



# US DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

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## VETERANS HEALTH ADMINISTRATION

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# Concern with Veterans Health Administration's Lung Cancer Screening Program Requirements

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## Executive Summary

The VA Office of Inspector General (OIG) conducted a focused review of Veterans Health Administration's (VHA) guidelines for lung cancer screening (LCS) and the requirements for facility establishment of an LCS program based on a memorandum published by the Deputy Under Secretary for Health for Operations and Management in 2017 and updated by the Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer in 2022.<sup>1</sup> An LCS program formalizes a way for a facility to systematically determine lung cancer screening eligibility, conduct the screening test, receive test results, and order appropriate follow-up testing.<sup>2</sup> VHA has 10 mandatory elements that must be in place for an LCS program, and "VA medical facilities may perform LCS only when all the . . . criteria for components of a high-quality LCS program are met."<sup>3</sup> If facilities do not have an LCS program, they may send patients into the community for LCS. The OIG reviewed the extent to which VHA facilities have established LCS programs compliant with VHA operational guidance.

### Lung Cancer

Lung cancer is the third most diagnosed type of cancer in the United States and is the leading cause of cancer deaths.<sup>4</sup> Lung cancer generally has a poor prognosis, but diagnosis at an early stage improves patients' survival. Yet, in the general population, only 17 percent are diagnosed at an early stage.<sup>5</sup> Within the veteran population, however, this was higher at 30 percent are diagnosed at an early stage.<sup>6</sup>

The US Preventive Services Task Force first recommended LCS in 2013 for people with a history of using cigarettes at high risk for lung cancer and updated the recommendation in 2021 to expand the high-risk population eligible for screening by lowering both the age and

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<sup>1</sup> VHA Deputy Under Secretary for Health for Operations and Management memorandum, "Lung Cancer Screening with Low Dose Computed Tomography," November 27, 2017; VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) memorandum, Revision Memorandum "Guidelines for Lung Cancer Screening in Veterans Health Administration," July 15, 2022.

<sup>2</sup> The establishment of an LCS program requires submission of a formal clinical restructuring request to responsible VHA program offices.

<sup>3</sup> VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) memorandum.

<sup>4</sup> National Institutes for Health, National Cancer Institute, *Cancer Stat Facts: Common Cancer Sites*, accessed September 29, 2022, <https://seer.cancer.gov/statfacts/html/common.html>.

<sup>5</sup> US Preventive Services Task Force, *Lung Cancer: Screening*, accessed October 4, 2022, <https://www.uspreventiveservicestaskforce.org/webview/#!/recommendation/1916>.

<sup>6</sup> Nicholas Maurice and Nichole Tanner, "Lung cancer screening at the VA: Past, present and future," *Seminars in Oncology* 10, (July 10, 2022):1-7.

cumulative smoking years.<sup>7</sup> Low-dose computed tomography (CT) scan is the only recommended screening test for lung cancer. LCS is currently recommended annually for patients at high risk for lung cancer.

Despite the impact LCS has on improving patients’ survival, LCS rates in the U.S. remain low. Multiple issues may explain these low LCS rates including patients’ lack of awareness, mistrust in the healthcare system, and financial or social factors. Provider specific issues include competing demands for time, lack of awareness, and limited training in shared decision-making. Finally, system-wide deficiencies such as the lack of support from health-system leaders, equipment, information technology infrastructure, and personnel are contributing factors to lower LCS rates.<sup>8</sup>

### VHA Lung Cancer Screening Program Guidelines

In November 2017, VHA issued its initial memorandum providing recommendations for LCS with low-dose CT scan at VHA facilities. This memorandum was most recently updated in July 2022 to specify LCS program accountability and oversight requirements through specific members of an Oversight Board, access to a multidisciplinary Lung Nodule Management Board, and access to a Tumor Board. The memorandum provided information that these newer program requirements could be fulfilled through assistance from other VA facilities. Additionally, the 2022 memorandum specified medical center directors’ responsibilities to coordinate with the Office of Community Care to ensure coordination of care, management, and quality assurance when LCS is accessed through the community. The OIG noted that the memoranda were referenced as “guidelines” while at the same time stipulating to VHA facilities that they may “only” perform LCS when all 10 mandatory elements are met. While VHA recommends but does not require LCS, if facilities elect to establish LCS programs, VHA guidelines require all 10 specific program elements listed in table 1 below.

**Table 1. Mandatory Elements of a VHA LCS program**

Program Element
Standardized, evidence-based criteria for eligibility, frequency, and duration of LCS.
Processes to facilitate identification of patients who meet VHA lung cancer screening eligibility criteria.
Patient education materials and shared decision-making for patients regarding participation in a program of lung cancer screening.
Clinical LCS coordinator(s) to coordinate the care and management of patients in the program.

<sup>7</sup> M. Ito Fukunaga, R.S. Wiener, and C.G. Slatore, “The 2021 US Preventive Services Task Force Recommendation on Lung Cancer Screening: The More Things Stay the Same...”, *JAMA Oncology*. 7, no. 5, (March 9, 2021):684–686.

<sup>8</sup> Maurice and Tanner, “Lung cancer screening at the VA: Past, present and future.”

Program Element
Access to an effective, evidence-based smoking cessation program.
[An] LCS Program Oversight Board responsible for the oversight of the conduct and management of the LCS program.
Access to a multidisciplinary Lung Nodule Management Board with clinical expertise in lung nodule management and diagnostic pathways.
Access to a Tumor Board with expertise in lung cancer treatment.
Optimized radiology CT protocols and standardized procedure names, along with standardized reporting methodology/codes and lung nodule management guidelines.
A patient management tool/registry to rigorously track and manage patients to ensure high levels of adherence to LCS management guidelines.

*Source: VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) memorandum, "Revision Memorandum: Guidelines for Lung Cancer Screening in Veterans Health Administration (VHA)," July 15, 2022.*

*Note: Program elements quoted from the memorandum have been truncated.*

## Findings

The OIG found that facility staff involved in LCS reported that VHA LCS guideline requirements presented barriers to broader adoption of LCS and did not ensure consistent implementation.

### Limited Utilization of Lung Cancer Screening at VHA Facilities

Despite an initial LCS memorandum recommending LCS dating back to 2017, the OIG determined just over half of surveyed VHA facilities reported having an established LCS program consistent with VHA guidelines for LCS in 2022.<sup>9</sup>

Facilities without an LCS program identified multiple barriers to implementing VHA operational memorandum LCS program requirements; the most frequently stated barriers were the absence of an LCS coordinator, the lack of adequate staffing, the absence of a patient registry, and the lack of a multidisciplinary board.

### Inconsistent Implementation of Lung Cancer Screening

VHA implemented guidelines to ensure the quality of LCS. However, facilities that reported having an LCS program identified varied use of VHA LCS program elements. LCS program implementation included inconsistent use of

- an LCS coordinator to manage patients in the program,

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<sup>9</sup> Five of seven facilities that did not conduct LCS had started the process to establish or recently established an LCS program.

- a registry to track patients, or
- a process using a clinical reminder or LCS coordinator to identify patients eligible for screening.

In addition, the OIG found that regardless of whether facilities had established a compliant LCS program, variability remained in how facilities identify patients that meet LCS criteria. VHA National Center for LCS recommends the use of clinical reminders as the preferred method to identify patients; however, not all facilities choose to use this method as it is not required. The clinical reminder can capture accurate smoking history information within the electronic health record to support identifying patients meeting LCS criteria.

Additionally, methods for interpreting low-dose CT scans varied among facilities. Ten sites completing low-dose CT scans for lung cancer reported not using an established system for classification of the results.<sup>10</sup> Not using the classification system could lead to inaccurate interpretation of the low-dose CT scan results and increase the risk for patient harm and health care costs.

The OIG made three recommendations to the Under Secretary for Health:

- Review the operational memorandum for lung cancer screening implementation and assess whether LCS rates could be enhanced by allowing a facility to conduct LCS while developing all mandated elements;
- Review the operational memorandum for LCS implementation and assess whether LCS rates could be enhanced by reevaluating, prioritizing, and clarifying the mandated elements; and
- Consider mandating eligible patients be offered LCS consistent with other required cancer screenings in the Veterans Health Administration.

