Supplementary Online Content


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This supplementary material has been provided by the authors to give readers additional information about their work.
eAppendix 1. Timeline, Resources, and Methods

Timeline

The VHA’s LCSDP was initiated at the request of Under Secretary for Health Robert Petzel in 2012, with funding for 3 years (2012-2015). The first year was spent planning for the project, selecting the project facilities, developing guidance for implementing the LCS program, and planning the evaluation of the project. Screening began in July 2013 at one of the project sites and continued through September 2015.

Facilities

The eight facilities selected, all academic tertiary care facilities that represented 8 separate Veterans Integrated Service Networks (VISNs), were: New York Harbor VA Healthcare System, New York, NY (VISN 3); Durham VA Medical Center, Durham, NC (VISN 6); Ralph H. Johnson VA Medical Center, Charleston, SC (VISN 7); Cincinnati VA Medical Center, Cincinnati, OH (VISN 10); VA Ann Arbor Healthcare System, Ann Arbor, MI (VISN 11); VA Portland Health Care System, Portland, OR (VISN 20); San Francisco VA Health Care System, San Francisco, CA (VISN 21); and Minneapolis VA Health Care System, Minneapolis, MN (VISN 23).

Project Oversight

The LCSDP was led by the VHA National Center for Health Promotion and Disease Prevention (NCP), in collaboration with the VHA National Radiology Program Office. Evaluation of the project was led by the Durham, NC, VA Medical Center Health Services Research and Development Center of Innovation. A steering committee, with representatives from primary care, pulmonary medicine, radiology, medical oncology, radiation oncology, cardiothoracic surgery, women’s health, mental health, health services research and development (HSR&D), tobacco policy, and public health, provided overall oversight and guidance for the project. Patient tracking support was provided by the Pittsburgh, PA, VA Medical Center (VAMC) Veterans Engineering Resource Center (VERC).

Resources Developed for VHA Lung Cancer Screening Demonstration Project

A. Implementation Guide: The Implementation Guide, written by the National Center for Health Promotion and Disease Prevention (NCP) and the National Radiology Program Office, with input from the Steering Committee, included information on all project materials listed below, as well as information about smoking cessation resources available in VA medical centers. It was a “live” document throughout the project, with frequent revisions and expansion, based on input from site leaders and LCS coordinators about their experience with implementation processes.

B. Process flow map outlining the clinical steps in a screening program: The process flow map was developed by NCP, in collaboration with the Pittsburgh Veterans Engineering Resource Center (VERC) and the Steering Committee. The flow map provided a graphical display of each step of the process of lung cancer screening, from identifying appropriate screening candidates to scheduling the LDCTs to following up any findings and scheduling subsequent exams and contacting patients with results. Each demonstration site was encouraged to use the flow map in planning its LCS program and to discuss with relevant clinical services how it would implement each step and who would be responsible for each action.

C. Set of 3 electronic clinical reminders: Primary care patients who were appropriate for LCS discussion were identified by a set of three clinical reminders developed specifically for the program. Clinical reminders are decision support tools available in the VA’s Computerized Patient Record System (CPRS) that prompt staff to screen, review or assess risk factors, or offer services that may be due for an individual patient, based on the patient’s age or other factors recorded in the electronic system. Clinical reminders and documentation templates include health factors, computerized components built to capture patient information for which no standard code exists in CPRS. Health factors are created to link specific answers to choices in the reminder/templates. This creates data points to retrieve information from centralized VA data systems (e.g., Corporate Data Warehouse). For the
demonstration project, health factors were created or modified by lead project staff and then exported with the reminders or templates and loaded into CPRS at the eight participating sites.

The three clinical reminders were:

1. **Tobacco Pack-Year Reminder**, which was active only for patients in the target age range for LCS (i.e., ages 55-80 years), who did not have a history of lung, pancreatic, liver or esophageal cancer, did not have a health factor on file indicating a life expectancy of less than 6 months (all permanent exclusions), and had not had a chest CT in the past 12 months (temporary exclusion). Primary care staff completed the reminder by indicating if the patient was a lifetime non-smoker, a former smoker or a current smoker. Former smokers who quit less than 15 years ago and all current smokers were asked how long they smoked and on average, how many cigarettes they smoked each day. A CPRS decision support application used this information to calculate the pack-year history (number of packs smoked per day times the number of years smoked). This reminder was built for the LCSDP since there is not a VHA system-wide smoking reminder and no known local facility smoking reminders that capture pack-year or years since quitting information. The demonstration sites were encouraged to activate this reminder for all Primary Care teams, so that we could obtain an estimate of the total number of Veteran patients who would meet the initial age and smoking history criteria.

