 2 possibly due to our relatively small patient sample size. Finally, our homogenous sample in a healthcare system limits generalizability. Although many of the lessons learned from our demonstration site apply to screening programs at other institutions, the VHA is a unique setting.

#### CONCLUSIONS

We implemented LCS as part of a National VHA Demonstration Project. LCS is unprecedented in its complexity compared with other cancer screenings, due in part to requirements for structured SDM and detailed guidelines for follow-up of large numbers of lung nodules. Patient participation rates were dependent on accurate TPY information capture and method of LCS invitation. Efficiencies included integration of the EHR with the LCS tracking system and standardized data capture templates for radiology reports and lung nodule tracking, all directed by a full-time LCS program manager. Methods of LCS invitation must optimize equity and access within the confines of institutional capacity and resources. Smoking cessation is a critical component of LCS, and more information is needed regarding the effects of LCS on smoking behavior when offered in conjunction with proactive smoking cessation. Further evaluation is needed to determine optimal methods of patient risk stratification, LCS invitation approaches, SDM, and the risks and benefits associated with the detection of small lung nodules and incidental findings.

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#### Lung Cancer Screening Program Evaluation

#### REFERENCES

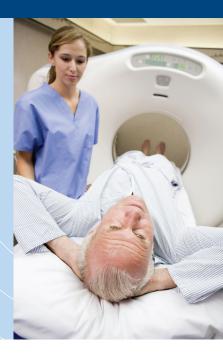
- Cancer Facts & Figures 2015. Atlanta, GA: American Cancer Society; 2015. cancer.org/content/dam/ cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2015/cancer-facts-and-figures-2015.pdf. Accessed December 20, 2015.
- Aberle DR, Adams AM, Berg CD, et al; National Lung Screening Trial Research Team. Reduced lungcancer mortality with low-dose computed tomographic screening. N Engl J Med. 2011;365(5):395-409. doi: 10.1056/NEJMoa1102873.
- 3. Moyer VA; U.S. Preventive Services Task Force. Screening for lung cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2014;160[5]:330-338. doi: 10.7326/M13-2771.
- 4. Providing guidance on lung cancer screening to patients and physicians. American Lung Association website. lung.org/assets/documents/lung-cancer/lung-cancer-screening-report.pdf. Published April 30, 2015. Accessed February 2, 2016.
- 5. Detterbeck FC, Mazzone PJ, Naidich DP, Bach PB. Screening for lung cancer: diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest.* 2013;143(suppl 5):e78S-e92S. doi: 10.1378/chest.12-2350.
- Jaklitsch MT, Jacobson FL, Austin JH, et al. The American Association for Thoracic Surgery guidelines for lung cancer screening using low-dose computed tomography scans for lung cancer survivors and other highrisk groups. J Thorac Cardiovasc Surg. 2012;144(1):33-38. doi: 10.1016/j.jtcvs.2012.05.060.
- 7. Wood DE. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for Lung Cancer Screening. *Thorac Surg Clin*. 2015;25(2):185-197. doi: 10.1016/j.thorsurg.2014.12.003.
- 8. Wender R, Fontham ET, Barrera E Jr, et al. American Cancer Society lung cancer screening guidelines. CA Cancer J Clin. 2013;63(2):107-117. doi: 10.3322/caac.21172.
- 9. Decision memo for screening for lung cancer with low dose computed tomography (LDCT) (CAG-00439N). CMS website. cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274. Published February 5, 2015. Accessed February 2, 2016.
- Patz EF Jr, Pinsky P, Gatsonis C, et al; NLST Overdiagnosis Manuscript Writing Team. Overdiagnosis in lowdose computed tomography screening for lung cancer. *JAMA Intern Med*. 2014;174(2):269-274. doi: 10.1001/jamainternmed.2013.12738.
- 11. Veronesi G, Maisonneuve P, Bellomi M, et al. Estimating overdiagnosis in low-dose computed tomography screening for lung cancer: a cohort study. *Ann Intern Med.* 2012;157(11):776-784. doi: 10.7326/0003-4819-157-11-201212040-00005.
- 12. de Koning HJ, Meza R, Plevritis SK, et al. Benefits and harms of computed tomography lung cancer screening strategies: a comparative modeling study for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2014;160(5):311-320. doi: 10.7326/M13-2316.