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<sup>10</sup> The American College of Radiology recommends use of Lung-RADS as the standard reporting tool for LCS. Lung-RADS is a quality assurance tool designed to standardize lung cancer screening CT reporting and management recommendations, reduce confusion in lung cancer screening CT interpretations, and facilitate outcome monitoring.

## Comments

The Under Secretary for Health concurred with the recommendations and provided an acceptable action plan (see appendix B). The OIG will follow up on the planned actions until they are completed.



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## Abbreviations

CT scan	computed tomography scan
LCS	lung cancer screening
OIG	Office of Inspector General
VHA	Veterans Health Administration



## Introduction

The VA Office of Inspector General (OIG) conducted a focused review to assess Veterans Health Administration (VHA) guidelines for lung cancer screening (LCS) programs at VHA facilities. This focused review assessed the potential impact of VHA guidelines on the application of LCS completed at VHA facilities.

The OIG initiated this review in the course of conducting a review of LCS through care in the community. The OIG was concerned VHA guidelines may have delayed facility initiation of LCS and affected uniformity in offering and coordinating follow-up for LCS. Given the overlapping focus of the two reviews, some sections of this report will be replicated in the community care report in order to provide pertinent information independently for the readers of each respective report.

The OIG recognizes VHA's significant health promotion and disease prevention efforts, to include the substantial efforts by VHA leaders and staff to develop and implement LCS.

## Background

The VHA health care system cares for more than nine million enrolled veterans.<sup>1</sup> VHA care includes preventive health screenings "to detect disease at an early stage when treatment may be more effective, or to detect risk factors for disease or injury."<sup>2</sup> The VHA National Center for Health Promotion and Disease Prevention has published screening guidance statements for 17 clinical conditions, including lung cancer.<sup>3</sup>

## Lung Cancer Screening

Lung cancer is the third most diagnosed type of cancer in the United States and is the leading cause of cancer deaths.<sup>4</sup> Smoking is the leading risk factor for the development of lung cancer. There are higher percentages of smokers in the veteran than in the general population and

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<sup>1</sup> "Veterans Health Administration," VA, accessed September 29, 2022, <https://www.va.gov/health/aboutvha.asp>.

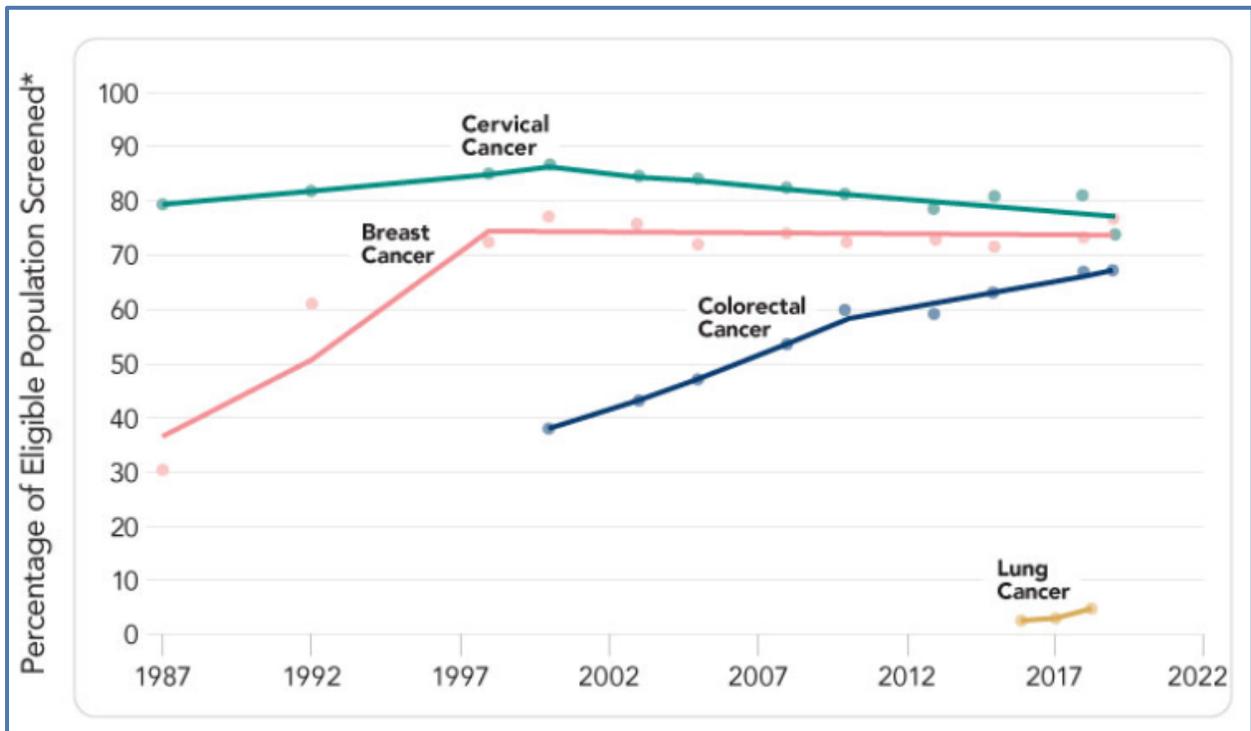
<sup>2</sup> VHA Directive 1120.05, The National Center for Health Promotion and Disease Prevention and the Coordination and Development of Clinical Preventive Services Guidance, July 31, 2020.

<sup>3</sup> "Index of Clinical Preventive Service Guidance Statements," VHA National Center for Health Promotion and Disease Prevention. Screening guidance statements include other conditions like colorectal cancer, osteoporosis, and breast cancer.

<sup>4</sup> National Institutes for Health, National Cancer Institute, *Cancer Stat Facts: Common Cancer Sites*, accessed September 29, 2022, <https://seer.cancer.gov/statfacts/html/common.html>.

veterans may engage in heavier smoking than the general population with an estimated pool of 900,000 patients in VHA that may qualify for screening.<sup>5</sup>

LCS rates in the US remain low (see figure 1) compared to other cancer screenings. In the US, multiple issues may explain these low LCS rates, including patients’ lack of awareness, mistrust in the healthcare system, and financial or social factors. Provider specific issues include competing demands for time, lack of awareness, and limited training in shared decision-making. Finally, system-wide deficiencies such as the lack of support from health-system leaders, equipment, information technology infrastructure, and personnel are contributing factors to lower LCS rates. Published data from 2021 indicates the recent five-year survival rate for lung cancer improves when the cancer is diagnosed at an earlier stage.<sup>6</sup> This improvement in survival may be related to finding cancers earlier and the development of more effective treatments.



**Figure 1. US Cancer Screening Rates**

Source: President’s Cancer Panel, *Closing Gaps in Cancer Screening: Connecting People, Communities, and Systems to Improve Equity and Access*, accessed October 17, 2022,

<https://prescancerpanel.cancer.gov/report/cancerscreening/Part1.html>.

Note: \*Currently available screening tests recommended by the US Preventive Services Task Force.

<sup>5</sup> Nicholas Maurice and Nichole Tanner, “Lung cancer screening at the VA: Past, present and future,” *Seminars in Oncology* 10, (July 10, 2022):1-7; Kinsinger, MD, MPH, et. al., “Implementation of Lung Cancer Screening in the Veterans Health Administration,” *JAMA Internal Medicine* 177, (March 1, 2017): 399-406.

<sup>6</sup> Apar Kishor Ganti, MD, et. al., “Update of Incidence, Prevalence, Survival, and Initial Treatment in Patients With Non-Small Cell Lung Cancer in the US,” *JAMA Oncology* 7, (October 21, 2021):1824-1832.