2. **Initial Lung Cancer Screen (Provider) Reminder**, which was completed by providers for patients who met the smoking history criteria (current smoker or former who had quit less than 15 years previously, with 30 pack-years or more of smoking) to indicate if the patients had other clinical exclusions that would not make them good candidates for LCS. “Other clinical exclusions” included symptoms suggestive of lung cancer, estimated life expectancy of less than 5 years or other exclusions determined by provider assessment. If the patient did not have any other exclusions and thus was deemed appropriate for LCS discussion, the provider could choose to: 1) refer the patients to the LCS coordinator for discussion of screening; or 2) continue the process by discussing screening with the patient, documenting the patient's decision concerning screening (to be screened or decline screening for one year or indefinitely) and ordering the LDCT scan for patients who chose to be screened. In addition, patients who were current smokers were asked if they were interested in quitting. Sites could input their local tobacco cessation referrals and prescription medication orders into the reminder if desired. At all sites, patients had the opportunity for tobacco cessation counseling, nicotine replacement therapy, or other medications to assist with tobacco cessation. This reminder was activated only for providers who were actively participating in the LCS process. As noted above, the number of providers offering LCS was intentionally kept small initially and then gradually increased, as sites were ready to expand their programs.

3. **Repeat Lung Cancer Screen (Provider) Reminder**, which allowed providers to re-assess patients’ appropriateness for annual screening on a yearly basis, as long as they continued to meet the age and smoking history criteria. The reminder did not appear for patients who reached the upper age limit or, if former smokers, who reached the 15-year mark since quitting. This reminder was activated only for providers for whom the Initial Provider Reminder was active.

**D. Documentation template for site LCS coordinators to record patient information:** The documentation template was an electronic tool in CPRS that allowed coordinators to document patient information about screening process, results, and follow-up. The template consisted of sections that matched patients’ flow through the screening process. Coordinators chose the template section that was appropriate to each patient’s care and entered his/her clinical information. That process generated health factors that populated the patient tracking tool and were used for nodule follow-up or to trigger clinical reminders for repeat screening.

**E. Read-only patient tracking tool/database for coordinators to monitor patients’ status in the program:** A tracking tool, a read-only Access database developed by the Pittsburgh VERC, was installed at each of the 8 sites for use by the LCS coordinators to track patients who were being screened, those with nodules, and those undergoing diagnostic evaluation for possible lung cancer. This tool, which was

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automatically populated based on health factors identifying patients in the LCS program, was designed to support the daily clinical work of the LCS coordinators, providing for them lists of patients in each stage of the screening and follow-up process. The tool was frequently modified by the VERC during the LCSDP, as coordinators identified changes that would better assist them in their daily work.

F. Patient education materials: Patient education materials were developed by NCP for use by providers and coordinators to help patients make decisions about whether they wanted to be screened. The main brochure, *Screening for Lung Cancer* (17), was a shared decision-making tool, which gave information about the benefits and harms of screening, shown in eFigure 2, and helped patients think through their values and preferences about screening. Other materials encouraged smokers with negative LDCT screening exams to quit smoking (*My Lung Cancer Screening Did Not Show Cancer – Now What?*) or explained the meaning of a small nodule result on a LDCT screening exam and discussed why surveillance of the nodule is often recommended, rather than immediate work-up (*Small Lung Nodules – What You Need to Know*). This was adapted from a brochure initially developed by Chris Slatore, MD, MS, Oregon Health Sciences University, Portland, OR.

G. Radiology report dictation guide and nodule follow-up guidelines: The radiology dictation guide was developed to encourage radiologists reading the LDCTs to report the findings in a standard way, so that coordinators, who entered information about the LDCT findings into their documentation template, could easily find the information needed. The dictation was to include:

- Date of comparison exam, if available
- Technique and dose used
- Findings
  - Nodules
    - Average diameter
    - Density
    - Location
    - Image
    - Suspicious features
    - Other characteristics
    - Change in diameter (if prior CT available)
  - Other lung findings
    - Mediastinum
    - Pleura
    - Bones and soft tissues
    - Visualized upper abdomen
  - Impression, including:
    - Nodule imaging follow-up recommendations
    - Incidental findings for which follow-up may be indicated
      - Thyroid nodules
      - Abdominal masses/cysts/other findings
      - Aortic dilatation/aneurysm
      - Infectious/inflammatory/interstitial processes
      - Other

The guide also provided detailed follow-up recommendations for nodules of various sizes and characteristics, to ensure a consistent approach among the 8 sites and multiple radiologists. The nodule follow-up guidelines were based on slightly modified Fleishner Society guidelines (18,19), with input from radiology and pulmonary members of the Steering Committee. Laminated copies of the dictation guide/nodule guidelines were distributed to all radiologists at each site who read LDCTs. Participating radiologists received training in these materials through conference calls led by the Chief Consultant for Diagnostic Services. At the conclusion of the project, the guide was extensively re-written to incorporate American College of Radiology lung cancer screening guidelines.
H. Frequently-asked questions document for clinicians: A “frequently asked questions” document for clinicians was shared with the 8 sites to help them explain the LCSDP to participating clinicians and what it meant for their clinical work.