- 13. Slatore CG, Sullivan DR, Pappas M, Humphrey LL. Patient-centered outcomes among lung cancer screening recipients with computed tomography: a systematic review. *J Thorac Oncol*. 2014;9(7):927-934. doi: 10.1097/JTO.00000000000010.
- 14. Wiener RS, Gould MK, Woloshin S, Schwartz LM, Clark JA. 'The thing is not knowing': patients' perspectives on surveillance of an indeterminate pulmonary nodule. Health Expect. 2015;18(3):355-365. doi: 10.1111/hex.12036. 15. Kinsinger LS, Anderson C, Kim J, et al. Implementation of lung cancer screening in the Veterans Health Administration. JAMA Intern Med. 2017;177(3):399-406. doi: 10.1001/jamainternmed.2016.9022.
- 16. ACR-STR Practice Parameter for the performance and reporting of lung cancer screening thoracic computed tomography (CT). American College of Radiology website. acr.org/-/media/ACR/Files/Practice-Parameters/ct-lungcascr.pdf?la=en. Published 2014. Accessed May 4, 2018.
- 17. MacMahon H, Austin JH, Gamsu G, et al; Fleischner Society. Guidelines for management of small pulmonary nodules detected on CT scans: a statement from the Fleischner Society. *Radiology*. 2005;237(2):395-400. doi: 10.1148/radiol.2372041887.
- 18. Naidich DP, Bankier AA, MacMahon H, et al. Recommendations for the management of subsolid pulmonary nodules detected at CT: a statement from the Fleischner Society. *Radiology*. 2013;266(1):304-317. doi: 10.1148/radiol.12120628.
- 19. Gruden JF, Ouanounou S, Tigges S, Norris SD, Klausner TS. Incremental benefit of maximum-intensity-projection images on observer detection of small pulmonary nodules revealed by multidetector CT. AJR Am J Roentgenol. 2002;179(1):149-157. doi: 10.2214/ajr.179.1.1790149.
- 20. Aberte DR, Berg CD, Black WC, et al; National Lung Screening Trial Research Team. The National Lung Screening Trial: overview and study design. Radiology. 2011;258(1):243-253. doi: 10.1148/radiol.10091808. 21. Pinsky PF, Gierada DS, Nath PH, Kazerooni E, Amorosa J. National Lung Screening Trial: variability in nodule detection rates in chest CT studies. Radiology. 2013;268(3):865-872. doi: 10.1148/radiol.13121530. 22. Lung CT screening reporting & data system. American College of Radiology website. acr.org/quality-safety/
- resources/lungrads. Accessed January 25, 2017.
  23. Sullivan DR, Golden SE, Ganzini L, Hansen L, Slatore CG. 'I still don't know diddly': a longitudinal qualita-
- 23. Sullivan DR, Golden SE, Ganzini L, Hansen L, Statore CG. 1 still don't know diddly': a longitudinal qualitative study of patients' knowledge and distress while undergoing evaluation of incidental pulmonary nodules. NPJ Prim Care Respir Med. 2015;25:15028. doi: 10.1038/npjpcrm.2015.28.
- 24. Gareen IF, Duan F, Greco EM, et al. Impact of lung cancer screening results on participant health-related quality of life and state anxiety in the National Lung Screening frial. Cancer. 2014;120(21):3401-3409. doi: 10.1002/cncr.28833. 25. Harris RP. The psychological effects of lung cancer screening on heavy smokers: another reason for concern. JAMA Intern Med. 2015;175(9):1537-1538. doi: 10.1001/jamainternmed.2015.3571.

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## Screening for Lung Cancer





REMEMBER: The best way to prevent lung cancer is to STOP SMOKING. If you are still smoking, talk with your VA health care team and call 1-855-QUIT VET (1-855-784-8838). WE CAN HELP!

Lung cancer is the leading cause of cancer death in the United States. Lung cancer begins when abnormal cells in the lung grow out of control. Unfortunately, many times lung cancer does not cause symptoms until it has spread to other parts of the body. However, the most common type—non-small cell lung cancer—can sometimes be cured if it is found early enough.