LCS entails the completion of low-dose computed tomography (CT) scan annually for patients meeting LCS eligibility requirements. Low-dose CT scan is the only recommended screening test for lung cancer by the Centers for Disease Control and Prevention and the US Preventive Services Task Force.<sup>7</sup> As described by the Centers for Disease Control and Prevention, “during an LDCT [low-dose CT scan]. . .an X-ray machine uses a low dose (amount) of radiation to make detailed images of your lungs. The scan only takes a few minutes and is not painful.” Offering a low-dose CT scan requires a multi-step process of determining whether a patient qualifies for the study by age and years of smoking; determining clinical circumstances that are appropriate for testing; and ultimately providing a discussion of how normal and abnormal results are typically followed. Once the study is obtained, care coordination is required to schedule the patient for testing annually, if still eligible; scheduling another low-dose CT scan for follow-up if results are abnormal; or consulting with specialists to determine how to approach highly suspicious lesions.

## VHA Lung Cancer Screening

The VHA National Center for Health Promotion and Disease Prevention guidance for LCS is consistent with the US Preventive Services Task Force recommendation.<sup>8</sup> The US Preventive Services Task Force determined that the recommendation for LCS was a Grade B recommendation, indicating that “there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial,” and the action would be to offer or provide LCS. The US Preventive Services Task Force first recommended LCS in 2013 for smokers at high risk for lung cancer and updated the recommendation in 2021 to expand the high-risk population eligible for screening by lowering both the age and cumulative smoking years.<sup>9</sup> Other screening programs in VHA consistent with US Preventive Services Task Force Grade B recommendations include screening studies for breast cancer, hepatitis B and C, abdominal aortic aneurysm, and osteoporosis.

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<sup>7</sup> Centers for Disease Control and Prevention, *Who Should be Screened for Lung Cancer*, accessed September 22, 2022, [https://www.cdc.gov/cancer/lung/basic\\_info/screening.htm](https://www.cdc.gov/cancer/lung/basic_info/screening.htm).

<sup>8</sup> US Preventive Services Task Force, *Final Recommendation Statement, Lung Cancer: Screening*, March 9, 2021, accessed March 23, 2023, <https://uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening>. In 2013, the US Preventive Services Task Force published the first recommendation for low-dose CT scans for lung cancer screening. In 2021, the Task Force updated the recommendation, expanding the population for whom screening was recommended.

<sup>9</sup> M. Ito Fukunaga, R.S. Wiener, and C.G. Slatore, “The 2021 US Preventive Services Task Force Recommendation on Lung Cancer Screening: The More Things Stay the Same...”. *JAMA Oncology*. 7, no. 5 (March 9, 2021):684–686.

The guidance recommends LCS for persons

- Aged 50 to 80 years who have a 20 or more pack-year smoking history;<sup>10</sup>
- Currently smoke or have quit within the past 15 years; and
- Have a life expectancy of more than five years.

The guidance recommends that this group receive annual screening until

- The person has not smoked for 15 years;
- Develops a health problem that substantially limits life expectancy to five years or less; or
- Does not plan to undergo curative lung surgery, stereotactic radiotherapy, or other potentially curative local therapies.

In addition to VHA and US Preventive Services Task Force, the importance of LCS is recognized by the American Cancer Society, the National Comprehensive Cancer Network, the American Association for Thoracic Surgery, and the American College of Chest Physicians.

### *VHA Lung Cancer Screening Program*

The VHA National Center for Lung Cancer Screening outlined a process for LCS programs that begins with a primary care nurse and provider reviewing and determining whether a patient meets criteria for referral for a low-dose CT scan for LCS. If the primary care provider determines the patient is eligible and agrees to referral, the primary care provider places a consult to the LCS program. An LCS coordinator reviews the patient's medical records to confirm eligibility, contacts the patient to review the decision for screening, and then, if the patient agrees, orders a low-dose CT scan. The screening program uses a tool within the electronic health record to guide primary care assessment and documentation, enable patient tracking, and provide clinical reminders.<sup>11</sup>

### *VHA Lung Cancer Screening Milestones*

**May 2012.** VHA tasked the National Center for Health Promotion and Disease Prevention with conducting an LCS demonstration project across eight facilities.

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<sup>10</sup> National Cancer Institute, *NCI's Dictionary of Cancer Terms, Pack Year*, accessed September 30, 2022, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pack-year>. Pack-year is a measurement of the amount a person has smoked over time, "calculated by multiplying the number of cigarette packs smoked per day by the number of years the person has smoked. For example, 1 pack-year is equal to smoking 1 pack per day for 1 year, or 2 packs per day for half a year, and so on." The US Preventive Services Task Force LCS guidance on smoking history refers to tobacco cigarettes.

<sup>11</sup> The electronic health record tool is not available with the Oracle Cerner electronic health record and is under development.

**March 2016.** VHA published results of the LCS demonstration project. VHA concluded that significant resources would be needed if facilities utilized similar configurations as the demonstration project.

**November 2017.** VHA Deputy Under Secretary for Health for Operations and Management issued a memorandum providing implementation recommendations for LCS with low-dose CT scan at VHA facilities.<sup>12</sup>

**Early 2021.** VHA established the Lung Precision Oncology Program (LPOP). LPOP has several aims, including increasing access to high-quality LCS.

**By Late 2021.** VHA established the National Center for LCS. An Integrated Project Team met to review and develop the business requirements to systematically identify and offer LCS to eligible Veterans and then track them through annual follow-up procedure per VHA.

**March 2022.** The Assistant Under Secretary for Health for Clinical Services (VHA Chief Medical Officer) published an updated memorandum with guidelines for LCS in VHA.<sup>13</sup>

**July 2022.** The Assistant Under Secretary for Health for Clinical Services (VHA Chief Medical Officer) released a “revision memorandum” to provide, as requested by VHA facilities, clarification of processes and requirements of the March 2022 memorandum. The latest memorandum specified LCS program accountability and oversight requirements through specific members of an Oversight Board, access to a multidisciplinary Lung Nodule Management Board, and access to a Tumor Board. The memo provided information that these newer program requirements could be fulfilled through assistance from other VHA facilities. Additionally, the memorandum specified “Medical Center Director should coordinate with the Office of Community Care to ensure that appropriate LCS procedures are in place for Veteran care coordination, management, and quality assurance” when LCS is accessed through the community.<sup>14</sup>

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<sup>12</sup> VHA Deputy Under Secretary for Health for Operations and Management, "Lung Cancer Screening with Low Dose Computed Tomography," November 27, 2017. An operational memorandum provides guidance but is not considered VHA policy.

<sup>13</sup> VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) memorandum, “Guidelines for Lung Cancer Screening in Veterans Health Administration (VHA),” March 24, 2022. This was an update to the Deputy Under Secretary for Health for Operations and Management memorandum from 2017.

<sup>14</sup> VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) memorandum, “Guidelines for Lung Cancer Screening in Veterans Health Administration (VHA),” July 15, 2022. The memorandum served as a revision memorandum, replacing prior guidance from a March 24, 2022, memorandum.

## Prior OIG Reports

The OIG published two prior OIG reports on LCS.<sup>15</sup>

## Concern

Low nationwide screening rates affect the diagnosis and treatment for lung cancer, the type of cancer that takes the most U.S. lives. Per the memorandum, a high-quality LCS program was defined as having the entirety of 10 program elements prior to completing in-house LCS.<sup>16</sup> In effect, this operational definition could exclude patients who should be offered LCS but could not be accommodated in-house based on not having a high-quality LCS program as defined by VHA. The OIG's concern focuses on the VHA memorandum mandating all 10 requirements that facilities must have to complete LCS in-house, and at the same time, not requiring that facilities offer LCS to all patients who are eligible for screening. Without an LCS program in place at a facility, providers may refer patients to care in the community. Further, without a "centralized" program within a facility, providers have to default to a "decentralized" approach to LCS, with less accurate patient selection for screening, fewer patients screened, and unreliable follow-up care. This may affect the already low LCS numbers as compared to other cancer screenings.

## Scope and Methodology

In January 2022, the OIG initiated a national review of low-dose CT scans for LCS provided through care in the community focusing on follow-up care for abnormal results and completion of annual screening for normal results. From May through July 2022, the OIG conducted this review of LCS provided at VHA facilities focusing on the impact of the LCS requirements specified in the 2022 memoranda "Guidelines for Lung Cancer Screening in Veterans Health Administration" and 2017 "Lung Cancer Screening with Computed Tomography."

