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Implementation of Lung Cancer Screening in the Veterans Health Administration

Linda S. Kinsinger, MD, MPH; Charles Anderson, MD, PhD; Jane Kim, MD, MPH; Martha Larson, BSN, MS; Stephanie H. Chan, MPH; Heather A. King, PhD; Kathryn L. Rice, MD; Christopher G. Slatore, MD, MS; Nichole T. Tanner, MD, MSCR; Kathleen Pittman, BSN, MPH; Robert J. Monte, MBA; Rebecca B. McNeil, PhD; Janet M. Grubber, MSPH; Michael J. Kelley, MD; Dawn Provenzale, MD, MSc; Santanu K. Datta, PhD; Nina S. Sperber, PhD; Lottie K. Barnes, MPH; David H. Abbott, MS; Kellie J. Sims, PhD, MS; Richard L. Whitley, BS; R. Ryanne Wu, MD, MHS; George L. Jackson, PhD, MHA

IMPORTANCE The US Preventive Services Task Force recommends annual lung cancer screening (LCS) with low-dose computed tomography for current and former heavy smokers aged 55 to 80 years. There is little published experience regarding implementing this recommendation in clinical practice.

OBJECTIVES To describe organizational- and patient-level experiences with implementing an LCS program in selected Veterans Health Administration (VHA) hospitals and to estimate the number of VHA patients who may be candidates for LCS.

DESIGN, SETTING, AND PARTICIPANTS This clinical demonstration project was conducted at 8 academic VHA hospitals among 93 033 primary care patients who were assessed on screening criteria; 2106 patients underwent LCS between July 1, 2013, and June 30, 2015.

INTERVENTIONS Implementation Guide and support, full-time LCS coordinators, electronic tools, tracking database, patient education materials, and radiologic and nodule follow-up guidelines.

MAIN OUTCOMES AND MEASURES Description of implementation processes; percentages of patients who agreed to undergo LCS, had positive findings on results of low-dose computed tomographic scans (nodules to be tracked or suspicious findings), were found to have lung cancer, or had incidental findings; and estimated number of VHA patients who met the criteria for LCS.

RESULTS Of the 4246 patients who met the criteria for LCS, 2452 (57.7%) agreed to undergo screening and 2106 (2028 men and 78 women; mean [SD] age, 64.9 [5.1] years) underwent LCS. Wide variation in processes and patient experiences occurred among the 8 sites. Of the 2106 patients screened, 1257 (59.7%) had nodules; 1184 of these patients (56.2%) required tracking, 42 (2.0%) required further evaluation but the findings were not cancer, and 31 (1.5%) had lung cancer. A variety of incidental findings, such as emphysema, other pulmonary abnormalities, and coronary artery calcification, were noted on the scans of 857 patients (40.7%).

CONCLUSIONS AND RELEVANCE It is estimated that nearly 900 000 of a population of 6.7 million VHA patients met the criteria for LCS. Implementation of LCS in the VHA will likely lead to large numbers of patients eligible for LCS and will require substantial clinical effort for both patients and staff.

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Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Linda S. Kinsinger, MD, MPH, Veterans Health Administation National Center for Health Promotion and Disease Prevention, 3022 Croasdaile Dr, Ste 200, Durham, NC 27705 (lkinsinger@mac.com).

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The results of the National Lung Screening Trial (NLST), which found a reduction in mortality from lung cancer of 3 deaths per 1000 high-risk individuals screened,[1,2] led to a 2013 US Preventive Services Task Force recommendation[3] in favor of implementing lung cancer screening (LCS) with low-dose computed tomography (LDCT). A process studied in a clinical trial setting, however, may not be directly transferable to real-world clinical practice. The American Academy of Family Physicians cites concerns about the ability to replicate the NLST findings in community practice as a reason not to recommend screening,[4] and primary care physicians and pulmonologists have questioned practical aspects of implementing LCS in practice.[5,6] Although guidelines about components of high-quality screening programs have been issued,[7-9] published experience with implementation of LCS is limited.[10]

The Veterans Health Administration (VHA) provides care for 6.7 million mostly older male US veterans each year,[11] many of whom are current or former smokers[12] but who also have multiple medical conditions.[13,14] Implementation of an LCS program for VHA patients would potentially require substantial resources and effort by clinical staff and facilities for an uncertain benefit of reduced mortality from lung cancer.

To understand the feasibility and implications for VHA patients and clinical staff of programmatic LCS, the VHA implemented a 3-year Lung Cancer Screening Demonstration Project (LCSDP) in 8 geographically diverse hospitals.[15,16] The specific goals were to describe the organizational effort and resources needed to implement a comprehensive LCS program, patient interest in and acceptance of screening, and the clinical experience of patients who underwent LCS in terms of positive test results, lung cancers detected, and incidental findings. We also wanted to estimate the size of the VHA population that potentially meets eligibility criteria for LCS. This article describes the initial experience of the LCSDP toward these goals.