#### Should I be screened for lung cancer?

You should consider being screened if you have all three of these risk factors:

- 55–80 years old and
- A current smoker or a former smoker who quit less than 15 years ago and
- A smoking history of at least 30 pack-years (this means 1 pack per day for 30 years or 2 packs a day for 15 years, etc.). The more you smoke and the longer you smoke, the higher your risk for lung cancer.

#### What is screening?

- Screening is looking for a disease before a person has any symptoms. Screening helps find lung cancer in an early, more treatable stage.
- Based on research, if a group of 1000 people were screened once a year for 3 years, 3 fewer people

in 1000 would die of lung cancer after 6 years. This means that, instead of 21 people, 18 people per 1000 would die of lung cancer.

#### Why not screen everyone?

- There is no proof from research that it is best to screen everyone.
- Screening people who are not at high risk or who are very ill may cause more harm than good. False alarms can lead to more testing and risk of harm.

### Are there any symptoms of lung cancer that I should watch for?

If you notice any of the following, you should contact your health care team:

- Have a new cough that doesn't go away
- Notice a change in a chronic cough
- · Cough up blood, even a small amount
- Develop shortness of breath or chest pain
- Lose weight without trying

#### Is there a cost for the screening?

If you are charged co-pays for your VA visits, you will be charged a \$50.00 co-pay for the day you have the low-dose chest Computed Tomography scan (LDCT). Talk with the Lung Cancer Screening coordinator if you are charged co-pays. Scheduling the scan on the same day as another visit may decrease the total charges.

#### How is screening for lung cancer done?

- We screen for lung cancer using a LDCT scan. This LDCT scan gives a detailed picture of your lungs.
- You will go to the Radiology (X-Ray) department for your LDCT scan. You will lie on a table and raise your arms above your head. Then the table will slide into the scanner. We will ask you to hold your breath for about 20 seconds during the scan.

#### How often should screening be done?

Based on current research, screening should be done once a year for as long as recommended by your provider.

#### Is there a down side to screening?

Yes, all screening tests have both pros and cons.

#### False alarms

- Screening for lung cancer by LDCT scan may find something that is suspicious but, after further testing, turns out not to be cancer. This is called a "false positive."
- Based on research, in a group of 1000 people screened once a year for 3 years:
  - 365 people would get a false positive result (they didn't have lung cancer). Most false positive results are resolved with further LDCT testing.
  - 26 people would get a true positive (they did have lung cancer).

#### Complications of further testing

About 25 of the 365 people who got a false positive result needed to have extra testing that involved putting a tube in the body or having surgery (these are called "invasive procedures").

- About 3 people out of the 25 people who had an extra test had at least one major complication from the testing or surgery.
- Complications can include bleeding, infections, or rarely, a collapsed lung.

#### Radiation

Exposure to radiation from LDCT scans increases your risk of cancer by a very small amount. We want to keep your chances of getting cancer from

radiation very low. We do that by using "low-dose" CTs that use much less radiation than a standard CT.

#### Stress/Anxiety

It is normal to feel stressed or anxious while waiting for your results or if you have something that is suspicious for lung cancer. Most patients with suspicious findings are reassured when they learn that most of these are false positives. Your health care team wants to hear from you if you have stress and anxiety about your results so that we can help.

#### Over-diagnosis

Sometimes screening tests find cancers that would have never caused problems. This is called over-diagnosis. Unfortunately, it is often impossible to tell which cancers fall into this category. So there is a very small chance someone may be treated unnecessarily for a cancer that would not have harmed them.