The OIG reviewed relevant VHA directives, VHA memoranda, VHA guidelines specific to LCS, and relevant external standards. The OIG team interviewed subject matter experts from the National Center for LCS and the VHA National Center for Health Promotion and Disease Prevention.

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<sup>15</sup> VA OIG, [\*Deficiencies in a Patient's Lung Cancer Screening, Renal Nodule Follow-Up, and Prostate Cancer Surveillance at the VA Southern Nevada Healthcare System in Las Vegas\*](#), Report No. 21-01038-49, December 16, 2021; VA OIG, [\*Delayed Cancer Diagnosis of a Veteran Who Died at the Raymond G. Murphy VA Medical Center in Albuquerque, New Mexico\*](#), Report No. 20-03700-35, November 23, 2021.

<sup>16</sup> VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) memorandum.

The OIG developed a questionnaire related to LCS practices and procedures and distributed it electronically to 139 of 140 VHA facility points of contact<sup>17</sup> The questionnaire focused on how facilities completed LCS from October 1, 2018 through March 31, 2022, under the requirements delineated in VHA's operational memorandum for LCS.<sup>18</sup> The questionnaire also queried facilities that had not implemented an LCS program as described in the VHA memorandum "Guidelines for Lung Cancer Screening in Veterans Health Administration" (see appendix A for list of questions and response options that were used for this report). The OIG provided respondents opportunities to amend their responses following OIG's determination that some answers required clarification.

For those facilities where the point of contact indicated that the facility did not complete any low-dose CT scans for LCS, the OIG interviewed facility staff to gain information about the current state of LCS at those facilities and what barriers were encountered in LCS. The OIG conducted interviews from June 6 through 27, 2022.

The OIG did not independently verify VHA responses and data for accuracy or completeness. The OIG evaluated the questionnaire responses to determine whether facilities with established LCS programs included the required elements defined in the LCS operational memorandum. Additionally, for those facilities that were providing LCS without an established program, OIG identified the missing elements and conducted a thematic analysis on the identified barriers to establishing an LCS program as defined in the VHA memorandum.

In the absence of current VA or VHA policy, the OIG considered previous guidelines to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s). Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the review in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

## Inspection Results

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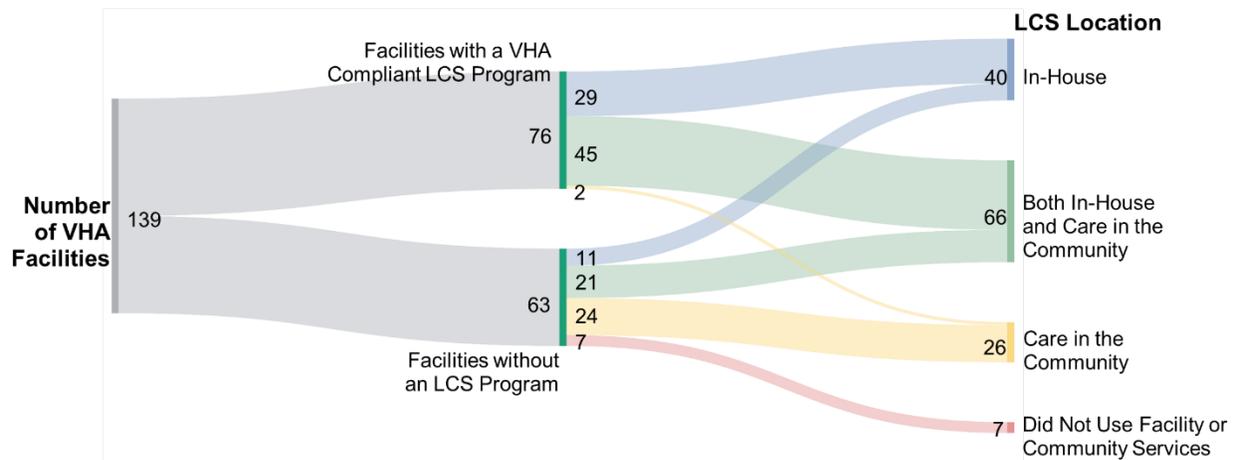
<sup>17</sup> The questionnaire was initially developed for an OIG report addressing lung cancer screening completed by care in the community resources. The OIG included additional questions for this review. The VA Manila Outpatient Clinic in Pasay City, Philippines, was excluded due to its unique status as the only VA healthcare facility located in a foreign country. Services available to service-connected veterans are limited. Services and costs related to the treatment of non-service-connected disabilities are the veteran's responsibility.

<sup>18</sup> The questionnaire was distributed on March 31, 2022. At the time, the March 24, 2022, VHA memorandum on lung cancer screening was active. The OIG did not find that the later July 15, 2022, VHA "revision memorandum" changed the results and conclusions from the questionnaire.

Despite initial LCS guidelines dating back to 2017, the OIG determined there has been irregular adoption of LCS programs since that time. More than half of surveyed VHA facilities (76 of 139) reported having an established LCS program consistent with VHA guidelines, while 63 of 139 facilities reported not having an LCS program consistent with VHA guidance.<sup>19</sup> Facilities without an LCS program identified multiple barriers to implementing VHA operational memorandum requirements and the OIG found variation among how facilities approached LCS.

## 1. Facilities Identified Barriers to Lung Cancer Screening Due to VHA Requirements

An OIG survey found that 55 percent of VHA facilities reported establishing an LCS program consistent with VHA guidelines and 45 percent of VHA facilities had not established LCS programs consistent with VHA guidelines at the time of the OIG questionnaire.<sup>20</sup> Facilities’ implementation varied (see figure 2). Some facilities that had not established LCS programs were completing LCS low-dose CT scans in-house, some used care in the community to complete low-dose CT scans, some used a combination of in-house and care in the community to complete low-dose CT scans, while some did not offer LCS at all. The first program was established in 2013, and the most recent programs were established in 2022.



**Figure 2.** Sankey diagram identifying number of facilities with and without LCS programs and location of where low-dose CT scans are performed.

Source: OIG analysis of questionnaire responses.

<sup>19</sup> One facility point of contact responded that the facility had an established an LCS program consistent with VHA guidance, however, during a healthcare inspection following survey closure the OIG learned no program had been established. The OIG did not change the questionnaire response from the facility based on this finding.

<sup>20</sup> Two facilities points of contact responded that an LCS program had been established consistent with VHA guidance; however, the facilities did not have LCS coordinators.

## Relevant Guidelines

In July 2022, VHA published the operational memorandum, “Guidelines for Lung Cancer Screening in Veterans Health Administration.”<sup>21</sup> The guidelines recommend low-dose CT scans for eligible veterans which is consistent with the VHA National Center for Health Promotion and Disease Prevention screening recommendations for LCS. The guidelines do not require VHA medical facilities to conduct LCS but do require that VHA medical facilities may *only* perform LCS when 10 mandatory criteria (see table 1) of “a high-quality LCS program are met.” The OIG noted that the memoranda were referenced as “guidelines” while at the same time stipulating requirements.