Key Points

Question What are the implications for patients and staff of implementing a proactive, population-based, comprehensive lung cancer screening program in a large, multi-site health care system?

Findings This clinical demonstration project showed that, in Veterans Health Administration facilities, development and implementation of a comprehensive lung cancer screening program is a complex and challenging undertaking and that most patients will have findings that require follow-up; however, few patients will have early-stage lung cancers.

Meaning Implementation of a comprehensive lung cancer screening program requires significant clinical effort for as-yet uncertain patient benefit.

Methods

Site Selection

The 8 sites, all academic medical centers, were chosen from 35 facilities that volunteered for the demonstration project (eFigure 1 in the Supplement). Selection criteria included having strong support from facility leadership, clinical champions, an onsite CT scanner and radiologist (preferably with training in chest radiology), a multidisciplinary lung cancer program, and a tobacco cessation program.

Project Design and Patient Criteria

The LCSDP was designed as a population-based screening program that proactively identified appropriate patients at the 8 sites for consideration of LCS. First, those aged 55 to 80 years without a diagnosis of esophageal, liver, or pancreatic cancer (following standard VHA protocol) or lung cancer and without a documented estimated life expectancy of fewer than 6 months were identified by an algorithm applied to the VHA electronic medical record. Nurses then reviewed those patients' smoking histories to identify current or former (quit less than 15 years ago) cigarette smokers who had smoked a minimum of 30 pack-years (number of packs per day multiplied by number of years smoked). Based on clinical judgment, patients' primary care professionals excluded those who met initial criteria but who had competing medical conditions that would preclude them from screening (ie, serious comorbid conditions or estimated life expectancy of fewer than 5 years). Patients with documented chest CT scans within the past 12 months were excluded until 12 months had elapsed, as were those with symptoms suggestive of possible lung cancer or those receiving active therapy for cancer other than nonmelanoma skin cancer. Patients without exclusion criteria discussed their interest in undergoing LCS with clinical staff, using a shared decision-making process and brochure (eFigure 2 in the Supplement).[17] Sites were encouraged to start LCS implementation with a small number of interested primary care teams and then expand as resources allowed. One site began screening July 1, 2013; other sites began as they hired clinical LCS coordinators.

Project Materials

Project materials developed for patients and staff are described in detail in eAppendix 1 in the Supplement. An Implementation Guide provided detailed guidance on a recommended approach to conduct the screening program and included resources, tools, and the evaluation plan. Staff at all sites were encouraged to follow the guidance but were allowed to make changes based on local resources and procedures.

Organizational Effort and Processes

Organizational-level effort and processes reported include brief descriptions of national LCSDP leadership efforts, site leadership activities, and local implementation processes used by the 8 LCSDP screening sites.

Patient Outcomes

Patient-level outcomes include percentage of candidates eligible for LCS who agreed to undergo screening, percentage of LDCT results that led to positive test results (nodules needing to be tracked or suspicious findings requiring further evaluation), percentage of screened patients found to have lung

cancer and descriptions of cancers, percentage of LDCT results with incidental findings, and estimated number of VHA patients who may be candidates for LCS. The designation "nodules needing to be tracked" was based on nodule follow-up guidelines adopted from Fleischner Society guidelines.[18,19] Generally, these were solid nodules 8 mm or smaller without suspicious features (eg, irregular or spiculated borders) and not known to be new or growing based on results of prior imaging (if available), ground glass nodules larger than 5 mm, or mixed solid and ground glass nodules of any size. Patients with solid nodules 8 mm or smaller with suspicious features or nodules known to be new or growing and those with nodules larger than 8 mm were referred for further evaluation.

Following VHA policy,[21] neither the demonstration project nor the evaluation was considered to be research; they were declared nonresearch clinical operations activities by the VHA National Center for Health Promotion and Disease Prevention, the VHA Office of Research Oversight, and the Durham Veterans Affairs Medical Center Institutional Review Board. As a clinical operations activity, patient consent was not required. Patient data were deidentified in analyses.

Data Sources

Organizational-level effort data at the 8 sites were collected from internal project notes, telephone calls and email with LCSDP site leaders and coordinators, and monthly site reports. Patient-level data were captured via clinical reminders developed for the project (eAppendix 1 in the Supplement). These electronic tools allowed gathering of data in the medical record that are not recorded using standardized codes (eg, *International Classification of Diseases*). These data and other standard coded data were obtained from a VHA central data repository.[20] For the estimated number of VHA patients who may be candidates for LCS, VHA central data were used to determine the national number of primary care patients with at least 1 visit to VHA primary care in fiscal year 2014 who met the age and clinical criteria of the cohort eligible for LCS. That number was multiplied by the mean percentage of patients in the project with the appropriate smoking history.