Training of LCS Coordinators and Site Radiologists

LCS coordinators received two hours of initial training by conference call from NCP staff on the rationale for lung cancer screening; the importance of shared decision-making, including the decision aid and other patient education materials developed for the project; smoking cessation counseling; the use of the clinical reminders, the documentation template, and the patient tracking tool/database; and reporting requirements back to NCP and the evaluation team. Weekly hour-long conference calls were held with the coordinators to answer questions and address issues and problems, as they arose. The NCP Project Coordinator also had calls with individual coordinators as needed for further training and assistance. The coordinators were provided with a set of electronic slides and print materials for use in training primary staff about lung cancer screening and the demonstration project. Training times varied, depending on time available at each site.

Site radiologists received an interpretation guide that defined CT acquisition protocols, how to describe and measure nodules, how to report incidental findings, a dictation format, and treatment recommendations. They also received a summary of the guide to be placed at their workstations. The guide was presented on an initial hour-long conference call; several subsequent conference calls were held to reinforce the guidance and to answer questions.

Quality Assurance Review Activities

To ensure that the LCS coordinators were correctly recording patient information into the documentation template, including transcription of LDCT results, document of follow-up interval when indicated, and documentation of incidental findings, a peer quality assurance process was undertaken in August 2014, about half-way through the LCSDP. In this process, a random sample of 35 patients followed by coordinators at 7 of the 8 sites was selected (the 8th site had not yet hired a coordinator). The seven coordinators reviewed clinical information about 5 patients from 5 of the other 6 sites. Each patient’s information was sent anonymously and securely to another coordinator for review. Summary and individual coordinator reports were then generated. Overall, documentation was consistent regarding selection of the appropriate section of the coordinator template (97%), documentation of the highest-risk nodule (100%), and notification of findings to patients in a timely manner (96%). Documentation was less consistent for follow-up intervals matching the radiology report (90%), incidental findings (83%), and notifying primary care providers of incidental findings (58%). Some of the lower consistencies for incidental findings and notification of primary care providers concerning incidental findings could be related to the incidental finding already being on the patient’s problem list or survey-related issues.

A quality assurance review was also conducted regarding radiologists’ interpretations of LDCT and documentation of findings. In August, 2014, a random sample of 63 LDCT scans from each site (8 scans from 6 sites, 9 scans from 1 site and 6 scans from 1 site) was read by a VA radiologist identified by the National Radiology Program who had experience reading LDCT scans for LCS but who was not affiliated with any of the project sites. This radiologist completed an electronic assessment form for each patient. The level of agreement between the radiologist originally reading the scan and the radiologist providing a second read of the scan was then determined. There were potential questions related to adequacy of the image quality for almost half of the scans (47.6%) and appropriate radiation dose (less than 3 mGy) for 39.7% of scans. For 20-25% of the sample, there were clinical differences between impressions of the reviewing radiologist in relation to identification of nodules needing to be tracked and what was reported by the site radiologists. For example, 22.2% of nodules the reviewing radiologist considered needing to be tracked were not indicated as such by the site radiologist. The reviewer did not consider the location of the nodule needing to be tracked to have been reported correctly for 20.6% of nodules, and the diameter was not considered correctly measured by the site radiologist 25.4% of the time. The clinical significance of these differences was not fully assessed; many may have been small differences that would have had minimal clinical impact.
Health Factors and ICD Codes Used

The focus of this article is on the initial round of screening, so only health factors for positive findings (nodules to be tracked and suspicious findings requiring further evaluation) or incidental findings that were recorded within 50 days of the initial screening LDCT were used. The 50-day time frame was chosen based on manual review and counts of the distribution of the dates health factors were entered into CPRS. Health factors entered after that time were not used because they may have been related to surveillance of nodules, rather than screening. Because the time necessary to confirm a lung cancer diagnosis can vary based on a patient’s clinical circumstances, codes for lung cancer were searched for up to 330 days (11 months) following the LDCT. A diagnosis of lung cancer is based on a patient having one of the following ICD codes for malignant neoplasm of trachea, bronchus, lung or malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs: ICD-9-CM codes 162.0, 162.2, 162.3, 162.4, 162.5, 162.8, 162.9, 165.0, 165.8, and 165.9 or ICD-10-CM codes C33, C34.00, C34.01, C34.02, C34.10, C34.11, C34.12, C34.2, C34.30, C34.31, C34.32, C34.80, C34.81, C34.82, C34.90, C34.91, C34.92, C39.0, and C39.9. Lung cancer cases were confirmed by medical record review for staging and histology.