**Table 1. Mandatory Elements of a VHA LCS Program**

Program Element
Standardized, evidence-based criteria for eligibility, frequency, and duration of LCS.
Processes to facilitate identification of patients who meet VHA lung cancer screening eligibility criteria.
Patient education materials and shared decision-making for patients regarding participation in a program of lung cancer screening.
Clinical LCS coordinator(s) to coordinate the care and management of patients in the program.
Access to an effective, evidence-based smoking cessation program.
[An] LCS Program Oversight Board responsible for the oversight of the conduct and management of the LCS program. At a minimum, the Board should include representation from Pulmonary Medicine Service, Radiology Service, and Primary Care Service, with consideration to add other relevant stakeholders (e.g., medical, surgical, and radiation oncology providers, Veteran Engagement specialists, etc.). It [The oversight Board] can operate through a “hub and spoke” model for facilities without all necessary specialties onsite. The LCS coordinator participates on this Board.
Access to a multidisciplinary Lung Nodule Management Board with clinical expertise in lung nodule management and diagnostic pathways (e.g., performance of nonsurgical biopsies, minimally invasive surgical biopsies, bronchoscopy, etc.). The Board should meet on a regular basis. It [The multidisciplinary Lung Nodule Management Board] can operate through a “hub and spoke” model for facilities without all necessary specialties onsite. At a minimum, the following specialties/professions should be represented: <ul style="list-style-type: none"> <li>i. Radiology (diagnostic).</li> <li>ii. Pulmonary Medicine.</li> <li>iii. Lung cancer screening coordinator.</li> </ul>
Access to a Tumor Board with expertise in lung cancer treatment is also required; this can operate through a “hub and spoke” model for facilities without all necessary specialties onsite. In addition

<sup>21</sup> VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) memorandum. An operational memorandum provides guidance but is not considered VHA policy. The memorandum was published as a revision memorandum to provide clarification to VA medical centers and replace prior guidance from a March 24, 2022, memorandum. The original guidelines were published in a November 2017 memorandum.

### Program Element

to the specialties in [The multidisciplinary Lung Nodule Management Board], a Tumor Board may typically also include representation from:

- i. Radiology (interventional).
- ii. Pathology.
- iii. Thoracic Surgery.
- iv. Medical Oncology.
- v. Radiation Oncology.
- vi. Palliative Care.

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Optimized radiology CT protocols and standardized procedure names, along with standardized reporting methodology/codes and lung nodule management guidelines (i.e., Lung CT Screening Reporting & Data System (Lung-RADS)).

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A patient management tool/registry to rigorously track and manage patients to ensure high levels of adherence to LCS management guidelines.

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*Source: VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) memorandum, "Revision Memorandum: Guidelines for Lung Cancer Screening in Veterans Health Administration (VHA)," July 15, 2022.*

*Note: Program elements quoted from the memorandum have been truncated.*

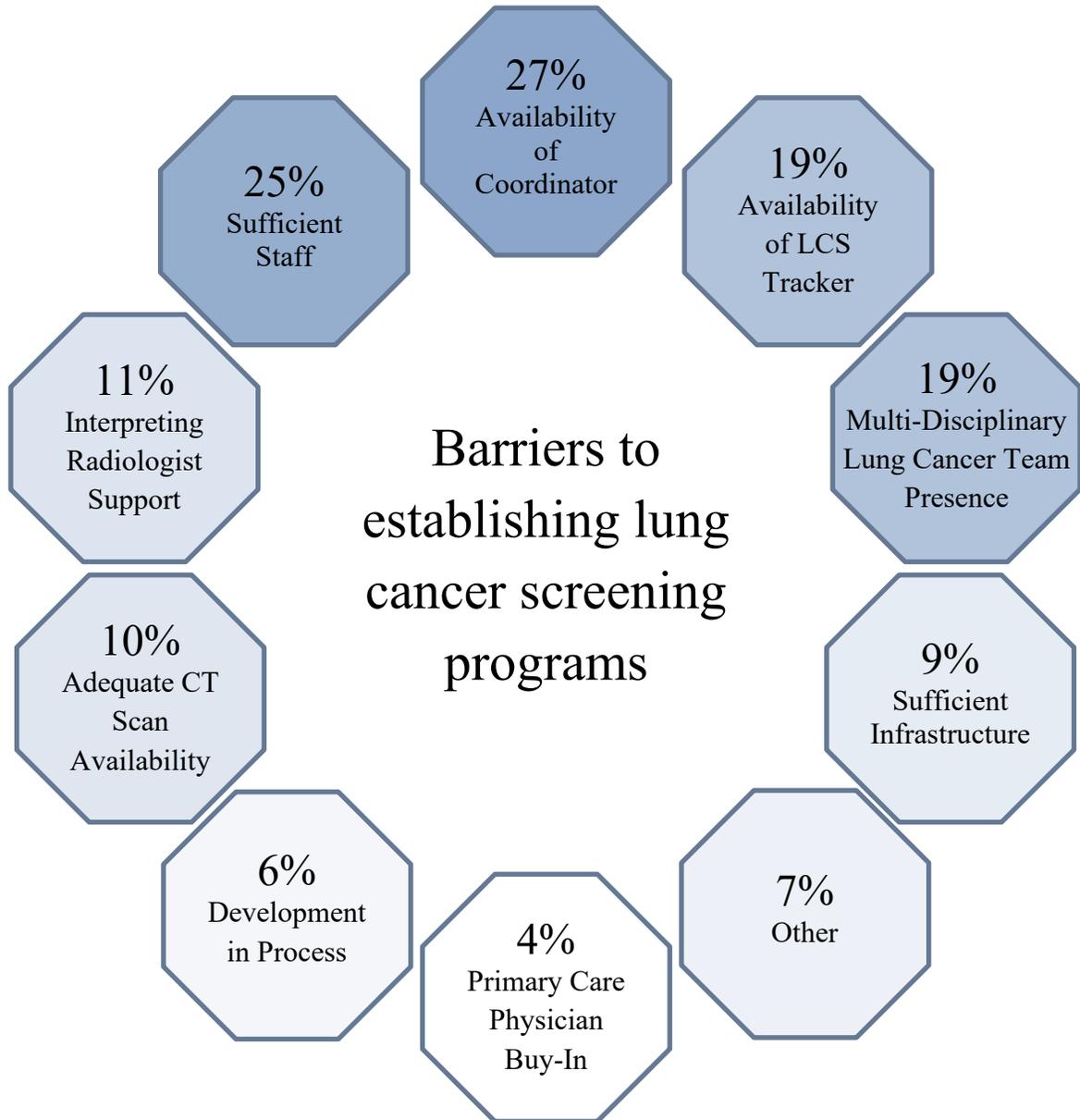
VHA's National Center for LCS conveyed that implementation of comprehensive LCS programs should be in place to ensure high-quality LCS.

The operational memorandum **recommends**, but **does not require**, offering low-dose CT scans for eligible veterans consistent with the VHA National Center for Health Promotion and Disease Prevention recommendations for LCS.

## Findings

The OIG made the following determinations:

**Facilities without an established LCS program described the lack of mandatory LCS program resources as a barrier to establishing an LCS program.** "Availability of a coordinator" was the most frequent barrier identified in the OIG questionnaire. Four of the top five barriers identified were related to the availability of staff (see figure 3). Frequently identified barriers also included technological and physical resources such as an LCS tracking system, equipment, and infrastructure.