Statistical Analysis

Patients determined to be eligible for LCS as of March 31, 2015, with an initial LDCT scan completed at 1 of the 8 sites by June 30, 2015, are included in these analyses. All patients were followed up through administrative data analysis for 330 days from their initial LDCT scan. They were identified as having confirmed lung cancer if they had at least 1 *International Classification of Diseases, Ninth Revision, Clinical Modification* or *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Clinical Modification* code for malignant neoplasm of the trachea, bronchus, lung, or other sites within the respiratory system and intrathoracic organs (see eAppendix 1 in the Supplement for a list of codes) and if confirmatory pathologic reports with staging and/or histologic findings were found on review of the electronic medical record. Patients were classified as having other positive test results (nodules needing to be tracked or suspicious findings requiring further evaluation) and incidental findings if indications of these events were found within 50 days of the date of the initial LDCT scan (see eAppendix 1 in the Supplement for methodological details about determining initial dates of the LDCT scan). Data were descriptively summarized using counts, percentages, means, and ranges using SAS, version 9.4 (SAS Institute Inc). Cost and budget effect analyses will be reported separately.

Results

Organizational Effort and Processes

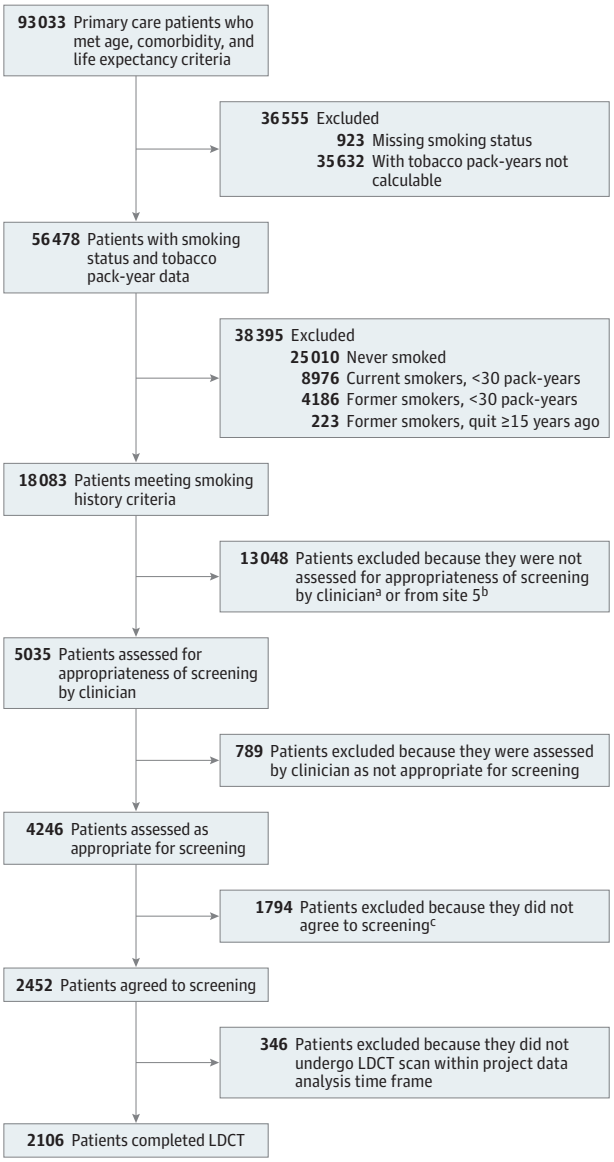
Each of the 8 sites named a physician leader (6 pulmonologists, 1 medical oncologist, and 1 radiologist, including K.L.R. and N.T.T.) and hired a full-time LCS clinical coordinator with salary support provided by the VHA (all but 1 were registered nurses or mid-level health care professionals). Coordinators were involved in all daily activities of patient care coordination, including identification of appropriate candidates for screening, delivery of patient education about LCS, participation in shared decision making about screening, scheduling of LDCT scans, notification of patients about results, and follow-up care, as needed, in close collaboration with the physician site leaders. Coordinators were also responsible for educating primary care staff about program procedures. Details about coordinator and site radiologist training and quality assurance review activities are provided in eAppendix 1 in the Supplement.

