Veterans Health Administration Lung Cancer Screening Demonstration Project: Results & Lessons Learned

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Background: Veterans Health Administration (VA)

• Nation’s largest integrated healthcare system
  – 8.3 million Veterans treated per year
  – 150+ medical facilities, 1,400 community-based outpatient clinics

• Approximately **7,500 cases of lung cancer** are diagnosed in VA-enrolled patients each year; about 5,500 deaths occur.

• Due to high prevalence of ever smoking (70%), many Veterans in VA at increased risk
Overview of the VA Demonstration Project

• The eight-site Lung Cancer Screening (LCS) demonstration project was conducted from 2013-2015
• It was designed to provide guidance on key aspects of potentially implementing low-dose computed tomography (LDCT) for lung cancer screening across the healthcare system
• Smoking cessation resources already widely available in VA
• Central VA funding was provided for:
  – Clinical coordinator for each site
  – Development of electronic tools
  – Evaluation of project
  – 3 years total
The purpose was to learn about:

1) The number of Veterans who meet criteria for screening and their interest in undergoing screening

2) The impact on primary care services to identify appropriate patients and discuss screening

3) The impact on radiology services to add additional procedures to their schedules and to read LDCT scans;

4) The impact on pulmonary, surgery, medical and radiation oncology services to provide follow-up care
Sites with expertise in lung nodule detection and lung cancer treatment, but who were not already engaged in lung screening research, were chosen for this demonstration project.
Components of the LCS Program

Primary care patients at the eight demonstration sites
- Patients were assessed for appropriateness for LCS
- Electronic clinical reminders were built to select patients eligible for LCS.

Developed patient education materials
- Assist patients in making an informed decision about whether to be screened for lung cancer.
- Handouts for patients explaining the meaning of negative and positive LDCT results.

Development of an Electronic Tracking Method
- Keep track of patients in the screening program
- LCS Coordinators used this database and electronic templates to document care in the medical record
- Used to ensure that patients were not lost to follow-up
Patient Educational Materials - Screening

Screening for Lung Cancer

Should I be screened for lung cancer?
You should consider being screened if you have all three of these risk factors:
- 55–79 years old and
- A current smoker or former smoker who quit less than 15 years ago and
- You have a smoking history of at least 30 pack-years (this means 1 pack per day for 30 years or 2 packs a day for 15 years, etc.). The more you smoke and the longer you smoke, the higher your risk for lung cancer.

What is screening?
- Screening is looking for a disease before symptoms appear. Screening helps find lung cancer in an earlier, more treatable stage.
- In a group of 1000 people screened once a year for 3 years, 3 fewer people in 1000 died of lung cancer after 6 years. This means, instead of 21 people, 18 people per 1000 died of lung cancer.

Why do we not screen everyone?
- There is no proof from research that it is best to screen everyone.
- Screening everyone can cause more harm than good. False alarms lead to more testing and risk of harm.

Is there a cost for the screening?
If you are charged co-pays for your VA visits, you will be charged a $50.00 co-pay for the day you have the CT scan visit.

How is screening for lung cancer done?
- We screen for lung cancer using a low-dose chest Computerized Tomography scan (CT Scan). This CT scan gives a detailed picture of your lungs.
- You will go to the Radiology (x-ray) department for your CT scan. You will lie on a table and raise your arms above your head. Then the table will slide into the CT scanner. We will ask you to hold your breath for a few seconds during the scan.

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>18 PEOPLE DIED from lung cancer in group of 1000 people who were screened. This was 3 FEWER DEATHS from lung cancer compared to the NOT SCREENED group.</td>
<td></td>
</tr>
<tr>
<td>21 PEOPLE DIED from lung cancer in group of 1000 people who were not screened. This was 3 ADDITIONAL DEATHS from lung cancer compared to the group that was screened.</td>
<td></td>
</tr>
</tbody>
</table>

3 PEOPLE developed a MAJOR complication from the invasive procedure.

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

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

Small Lung Nodules: What You Need to Know

Why have I been given this handout?
One or more small lung nodules were seen on your low-dose chest CT that was done as a screening test for lung cancer.

What is a lung nodule?
Commonly called a “spot on the lung,” a nodule is a round area that is more solid than normal lung tissue. It shows up as a white spot on a CT (“cat”) scan.

What is considered a small lung nodule?
A nodule is generally considered small if it is less than 9 mm in diameter.

Why should I care about having a small nodule?
Usually a small nodule (less than 9mm) is not a cancer; but sometimes it can be a cancer. The best ways to tell if a small nodule is cancer are by:
1. Seeing how it looks on the CT scan, or
2. Seeing whether it grows over time.

How likely is the nodule an early lung cancer?
Most small nodules are not early lung cancer. Fewer than 5 percent of small nodules, or 5 out of 100, turn out to be cancer.

Did you just say “lung cancer”?
Hearing the words “lung cancer” can be distressing. It is normal to be worried and anxious when there is even a small chance you might have lung cancer. Please talk with your health care team about any worries or concerns that you have.