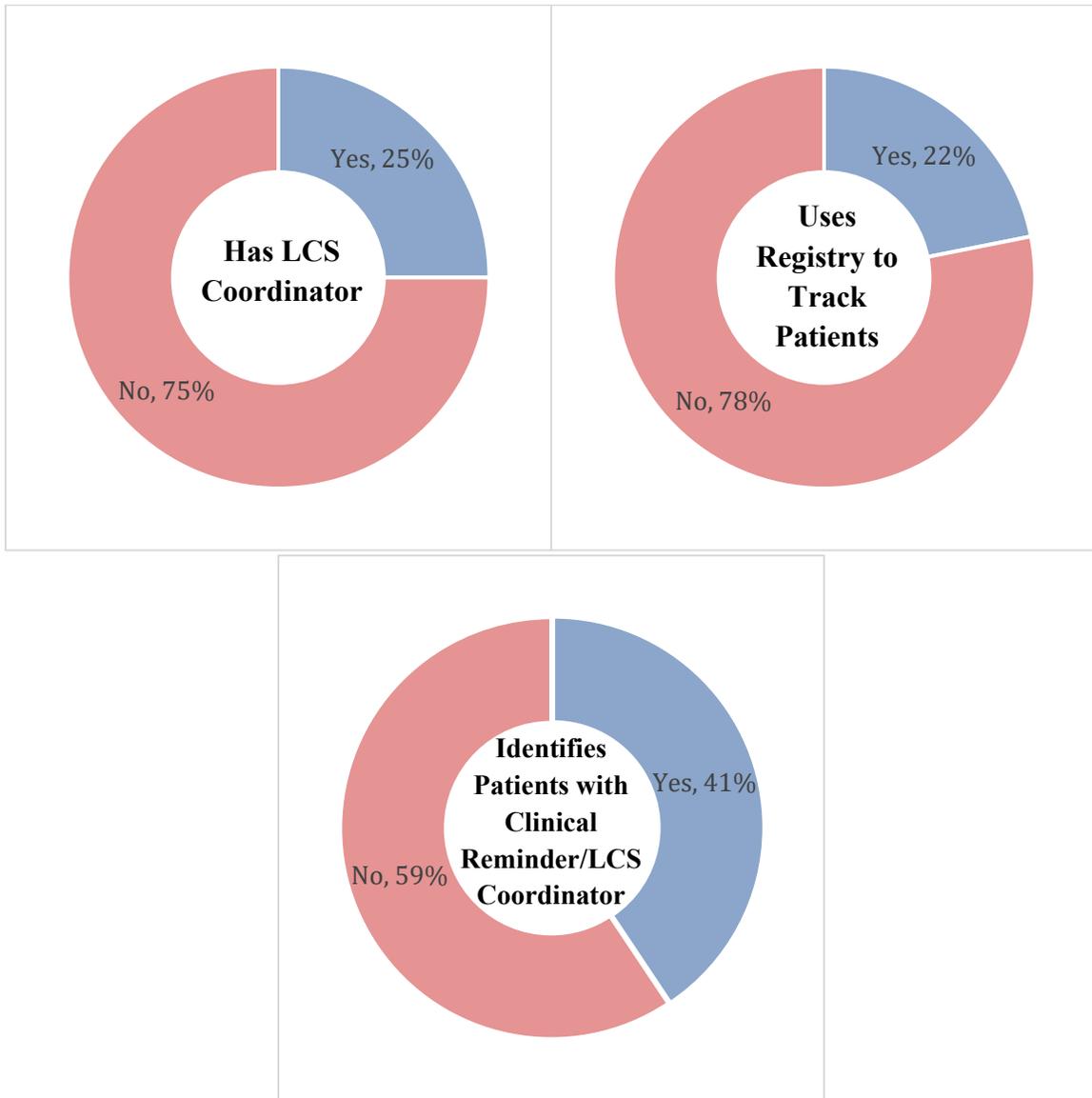
*Figure 3. Barriers to establishing LCS programs.  
Source: OIG analysis of questionnaire responses.*

**Thirty-two facilities without established LCS programs provided low-dose CT scans in-house.** While facilities informed the OIG they had not yet established a program in compliance with VHA guidelines, some had implemented program components such as an LCS coordinator to manage patients, a registry to track patients, and a process using a clinical reminder or LCS coordinator to identify patients eligible for screening (see figure 4). The VHA National Center for LCS maintains a national LCS platform to track patients, which includes a national clinical

reminder, that facilities can adopt.<sup>22</sup> These tools are available to facilities and fulfill part of the 10 components in the LCS memorandum. The memorandum, however, did not account for facilities performing LCS in-house when all requirements in the memorandum were not met. The OIG acknowledges that while these 32 facilities provide LCS without a program as defined by VHA policy, they are providing preventive care that patients would not have otherwise received.

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<sup>22</sup>“Lung Cancer Screening Platform (LCSP),” National Center for Lung Cancer Screening (NCLCS). “The Lung Cancer Platform is a suite of EHRM [electronic health record management] Medi-tools for clinical decision support. It starts with clinical reminders that enable Veterans to be assessed for lung cancer screening. Currently in VA there is no required way to assess whether the Veteran meets the cigarette smoking eligibility. This screening starts with asking all Veterans between [ages] 50–80 the qualifying questions. The platform takes the data health factors and turns them into reminders for their primary and other provider to offer lung cancer screening. The platform also uses [data] from the radiologist through structured data codes about what follow up is required after the low dose cancer screening.”



**Figure 4.** Program component use by facilities without LCS programs.

Source: OIG Analysis of questionnaire responses.

**Seven facilities did not complete low-dose CT scans for LCS in-house or through care in the community.** However, five of the seven facility points of contact informed the OIG that since completing the OIG questionnaire they had started or recently established an LCS program. Staff from the seven facilities described the lack of resources required by VHA guidelines, including staff and equipment, as barriers to timely implementing programs. Additionally, staff described barriers to using care in the community for LCS included issues with receiving timely

results, limited availability of services within the community, and the facility's preference to use interfacility consults.<sup>23</sup>

**VHA requires offering preventive screening for some conditions, but not lung cancer.** VHA requires that facilities offer preventive services for other conditions, including screening for colorectal cancer and breast cancer.<sup>24</sup> That is not the case for lung cancer, despite the risk faced by veterans. The percentage of smokers in the veteran population is higher than the general population and veterans who smoke tend to smoke more heavily than the general population. Veterans who access VHA health care have a prevalence rate for smoking that is 1.5 times higher than veterans who do not obtain health care from VHA. Age-specific rates of lung cancer for male VHA patients is estimated to be 76 percent higher than that of US males in the general population.<sup>25</sup> Researchers have estimated that close to 900,000 VA patients meet criteria for LCS.<sup>26</sup> Additionally, patients who had military exposure to lung carcinogens such as agent orange, burn pits, chromium, ionizing radiation, asbestos, and mustard gas may have increased lung cancer risks but are not considered in the LCS selection if smoking qualifications are not met. However, the population of veterans who do qualify for LCS and have yet to be screened underscores the importance of LCS in VHA. Despite the high number of unscreened patients and the value of LCS, VHA guidelines recommend but do not require offering patients LCS.

The OIG determined that despite the established benefit of LCS, facility implementation of LCS consistent with VHA guidelines varies significantly. Multiple facilities reported that obtaining all the mandatory program elements denoted in the memoranda were barriers to establishing a program. Some facilities without all 10 elements are conducting LCS as recommended by US Preventive Services Task Force for their patients. VHA has not provided guidance in their memoranda for how these facilities should implement LCS while they are attempting to attain all 10 elements. Mandatory LCS program elements combined with not requiring providers to offer LCS may make improvement difficult for low LCS rates..

## **2. VHA Guidelines Have Not Ensured Lung Cancer Screening Consistency**

The OIG found that regardless of whether facilities had established a compliant LCS program, variability remained in identification of eligible patients and methods for interpreting low-dose CT scans. When determining whether LCS is appropriate for a patient, facilities use a variety of methods that differ at each to identify those eligible patients who should be considered for LCS.

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<sup>23</sup> Interfacility consults are used to refer patients from one VHA facility to another VHA facility.

<sup>24</sup> VHA Directive 1015, *Colorectal Cancer Screening*, April 3, 2020, amended November 22, 2022; VHA Directive 1330.01(6), *Health Care Services for Women Veterans*, February 15, 2017, amended September 9, 2022.

<sup>25</sup> The OIG did not find comparable studies for female veterans.

<sup>26</sup> Maurice and Tanner, "Lung cancer screening at the VA: Past, present and future."