The Implementation Guide was developed, expanded, and revised through frequent conference calls by national LCSDP leadership staff with steering committee members, site leaders, and LCS coordinators. The electronic tools and database were revised multiple times based on input from the coordinators. Patient education materials and guidelines for nodule follow-up were revised to improve clarity and usefulness. Site leaders and coordinators reported variability in how sites implemented their screening programs, especially in terms of identifying patients who met criteria for LCS, which staff engaged in shared decision making with candidates for screening, LCS coordinators' responsibilities, training of primary care staff and radiologists, communicating LCS results with patients, and responsibility for follow-up of incidental findings.

Seven of the 8 sites followed a similar process for offering LCS and obtaining patient agreement (eAppendix 1 the Supplement). At those 7 sites, patients meeting the initial inclusion criteria who were seen by health care professionals participating in the LCSDP were further assessed for eligibility for LCS. Clinicians determined that 4246 of 5035 patients (84.3%) were appropriate for screening (ie, they had no additional medical contraindications). The eighth site mailed patient education materials (the *Screening for Lung Cancer* brochure [eFigure 2 in the Supplement][17]) to patients eligible for LCS and then called them or requested they call the coordinator if interested in discussing LCS further or to request screening.

The 8 sites identified 93 033 patients who met the inclusion and exclusion criteria (**Figure**). A total of 36 555 patients (39.3%) were missing information about smoking status or, the tobacco pack-years were improperly calculated; they were not

Figure. Veterans Health Administration Lung Cancer Screening Demonstration Project (LCSDP) Patient Flow Diagram



LDCT indicates low-dose computed tomography.

[a] Patients may not have had the opportunity to be assessed for appropriateness of LDCT owing to phased rollout and variability in implementation of tobacco pack-year and initial clinician clinical reminders across LCSDP sites. Presence of clinician assessment was evaluated based on documentation of select health factors in patient record.

[b] Site 5 used an alternative recruitment process that conducted assessments of appropriateness for screening following preliminary discussions with patients interested in screening.

[c] Site 5 is not included in this number.

further assessed. Of the remaining 56 478 patients, 18 083 (32.0%) met the smoking history criteria for eligibility for screening.

Across the 8 sites, 2452 of 4246 patients (57.7%) who were offered LCS agreed to be screened (site range, 290 of 863 [33.6%] to 257 of 389 [66.1%]) (**Table 1**). Of those, 2106 patients (85.9%) completed their first LDCT scan by June 30, 2015. They were predominantly men (2028 [96.3%]) (**Table 2**); 1106 of 2106 patients (52.5%) were 65 years or older.

Patient Outcomes

Yield of LCS for Positive Test Results and Lung Cancers

There was wide variation among sites in the percentage of screening test results that were positive for nodules or possible lung cancer. Overall, 1257 of the 2106 patients (59.7%) screened had a positive test result (site range, 70 of 228 [30.7%] to 181 of 213 [85.0%]) (Table 1), including 1184 patients (56.2%) who had 1 or more nodules needing to be tracked (site range, 64 of 228 [28.1%] to 176 of 213 [82.6%]). Most nodules were small (<5 mm; 710 of 1293 [54.9%]) and solid (1079 of 1293 [83.4%]) (**Table 3**). A total of 73 patients (3.5% of all patients screened) had findings suspicious for possible lung cancer and underwent further diagnostic evaluation. Lung cancer was confirmed for 31 of those patients (1.5%; site range, 0 of 247 to 10 of 444 [2.3%]) within the 330-day follow-up period; 20 (64.5%) of the cancers were stage I (**Table 4**). The mean number of days from initial LDCT scan to cancer diagnosis was 137 (range, 5-330 days). The remaining 42 patients (2.0%; site range, 0 of 135 to 10 of 247 [4.0%]) who underwent evaluation were not confirmed to have lung cancer during that time frame. The proportion of all positive tests that were falsely positive was 97.5% (1226 of 1257) during the 330-day follow-up period (Table 1).

Yield of Incidental Findings

Radiologists and coordinators were asked to record only incidental findings that would likely require follow-up or further evaluation. Overall, 857 patients (40.7%) had 1 or more incidental findings reported (site range, 89 of 444 [20.0%] to 135 of 213 [63.4%]) (Table 1). Among the 1044 incidental findings reported, the most common were emphysema, other pulmonary abnormalities, and coronary artery calcification (eTable in the Supplement).

Size of VHA Population That Potentially Meets LCS Eligibility Criteria

Based on the central data analysis described above, we calculated that 2 780 933 primary care VHA patients potentially met the eligibility criteria for visits, age, and medical history. Using the mean of 32% of patients in the demonstration sites who met the additional criteria for smoking history, an estimated 889 899 VHA patients may be candidates for LCS.