#### What is the bottom line on screening?

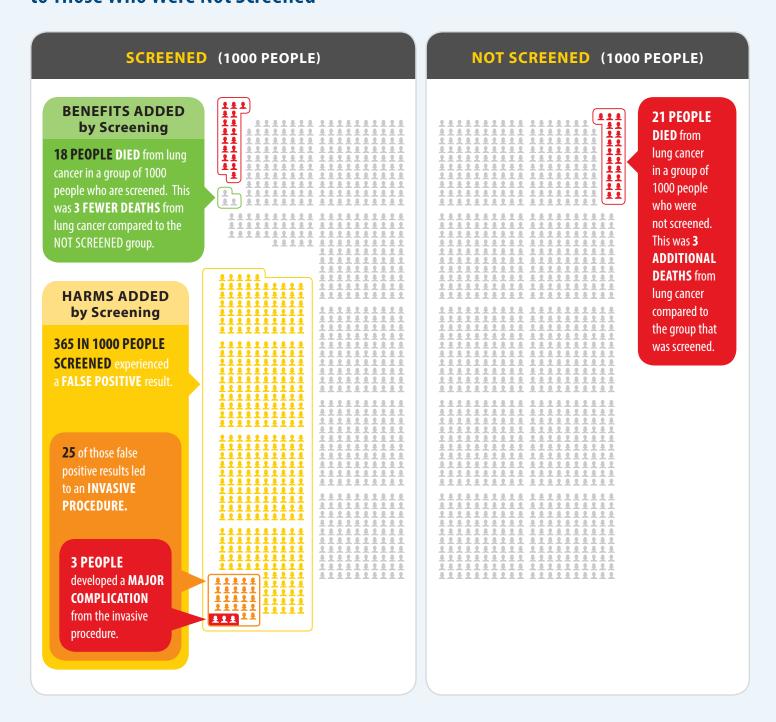
Overall, there are both pros and cons to lung cancer screening.

- **Pros:** Research shows lung cancer screening reduces the risk of dying from lung cancer.
- Cons: This benefit comes at some cost in terms of false positive results, extra tests, and possible complications of these tests.
- It is important that you weigh these pros and cons before you decide on screening. Every person is different; many people will choose to be screened with this information, but not everyone will.
   You should think about how you feel about the pros and cons and talk to your provider before deciding.

Regardless of your decision about screening, avoiding cigarettes is the most important thing you can do to lower your chance of dying from a variety of diseases, not just lung cancer. Quitting smoking helps with emphysema and heart and vascular diseases as well.

If you are still smoking and need help to quit, talk with your VA health care team and call 1-855-QUIT VET (1-855-784-8838).

# Benefits and Harms Experienced by People Ages 55—74 Who Were Screened for Lung Cancer With Low-Dose CT Scans Once a Year for 3 Years as Compared to Those Who Were Not Screened\*



\*The benefits and harms were measured after an average of 6.5 years.

The information in this graph was obtained from: Patient and Physician Guide: National Lung Screening Trial (NLST). See: http://www.cancer.gov/newscenter/qa/2002/NLSTstudyGuidePatientsPhysicians

Not everyone places the same amount of value on these benefits and harms. Think about how you value the benefits and harms described in this picture.

## Making a Personal Decision about Whether to Be Screened for Lung Cancer

Now that you know the pros and cons of lung cancer screening, you may be clear about your decision to be screened, or you may still have questions or concerns. If so, the following two steps can help you to make a decision that is right for you.

#### 1. Explore your options

• List the reasons to be screened and not to be screened for lung cancer, and think about how much each of these reasons matters to you. Then rate how important each reason is to you.

Review your ratings and choose one of the following options:

☐ **Unsure** (*Continue to Step 2*)

☐ **Yes** — Decide to be screened for lung cancer (*Tell your health care provider*).

□ **No** — Decide not to be screened for lung cancer (*Tell your health care provider*).

## 

**How important** 

2.	If	you checked "Unsure," think about what you need to reach a decision.
		<ul> <li>I need more information about the risks and benefits of screening.</li> <li>Review the information provided in this document.</li> <li>List your questions.</li> <li>Talk with your health care team.</li> </ul>
		<ul> <li>I need to think more about the reasons to be screened and not to be screened for lung cancer.</li> <li>Think about the importance you gave to the pros and cons, and the reasons behind your ratings.</li> <li>Talk with Veterans who have been screened for lung cancer.</li> <li>Read stories about others who have made a decision.</li> <li>Talk with others about what matters most to you.</li> </ul>
		<ul> <li>I need support from others to make a decision.</li> <li>Discuss your thinking with a trusted person (for example, friends, family, professionals).</li> <li>Find help to support your choice (for example, transportation, someone to come with me).</li> <li>I am not sure about the best choice for me.</li> <li>List anything else you need to make your decision.</li> </ul>



My notes or questions:	
	For more information, please contact your local VA Medical Center or Health Clinic.

#### **REFERENCES**

- The National Lung Cancer Screening Trial (NLST): http://www.cancer.gov/clinicaltrials/noteworthytrials/nlst
- 2. The Prostate, Lung, Colorectal and Ovarian Screening Trial (PLCO): http://prevention.cancer.gov/plco