Once a low-dose CT scan is performed, result interpretation and follow-up may vary by facility depending on whether or not radiologists use an established classification system to standardize the follow-up and management decisions of LCS results.<sup>27</sup>

## Relevant Guidelines

The July 2022 VHA memorandum, “Guidelines for Lung Cancer Screening in Veterans Health Administration” requires facilities meet **all** of the requirements for “a high-quality LCS program” (see table 1) **before** offering LCS. The memorandum does not provide allowance for establishing a program and sequentially adding program elements.<sup>28</sup>

## Findings

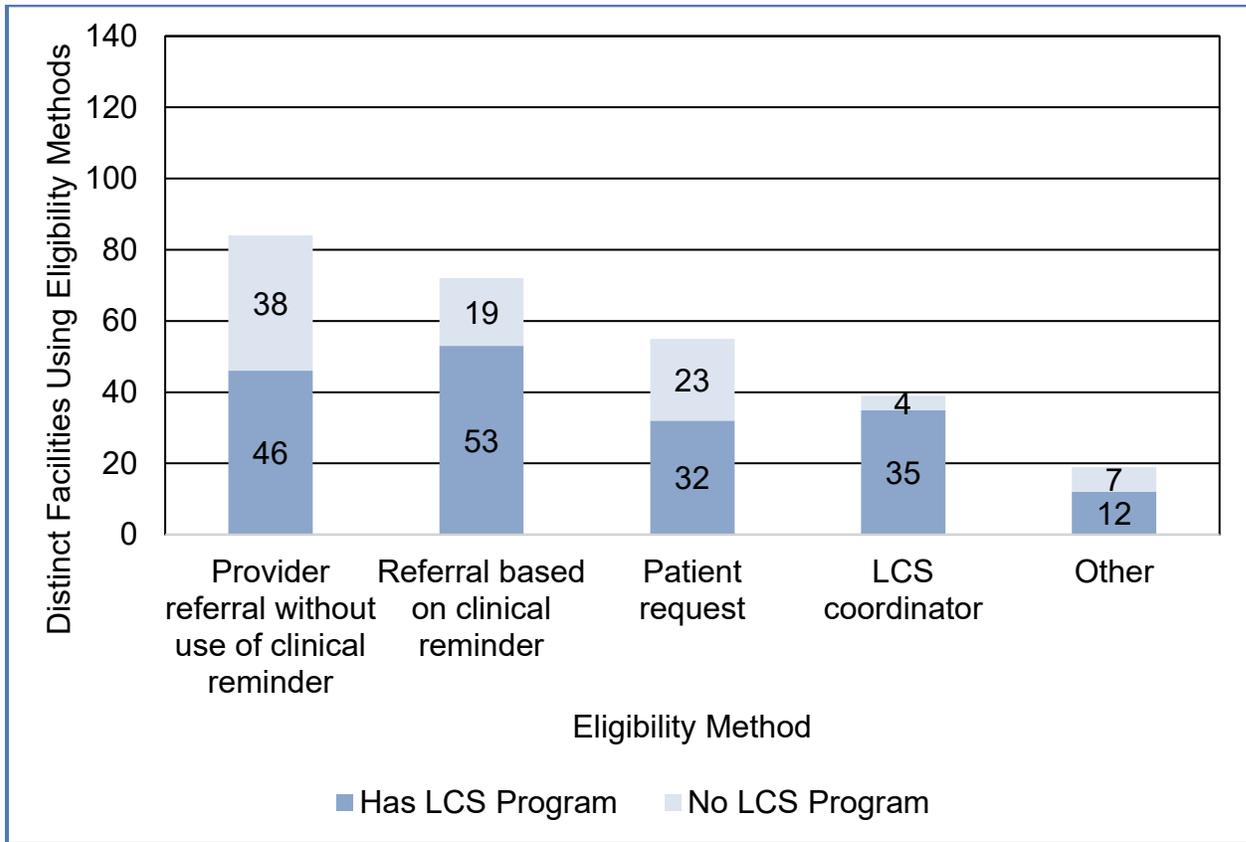
The OIG made the following determinations:

**Facilities do not use a consistent method to identify patients meeting LCS criteria.** Patients may be eligible for LCS based on US Preventive Service Task Force criteria of years and extent of smoking. How VHA facilities systematically identify those patients varied. VHA National Center for LCS recommends the use of clinical reminders as the preferred method to identify patients for LCS; however, not all facilities choose to use this method (see figure 5). The clinical reminder can capture accurate smoking history information within the electronic health record to support identifying patients meeting LCS criteria. Because patients’ eligibility changes annually based on smoking years, smoking status, and age, the clinical reminder requires ongoing maintenance to accurately identify LCS eligibility. The OIG found provider referral with the aid of a clinical reminder was the second most frequent approach to identifying patients meeting criteria for LCS. Provider referral of patients for LCS without aid of a clinical reminder was the most frequent method used by facilities to identify patients meeting criteria for LCS. Facilities with and without LCS programs used this method. Although individual providers at facilities without an LCS program can initiate LCS for their patients, providers are better supported and facility-wide impact improves with specific tools in place. Many studies have reported that sole reliance on individual clinicians to provide LCS is inferior to LCS with support processes. Provider referrals alone, without the use of a mechanism to remind providers of LCS eligibility, may not be sufficient.

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<sup>27</sup> Lung-RADS is a classification system used when interpreting low-dose CT scan.

<sup>28</sup> The memorandum does encourage incrementally adding capacity for in-house low-dose CT scans “as they attempt to offer access to high-quality LCS systematically and equitably to all eligible Veterans.”



**Figure 5.** Frequency of LCS eligibility methods used by VHA facilities,

Source: OIG analysis of questionnaire responses.

Note: N=132. Points of contact could select more than one patient eligibility method used at their facility. The seven facilities that did not utilize in-house services or care in the community for LCS were not asked this question.

**VHA did not ensure that facilities completing in-house low-dose CT scans used a quality assurance tool for reporting results.**<sup>29</sup> “Lung-RADS is a quality assurance tool designed to

- standardize lung cancer screening CT reporting and management recommendations,
- reduce confusion in lung cancer screening CT interpretations, and
- facilitate outcome monitoring.”<sup>30</sup>

Lung-RADS was developed by the American College of Radiology to identify and provide follow-up management of suspicious nodules found during LCS with low-dose CT scans. The goal of using Lung-RADS is to identify nodules that may represent lung cancer and provide

<sup>29</sup> The OIG surveyed facilities concerning the use of Lung-RADS as the quality assurance tool and considered the facility not using a quality assurance tool if Lung-RADS was not used.

<sup>30</sup> American College of Radiology, *Lung CT Screening & Data Systems*, accessed March 23, 2023, <https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads>.

timely management so that mortality can be reduced. The OIG found that all facilities with LCS programs as defined by VHA guidelines use Lung-RADS when reading low-dose CT scans as required; however, 10 of the 32 facilities completing low-dose CT scans for LCS without an LCS program as defined by VHA guidelines do not use the Lung-RADS classification system.

The OIG found that the Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer's approach of requiring all program elements before conducting LCS did not eliminate variability in LCS.

## Conclusion

VHA guidelines for LCS program requirements are designed to provide consistent high-quality care. However, OIG survey results found that close to half of VHA facilities had not established LCS programs consistent with VHA memoranda. Facilities reported that mandatory program elements of VHA guidelines served as barriers to implementation. With already low screening rates nationally, LCS rates may be negatively affected in VHA as all 10 elements are required prior to offering LCS in facilities while offering screening is not mandatory. The five-year survival rate for patients with lung cancer increases for earlier staged cancers. Major goals are to detect lung cancer at the earliest stages through screenings and to provide treatment. To that end, patients who are eligible for LCS should be offered the same care as eligible patients at facilities that do have an LCS program. This type of standardization is important to increase screening rates for both facilities that have LCS and those that do not. VHA has developed the requirements and initiated a national program office to provide support to facilities in establishing LCS programs. For facilities that do not initiate LCS programs and continue to provide screenings without the mandated 10 elements, further guidance from VHA is needed.

The OIG commends the VHA National Center for LCS for developing resources and providing support to facilities that have established an LCS program, are in the process of establishing an LCS program, and those conducting LCS without an established program. Further guidance to those facilities that could not build a program with the required elements or have limited access to community care LCS programs would be of benefit to all patients who are eligible for screening.

## **Recommendations 1–3**

1. The Under Secretary for Health reviews the operational memorandum for lung cancer screening implementation and assesses whether lung cancer screening rates could be enhanced by allowing a facility to conduct lung cancer screening while developing all mandated elements.
2. The Under Secretary for Health reviews the operational memorandum for lung cancer screening implementation and assesses whether lung cancer screening rates could be enhanced by reevaluating, prioritizing, and clarifying the mandated elements.
3. The Under Secretary for Health considers mandating eligible patients be offered lung cancer screening consistent with other required cancer screening in the Veterans Health Administration.