Discussion

The VHA LCSDP found implementing a comprehensive LCS program that followed recommendations[7-9] to be challenging and complex, requiring new tools and patient care processes for staff as well as dedicated patient coordination. For example, creating electronic tools to capture the necessary clinical data in real time that met the needs of the LCS coordinators proved to be difficult, even with the VHA's highly

Table 1. Summary Results for the Initial Round of Lung Cancer Screening in 8 LCSDP Sites

Characteristic	No. (%)								
	All Sites	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8
Patients who met all screening criteria	4246	869	472	389	779	288[a]	272	863	314
Patients who agreed to be screened[b]	2452 (57.7)	546 (62.8)	247 (52.3)	257 (66.1)	489 (62.8)	255 (NA[a])	177 (65.1)	290 (33.6)	191 (60.8)
Patients screened	2106 (85.9)	442 (81.0)	228 (92.3)	213 (82.9)	444 (90.8)	247 (96.9)	135 (76.3)	258 (89.0)	139 (72.8)
Patients with nodular findings on scans[c]	1257 (59.7)	340 (76.9)	70 (30.7)	181 (85.0)	248 (55.9)	153 (61.9)	63 (46.7)	112 (43.4)	90 (64.7)
Patients with nodules to be tracked[d]	1184 (56.2)	323 (73.1)	64 (28.1)	176 (82.6)	225 (50.7)	143 (57.9)	61 (45.2)	108 (41.9)	84 (60.4)
Patients with suspicious findings not confirmed to be lung cancer[e]	42 (2.0)	10 (2.3)	2 (0.9)	2 (0.9)	13 (2.9)	10 (4.0)	0	1 (0.4)	4 (2.9)
Patients with confirmed lung cancer	31 (1.5)	7 (1.6)	4 (1.8)	3 (1.4)	10 (2.3)	0	2 (1.5)	3 (1.2)	2 (1.4)
Patients with incidental, non-nodule findings on scans	857 (40.7)	211 (47.7)	106 (46.5)	135 (63.4)	89 (20.0)	149 (60.3)	54 (40.0)	81 (31.4)	32 (23.0)
Total LDCT scans completed[f]	2694	558	299	306	546	372	171	300	142

Abbreviations: LCSDP, Lung Cancer Screening Demonstration Project; LDCT, low-dose computed tomography; NA, not applicable.

[a] An alternative recruitment process was used at site 5.

[b] Percentage of those who met all eligibility criteria (age, smoking history, and no medical exclusions) who agreed to be screened.

[c] Total number of patients whose LDCT scans showed nodules to be tracked, possible lung cancer, and confirmed lung cancer; percentage of patients screened.

[d] Percentage of those screened based on Veterans Heath Administration LCSDP nodule follow-up guidelines.

[e] Percentage of patients screened who underwent further diagnostic evaluation and were not found to have lung cancer.

[f] Through June 30, 2015, including both initial and follow-up LDCT scans.

Table 2. Demographics and Smoking History of Patients Who Underwent Screening[a]

Characteristic	Value[b]
Age, mean (SD), y	64.9 (5.1)
Sex	
Male	2028 (96.3)
Female	78 (3.7)
Race	
White	1520 (72.2)
Black or African American	312 (14.8)
Other[c]	30 (1.4)
Unknown, declined, missing, or multiple races listed	244 (11.6)
Ethnicity	
Non-Hispanic or Latino	1976 (93.8)
Hispanic or Latino	27 (1.3)
Unknown, declined, missing, or multiple ethnicities listed	103 (4.9)
Smoking status	
Current smoker, ≥30 pack-years	1192 (56.6)
Former smoker, ≥30 pack-years, quit <15 y ago	914 (43.4)
Mean (SD) tobacco pack-years	54.7 (25.4)

[a] N = 2106.

[b] Data are presented as number (percentage) of patients unless otherwise indicated.

[c] American Indian, Alaskan Native, Asian, Native Hawaiian, or other Pacific Islander.

Table 3. Description of Nodules Identified on Initial Round of Low-Dose Computed Tomography Scans for Lung Cancer Screening

Characteristic	No. (%)
Nodule density[a]	
Solid	1079 (83.4)
Suspicious solid	66 (5.1)
Ground glass	86 (6.7)
Mixed solid and ground glass	62 (4.8)
Nodule size, mm[a]	
<5	710 (54.9)
5	150 (11.6)
6	120 (9.3)
7	88 (6.8)
8	51 (3.9)
>8	164 (12.7)
Unknown	10 (0.8)

[a] N = 1293.

regarded electronic medical record. Although computerized clinical reminders about current or recent smoking are widely used in the VHA,[22] more detailed information about pack-years smoked and years since quitting was required; this information is not fully captured in the electronic medical record.