Determining Initial LDCT and Results Dates

When a patient agreed to lung cancer screening, an electronic order was sent to radiology to conduct an LDCT. On the day of the scheduled radiology appointment, the order was marked as “started,” the LDCT was conducted, and then the results were determined by a radiologist. When the report was entered in the medical record, the original order was then marked as “completed.” Therefore, for each order placed for an LDCT, both a “started” and “completed” date were typically available. As noted in the Methods section, the initial LDCT date was defined as the completed date for the LDCT order in CPRS. However, there are a variety of scenarios in which the order completion date can be an inaccurate representation of the date on which the initial LDCT actually occurred. For example, there may be no record of an electronic LDCT order (and therefore no order dates), orders may be started but subsequently rescheduled, and radiologists may not always mark orders complete in a timely manner, even though results may have been sent to referring providers. In using administrative medical record data, such scenarios are not unexpected.

There were 104 patients whose initial LDCT completion dates occurred subsequent to at least one of their result dates. Replacing the order completion date with the order start date resolved this discrepancy for 70 of those patients. For the remaining 34 patients for whom this change failed to resolve the discrepancy, full EMR review was performed to determine the date on which the initial LDCT actually occurred and, if applicable, dates on which positive or incidental findings were identified.

Details of Incidental Findings

Radiologists and coordinators were asked to record only those incidental findings that would likely require follow-up or further evaluation. In an effort to minimize data input, they were given broad categories to characterize these findings: abdominal abnormalities; abdominal or thoracic aortic dilation or aneurysm; Infectious, inflammatory, or interstitial process; thyroid nodule; or other incidental findings. Nearly half of the reported findings were reported as “other”. This category included a wide variety of findings that were not all well described but most were reported to be emphysema and coronary artery calcifications. We did not collect data on follow-up diagnostic procedures that may have resulted from identification of these findings.
eAppendix 2. Participants in the VHA Lung Cancer Screening Demonstration Project

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*Each of the Demonstration Site Lung Cancer Screening Coordinators received full-time salary support, funded by the Veterans Health Administration, for their work.
^ The Pittsburgh Veterans Engineering Resource Center and the Durham VA Health Services Research & Development Center of Innovation both received funds from the Veterans Health Administration to support their work but individual salary support for Center staff was not provided.
Figure 1. Map of LCS Clinical Demonstration Sites

- Portland, OR
- Minneapolis, MN
- Ann Arbor, MI
- Cincinnati, OH
- New York, NY
- Durham, NC
- Charleston, SC
eFigure 2. Benefits and Harms Decision Aid

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

<table>
<thead>
<tr>
<th>SCREENED (1000 PEOPLE)</th>
<th>NOT SCREENED (1000 PEOPLE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BENEFITS ADDED by Screening</strong></td>
<td><strong>Harms Added by Screening</strong></td>
</tr>
<tr>
<td>16 PEOPLE DIED from lung cancer in a group of 1000 people who were screened. This was 3 FEWER DEATHS from lung cancer compared to the NOT SCREENED group.</td>
<td>21 PEOPLE DIED from lung cancer in a group of 1000 people who were not screened. This was 5 ADDITIONAL DEATHS from lung cancer compared to the group that was screened.</td>
</tr>
<tr>
<td>365 IN 1000 PEOPLE SCREENED were given a FALSE POSITIVE result.</td>
<td></td>
</tr>
<tr>
<td>25 of those false positive results led to an INVASIVE PROCEDURE.</td>
<td></td>
</tr>
<tr>
<td>3 PEOPLE developed a MAJOR COMPLICATION from the invasive procedure.</td>
<td></td>
</tr>
</tbody>
</table>

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

The information in this graph was obtained from: Patient and Physician Guide: National Lung Screening Trial (NLST). See: https://www.cancer.gov/newscenter/pressreleases/2012/NLST/LungScreeningGuideForPatients

Reference
**eTable. Incidental Findings**

<table>
<thead>
<tr>
<th>Type of Incidental Finding</th>
<th># Findings (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal abnormalities (i.e., mass, cyst, or other finding)</td>
<td>146 (14.0%)</td>
</tr>
<tr>
<td>Abdominal or thoracic aortic dilation or aneurysm</td>
<td>87 (8.3%)</td>
</tr>
<tr>
<td>Infectious, inflammatory, or interstitial process</td>
<td>265 (25.4%)</td>
</tr>
<tr>
<td>Thyroid nodule</td>
<td>25 (2.4%)</td>
</tr>
<tr>
<td>Other incidental findings (e.g., emphysema, coronary artery calcifications, hernias, etc.)</td>
<td>521 (49.9%)</td>
</tr>
<tr>
<td><strong>Total Number of Findings</strong></td>
<td><strong>1,044</strong></td>
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</tbody>
</table>