## Appendix A: Lung Cancer Screening Questionnaire<sup>31</sup>

**(1) From Fiscal Year 2019 to current, did staff utilize facility services or Community Care for Lung Cancer Screening?**

- Yes (Go to Q2)  
 No (End survey)

**(2) Is your facility equipped to complete low-dose computed tomography (LDCT) scans?**

- Yes (Go to Q2A-D)  
 No (Go to Q3)

**If Yes to Q2:**

**(A) Is there a radiologist credentialed and privileged in reading LDCT at your facility?**

- Yes  No

**(B) Is there a tele-radiologist credentialed and privileged in reading LDCT for your facility (either agreement with other VA facility or national teleradiology)?**

- Yes  No

**(D) Is the Lung-RADS reporting system being used?**

- Yes  No

**(4) Has your facility established a LCS program as described in the Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, Lung Cancer Screening with Low-Dose Computed Tomography, November 27, 2017, rescinded and replaced by Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memorandum, Guidelines for Lung Cancer Screening in Veterans Health Administration, March 24, 2022 (see email attachments)?**

- Yes (Go to Q4A-B)  
 No (Go to Q4C)

**If Yes to Q4:**

**(A) Approximately when was your LCS program established? (mm.yyyy)**

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**If No to Q4:**

**(C) What barriers hinder the establishment of a LCS program as described in the DUSHOM Memorandum? (Select all that apply)**

- Possible availability of a LCS tracker  
 Availability of coordinator  
 Supportive leadership  
 Presence of multidisciplinary lung cancer team  
 Adequate CT scan availability  
 Adequate interpreting radiologist support  
 Primary care physician buy-in

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<sup>31</sup> Questions that were not used in this report were removed; question numbering was not changed.

- Veteran's level of interest
- Sufficient staff/personnel
- Sufficient infrastructure
- None
- Other \_\_\_\_\_

**(5) How are patients that need LCS identified? (Select all that apply)**

- Referral based on clinical reminder
- Screening navigator/coordinator
- Patient request
- Provider referral without use of clinical reminder
- Other \_\_\_\_\_

**(6) Where does your facility complete LCS with LDCT? (Select all that apply)**

- In-house (completed at the facility/CBOC radiology department) (go to in-house section)
- Community Care (go to CC section)

**If Yes to Q6 In-house**

**In-house Lung Cancer Screening (Q7-13)**

**(7) Does your facility utilize a LCS registry/tracking system (see DUSHOM memo attached to email)?**

- Yes  No

**(8) Does your facility utilize a navigator/clinical coordinator to manage in-house LDCT activities?**

- Yes  No

## Appendix B: Office of the Under Secretary for Health Memorandum

### Department of Veterans Affairs Memorandum

Date: June 12, 2023

From: Under Secretary for Health (10)

Subj: National Review—Concern with Veterans Health Administration's Lung Cancer Screening Program Requirements

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the draft report regarding the Veterans Health Administration's (VHA) Lung Cancer Screening Program. VHA concurs with all three recommendations and submits the attached action plan.
2. I am pleased to share some successes achieved by the National Center for Lung Cancer Screening after OIG completed its review. As of 2023, approximately 170 Lung Cancer Screening coordinators are employed throughout VHA; 80 of whom are funded through the Lung Precision Oncology Program and other central mechanisms.
3. VHA adopted the comprehensive Lung Cancer Screening Platform that includes clinical reminders and health factors. To date, approximately 120 VHA facilities have installed or agreed to install the platform and additional implementation efforts are underway.
4. Thank you again for partnering with VHA to ensure our Veterans receive the high-quality healthcare they deserve. Comments regarding this memorandum may be directed to the GAO OIG Accountability Liaison Office at [VACOVHA10BGOALOIG@va.gov](mailto:VACOVHA10BGOALOIG@va.gov).

*(Original signed by:)*

Shereef Elnahal, M.D., MBA

### OIG Addendum to the Under Secretary for Health Memorandum

During VA's review of an OIG draft report, it is usual practice for VA to submit comments that may disclose information that could change OIG findings in the final report. VA provided the OIG comments referenced in the Under Secretary for Health memo during the draft review phase. The OIG considered and reviewed the comments and made refinements to the report in response. Based on the review, no changes were made to OIG findings in the report.

## Office of the Under Secretary for Health Response

### VETERANS HEALTH ADMINISTRATION (VHA)

#### Action Plan

### OIG Draft Report, Brief Report: Concern with Veterans Health Administration's Lung Cancer Screening Program Requirements (OIG 2022-01511-HI-1249)

**Recommendation 1.** USH reviews the operational memorandum for lung cancer screening implementation and assesses whether lung cancer screening rates could be enhanced by allowing a facility to conduct lung cancer screening while developing all mandated elements.

**VHA Comments:** Concur. VHA agrees that all facilities should provide access to high-quality lung cancer screening (LCS). VHA allows facilities to incrementally implement LCS so they can feasibly and sustainably ensure a high-quality process. The National Center for Lung Cancer Screening (NCLCS) and the National Radiology Program (NRP) published a clear process to the field. Currently, each facility is permitted to start LCS incrementally so their resources will not be overwhelmed. In addition, the NCLCS and NRP provides resources to guide and support implementation of all mandated elements of high-quality LCS programs. The Clinical Restructuring Request (CRR) process for LCS follows the guidance in VHA Directive 1043, *Restructuring of VHA Clinical Programs*, published November 2, 2016.

As of June 2023, 99 VA facilities that participate in the Lung Precision Oncology Program have committed to establishing all the mandated elements of high-quality LCS programs, many of which have an approved CRR. An additional 19 facilities have completed the CRR process. Thus, almost 120 facilities have, or soon will have, LCS programs with all mandated elements. The NCLCS will work with remaining VA facilities so that by the end of fiscal year 2024, all VA facilities will have an approved CRR for an LCS Program with all mandated elements. VHA asks OIG to consider closing this recommendation based on information provided.

Status: Completed

Completion Date: June 2023

### OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support the completion of a review and assessment of whether lung cancer screening rates at facilities that have not implemented a lung cancer screening program could be enhanced by allowing a facility to conduct lung cancer screening while developing all mandated elements.

**Recommendation 2. USH reviews the operational memorandum for lung cancer screening implementation and assesses whether lung cancer screening rates could be enhanced by reevaluating, prioritizing, and clarifying the mandated elements.**

**VHA Comments:** Concur. VHA agrees that all facilities should provide access to high-quality lung cancer screening. VHA allows facilities to incrementally implement LCS so they can feasibly and sustainably ensure a high-quality process. While the OIG collected the data for this draft report, VHA simultaneously reviewed and reevaluated the mandated elements in the Memorandum Guidelines for Lung Cancer Screening in Veterans Health Administration, which was published with those updates in July 2022. Following that most recent evaluation, NCLCS and NRP drafted a new LCS directive which has further clarified mandated elements and implementation requirements. VHA asks OIG to consider closing this recommendation based on the information provided.

Status: Completed

Target Completion Date: June 2023

### **OIG Comment**

The OIG considers this recommendation open to allow time for the submission of documentation to support that a review and assessment of whether lung cancer screening rates could be enhanced by reevaluating, prioritizing, and clarifying the mandated elements.

**Recommendation 3. USH considers mandating eligible patients be offered lung cancer screening consistent with other required cancer screening in the Veterans Health Administration.**

**VHA Comments:** Concur. VHA agrees that all eligible Veterans should be offered lung cancer screening consistent with other required cancer screenings in VHA but cannot ethically mandate or force Veterans to be screened. In 2023, the NCLCS and NRP drafted a new LCS directive. The directive consolidates content from several operational memoranda into a single policy that clarifies the mandated elements of LCS. The draft policy states, "It is VHA policy that all Veterans at increased risk of lung cancer be offered LCS in accordance with VHA clinical preventive services guidance, coordinated by the VHA National Center for Lung Cancer Screening." This directive is undergoing VHA review; the goal is to publish by early fiscal year 2024.

Status: In progress

Target Completion Date: October 2023

## OIG Contact and Staff Acknowledgments

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<b>Contact</b>	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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