If the eligibility percentage found in our 8-site project is representative of the VHA population as a whole, we estimate that nearly 900 000 veterans in the VHA health care system would meet the initial screening criteria for age, smoking history, and medical history. Even if this number is reduced by 16%, as found when longer-term medical contraindications were taken into account (Figure), the number of veterans who may be candidates for annual LCS is substantial. Accurately identifying these patients and discussing with them

Table 4. Stage and Histologic Findings of Lung Cancers Found on Initial Round of Lung Cancer Screening

Result	All Sites	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8
Total lung cancers found	31	7	4	3	10	0	2	3	2
Stage									
I	20	5	3	2	6	0	2	1	1
II	2	0	0	0	1	0	0	1	0
III	6	2	0	1	2	0	0	1	0
IV	2	0	1	0	1	0	0	0	0
Unknown	1	0	0	0	0	0	0	0	1
Histologic type									
Adenocarcinoma	12	2	2	1	3	0	2	2	0
Squamous cell carcinoma	12	4	2	1	4	0	0	0	1
Non-small-cell carcinoma or other	4	1	0	0	3	0	0	0	0
Small-cell carcinoma	2	0	0	1	0	0	0	1	0
Unknown	1	0	0	0	0	0	0	0	1

the benefits and harms of LCS will take significant effort for primary care teams. Based on LCSDP experience, only about 58% of candidates will agree to be screened. Patients' reasons for declining screening were not collected but may have included concerns about the need for LCS, exposure to radiation, psychological distress, effort required for the screening examinations, and others.[23,24]

In addition, performing screening LDCT scans for large numbers of patients may stress the capacity of radiology services, especially considering the number of repeat scans needed, potentially leading to delays for patients needing CT scans for other diagnostic indications. Pulmonary services may also see an increased workload in determining which nodules need follow-up. Finally, primary care will need to be involved in deciding which incidental findings need further evaluation. These clinical efforts will require coordination and communication among clinical services and between patients and staff. Lung cancer screening coordinators will likely be needed to manage population-based LCS programs, leading to additional personnel costs. Such programs will also require training for primary care staff and radiologists, quality assurance measures, and possibly additional CT scanners and radiology staff.

The veterans screened in the VHA demonstration project differed in several ways from the NLST participants.[1,25] They were generally older: 52.5% were 65 years or older compared with only 14 220 of 53 454 NLST participants (26.6%) in that age group at the time of enrollment. This difference may be owing, in part, to the higher upper age limit used in the LCSDP (≤80 years, as recommended by the US Preventive Services Task Force[3]). A much higher proportion of veterans were men (2028 [96.3%]) compared with those in the NLST (31 532 of 53 454 [59.0%]), reflective of the demographics of VHA patients. More VHA patients were current smokers (1192 [56.6%]) than were NLST participants (25 762 of 53 454 [48.2%]). Whether these differences will alter the benefit shown in the NLST is not known.

The rate of positive findings after 1 round of screening in the LCSDP was more than twice that in the NLST (1257 [59.7%] vs 7191 of 26 309 [27.3%]). The reason for the overall high rate of initially positive examination results in the VHA sites is not certain but may be owing, in part, to the older age and heavier smoking history of veterans screened.[26,27] Nodule follow-up guidelines in the LCSDP included a recommendation to follow up very small nodules (<4 mm) if they were new or growing, based on results of previous scans, or had suspicious features; the NLST did not follow up nodules smaller than than 4 mm. The wide range of nodular findings among the 8 sites (range, 70 of 228 [30.7%] to 181 of 213 [85.0%]) may reflect, in part, different geographical locations[28] or differences in interpretation by participating radiologists. A similar variability in positive findings by site was noted in the NLST (4% to 69%)[29] and suggests a need for better standardization to achieve consistency in reading results of LDCT scans.

After the LCSDP developed its nodule follow-up guidelines based on those of the Fleischner Society,[18,19] the American College of Radiology released its Lung CT Screening Reporting and Data System standards.[30] When these criteria were retrospectively applied to NLST data, the number of false-positive results was reduced from 26.6% (6939 of 26 090) to 12.8% (3343 of 26 090).[31] Since only about one-third of nodules identified as needing to be tracked in the LCSDP were 6 mm or greater, the positive rate might decline from nearly 60% to about 20%. However, this possibility assumes that patients with small nodules will continue to be screened annually and any growth will be detected in subsequent scans. Clearer guidance about management of very small nodules is needed, especially for patients who do not continue to be screened.

Approximately 40% of those screened in the LCSDP had a variety of incidental findings. Many reported findings, such as emphysema and coronary calcifications, may not require follow-up. However, inclusion of these findings in reports of LDCT scan results requires a health care professional's time to determine if additional testing is necessary.

This clinical demonstration project raises several important questions that warrant further investigation. For example, more needs to be understood about the smoking cessation experience of those who were screened. The study by Zeliadt et al[32] of current smokers who were offered LCS found that screening may negatively influence cessation efforts. We

also need to learn more about the optimal design of decision aids and ways to use shared decision making for LCS. In addition, the significance of and patient experience with incidental findings on results of LDCT scans needs to be further evaluated.

Limitations

These findings have important limitations. Data analysis was based on data in clinical records rather than on data collected by research staff. Missing or incorrectly recorded data about smoking pack-years or years since quitting, for example, were noted for 39.3% of patients who met the initial screening criteria. It is possible that individuals received follow-up care for positive LCS results outside the VHA health care system, and those records would not be available for our analysis. The number of patients treated for lung cancer may be underestimated. Some patients, especially those with significant medical comorbidities who underwent screening, may have received radiation therapy for presumed lung cancer; without diagnosis codes for confirmed lung cancer, those patients were not captured in project data. The follow-up period in this project was less than 1 year; longer follow-up time will be needed to determine the health outcomes of LCS. This project was performed in 8 selected VHA academic medical centers; implementation of LCS programs in smaller medical facilities with fewer resources may differ in many ways. Finally, these findings may not be generalizable to non-VHA health care systems and patients who are not veterans. The experience of the VHA, owing to its central organizational structure, may represent a best-case scenario, but even the VHA was challenged with implementing LCS.

Conclusions

The VHA LCSDP found that a comprehensive LCS program is a complex endeavor for both patients and staff. These results will help the VHA plan for broader implementation of such a program across its health care system and may help other groups considering such screening programs to better understand the multiple components involved and the initial clinical effect on patients.

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Author Affiliations: Veterans Health Administration National Center for Health Promotion and Disease Prevention, Durham, North Carolina (Kinsinger, Kim, Larson, Chan, Pittman); Veterans Health Administration National Radiology Program Office, Durham, North Carolina (Anderson); Durham Veterans Affairs Health Services Research and Development Center of Innovation, Durham, North Carolina (King, McNeil, Provenzale, Datta, Sperber, Barnes, Abbott, Sims, Whitley, Wu, Jackson); Department of Medicine, Duke University Medical Center, Durham, North Carolina (King, McNeil, Grubber, Kelley, Provenzale, Datta, Sperber, Wu, Jackson); Department of Medicine, Minneapolis Veterans Affairs Healthcare System, Minneapolis, Minnesota (Rice); Department of Medicine, Veterans Affairs Portland Health Care System, Portland, Oregon (Slatore); Department of Medicine, Ralph H. Johnson Veterans Affairs Medical Center, Charleston, South Carolina (Tanner); Pittsburgh Veterans Engineering Resource Center, Pittsburgh, Pennsylvania (Monte); Veterans Health Administration National Oncology Program, Durham, North Carolina (Kelley).

Author Contributions: Dr Kinsinger had full access to all the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.
Study concept and design: Kinsinger, Anderson, Kim, King, Rice, Slatore, Pittman, Monte, Kelley, Datta, Wu, Jackson.
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REFERENCES

1. Aberle DR, Adams AM, Berg CD, et al; National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. 2011;365(5):395-409.

2. National Cancer Institute. Patient and physician guide: National Lung Screening Trial (NLST). https://www.cancer.gov/types/lung/research/NLSTstudyGuidePatientsPhysicians.pdf. Accessed November 18, 2016.

3. Moyer VA; US Preventive Services Task Force. Screening for lung cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2014;160(5):330-338.

4. American Academy of Family Physicians. Clinical preventive service recommendation: lung cancer. http://www.aafp.org/patient-care/clinical-recommendations/all/lung-cancer.html. Accessed November 18, 2016.

5. Volk RJ, Foxhall LE. Readiness of primary care clinicians to implement lung cancer screening programs. *Prev Med Rep*. 2015;2:717-719.

6. Iaccarino JM, Clark J, Bolton R, et al. A national survey of pulmonologists' views on low-dose computed tomography screening for lung cancer. *Ann Am Thorac Soc*. 2015;12(11):1667-1675.

7. Mazzone P, Powell CA, Arenberg D, et al. Components necessary for high-quality lung cancer screening: American College of Chest Physicians and American Thoracic Society policy statement. *Chest*. 2015;147(2):295-303.

8. Wiener RS, Gould MK, Arenberg DA, et al; ATS/ACCP Committee on Low-Dose CT Lung Cancer Screening in Clinical Practice. An official American Thoracic Society/American College of Chest

Physicians policy statement: implementation of low-dose computed tomography lung cancer screening programs in clinical practice. *Am J Respir Crit Care Med*. 2015;192(7):881-891.

9. Fintelmann FJ, Bernheim A, Digumarthy SR, et al. The 10 pillars of lung cancer screening: rationale and logistics of a lung cancer screening program. *Radiographics*. 2015;35(7):1893-1908.

10. Boiselle PM, Chiles C, Ravenel JG, White CS. Computed tomographic screening for lung cancer trends at leading academic medical centers from 2013 to 2015. *JAMA Oncol*. 2016;2(5):682-684.

11. Department of Veterans Affairs. VA benefits and health care utilization. http://www.va.gov/vetdata/docs/pocketcards/fy2016q2.pdf. Updated January 29, 2016. Accessed November 18, 2016.

12. Department of Veterans Affairs. Tobacco use in VA. http://www.publichealth.va.gov/smoking/professionals/tobacco-use.asp. Updated January 12, 2016. Accessed February 18, 2016.

13. Agha Z, Lofgren RP, VanRuiswyk JV, Layde PM. Are patients at Veterans Affairs medical centers sicker? a comparative analysis of health status and medical resource use. *Arch Intern Med*. 2000;160(21):3252-3257.

14. Rogers WH, Kazis LE, Miller DR, et al. Comparing the health status of VA and non-VA ambulatory patients: the veterans' health and medical outcomes studies. *J Ambul Care Manage*. 2004;27(3):249-262.

15. Kinsinger LS, Atkins D, Provenzale D, Anderson C, Petzel R. Implementation of a new screening recommendation in health care: the Veterans Health Administration's approach to lung cancer screening. *Ann Intern Med*. 2014;161(8):597-598.

16. Wu RR, Kinsinger LS, Provenzale D, et al. Implementation of new clinical programs in the VHA healthcare system: the importance of early collaboration between clinical leadership and research. *J Gen Intern Med*. 2014;29(suppl 4):825-830.

17. Department of Veterans Affairs. Screening for lung cancer. http://www.prevention.va.gov/docs/LungCancerScreeningHandout.pdf. Updated April 2014. Accessed November 18, 2016.

18. MacMahon H, Austin JHM, 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.

19. 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.

20. Department of Veterans Affairs. Health services and research & development corporate data warehouse (CDW). http://www.hsrd.research.va.gov/for_researchers/vinci/cdw.cfm. Updated March 28, 2014. Accessed November 18, 2016.

21. Department of Veterans Affairs. VHA handbook 1058.05: VHA operations activities that may constitute research. http://www.research.va.gov/resources/policies/oro-120811.cfm. Updated November 20, 2013. Accessed November 18, 2016.

22. Fung CH, Woods JN, Asch SM, Glassman P, Doebbeling BN. Variation in implementation and use of computerized clinical reminders in an integrated healthcare system. *Am J Manag Care*. 2004;10(11, pt 2):878-885.

23. Crothers K, Kross EK, Reisch LM, et al. Patients' attitudes regarding lung cancer screening and decision aids: a survey and focus group study. *Ann Am Thorac Soc*. 2016;13(11):1992-2001.

24. Mishra SI, Sussman AL, Murrietta AM, et al. Patient perspectives on low-dose computed tomography for lung cancer screening, New Mexico, 2014. *Prev Chronic Dis*. 2016;13:E108.

25. Pinsky PF, Church TR, Izmirlian G, Kramer BS. The National Lung Screening Trial: results stratified by demographics, smoking history, and lung cancer histology. *Cancer*. 2013;119(22):3976-3983.

26. Balekian AA, Tanner NT, Fisher JM, Silvestri GA, Gould MK. Factors associated with a positive baseline screening exam result in the National Lung Screening Trial. *Ann Am Thorac Soc*. 2016;13(9):1568-1574.

27. Pinsky PF, Gierada DS, Hocking W, Patz EF Jr, Kramer BS. National Lung Screening Trial findings by age: Medicare-eligible versus under-65 population. *Ann Intern Med*. 2014;161(9):627-633.

28. Benedict K, Mody RK. Epidemiology of histoplasmosis outbreaks, United States, 1938-2013. *Emerg Infect Dis*. 2016;22(3):370-378.

29. 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):865-873.

30. American College of Radiology. Lung CT Screening Reporting and Data System (Lung-RADS). https://www.acr.org/Quality-Safety/Resources/LungRADS. Accessed Nov. 18, 2016.

31. 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.

32. Zeliadt SB, Heffner JL, Sayre G, et al. Attitudes and perceptions about smoking cessation in the context of lung cancer screening. *JAMA Intern Med*. 2015;175(9):1530-1537.