What will happen next?
Your provider will probably recommend getting repeat CT scans to keep a close eye on the small nodule to see if it changes. We call this “active surveillance.”
• Most non-cancer nodules won’t grow so seeing that they don’t get bigger after a period of time is reassuring.
• On the other hand, if the nodule is getting bigger, it should be looked at more closely to see if it is lung cancer.

Why shouldn’t I get a biopsy to make sure the nodule isn’t cancer?
• A biopsy means removing a small piece of your lung in order to look at it under a microscope. Biopsies are usually not recommended when nodules are small because it is very difficult to biopsy them safely. Doing a biopsy can cause harm such as trouble breathing, bleeding, or infection.
• Biopsies are often done for nodules larger than 9mm.

My Lung Cancer Screening Did Not Show Lung Cancer: Now What?

Your lung cancer screening CT scan did NOT show lung cancer. Now is a good time to decrease your risk for lung cancer.
• This result does not mean that you will never get lung cancer.
• Talk with your health care team about when you should be screened again.

What can I do to decrease my risk?
• If you have stopped smoking, you have already taken the most important step to decrease your risk for lung cancer and other illnesses.
• You can also decrease your risk by not being around others who smoke. This may be a good time to encourage those around you to consider quitting, as well.
• If you are still smoking, quitting now will lower your chance of developing lung cancer in the future.
• Quitting smoking is also the most powerful thing you can do to lower your chances of having or dying from a variety of diseases, such as heart disease, stroke, and other cancers.
• By quitting, you can also protect the health of those you care about, by reducing their exposure to secondhand smoke and reducing their risk for a number of illnesses, as well.

Help to quit smoking for good is available!
Quitting smoking isn’t easy and many smokers who want to quit have tried many times before. The good news is that we know more now about what helps smokers quit than we ever have.
• If you think that you may be ready to talk with someone about quitting smoking or if you need help to stay quit, make an appointment to talk with your primary care provider to learn more about what is available to help you quit.
• Someone on your primary care team can help you by providing information about setting a quit date, getting support, and providing a prescription for smoking cessation medications as part of your quit attempt.
• You and your provider can discuss a treatment plan that will meet your needs and that can include resources, such as a smoking cessation class or group, a telephone counseling quit line, online resources, or a referral to a member of your health care team who can help you with quitting.

You don’t have to quit smoking on your own, VA can help!

Ask your provider when you should get your next CT scan.

REMEmber: The best way to prevent lung cancer is to STOP SMOKING. If you are still smoking, talk with your VA health care team and call 1-888-QUIT-VET (1-888-774-8883). WE CAN HELP!
Demographics of Patients Who Agreed to be Screened (N = 2,452)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean Age</strong></td>
<td>64.8 Years</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td>96.5% Male</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td>71% White, 15% Black</td>
</tr>
<tr>
<td></td>
<td>93% Not Hispanic or Latino</td>
</tr>
<tr>
<td><strong>Smoking Status</strong></td>
<td>55% Current smoker &amp; ≥30 pack-years</td>
</tr>
<tr>
<td></td>
<td>41% Former smoker, quit &lt;15yrs ago &amp; ≥30 pack-yrs</td>
</tr>
<tr>
<td></td>
<td>Mean Pack-Years Smoked: 54.4 Years</td>
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</tbody>
</table>
LCS Results Through June 30, 2015

Patients Whose Smoking History Could Not be Determined 39% (N = 36,555)

 Patients with Smoking Status and Tobacco Pack-year Data 61% (N = 56,478)

 Patients with Confirmed Lung Cancer 1.3% (N = 28)

 Primary Care Patients Who Met Age & Life-Expectancy Criteria N = 93,033

 Patients Did Not Meet Smoking History Criteria 68% (N = 38,395)

 Patients with Suspicious Findings, Not Lung Cancer 2.0% (N = 42)

 Patients Did Not Agree or Did Not Complete LDCT 50% (N = 2,140)

 Provider Assessed Not Appropriate for LDCT or Not Assessed 77% (N = 13,837)

 Provider Assessed for LDCT Appropriateness 23% (N = 4,246)

 Patients Who Met Smoking History Criteria 32% (N = 18,083)

 Patients Who Met Smoking History Criteria 32% (N = 18,083)

 Patients with Nodules to be Tracked 56.3% (N = 1,186)

 Continue Annual Lung Cancer Screening 40.4% (N = 850)

 Patients Whose Smoking History Could Not be Determined 39% (N = 36,555)

 Incidental Findings 40.6% (N = 854)

 E.g., emphysema, coronary artery calcifications, abdominal masses or cysts

59.6% (n = 1,256) of Veterans had positive tests requiring tracking or further workup
## LCS Cancer Diagnosed (as of Sept 30, 2015)

Preliminary Findings Documented to Date

<table>
<thead>
<tr>
<th>Type</th>
<th>Stage→</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Unknown</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Adenocarcinoma</td>
<td>4</td>
<td>7</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Squamous-cell</td>
<td>4</td>
<td>9</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td></td>
<td>12</td>
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<tr>
<td>Other NSCLC*</td>
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<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>3</td>
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<tr>
<td>Small-cell</td>
<td>4</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Unknown</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>17</td>
<td>2</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>28</td>
</tr>
</tbody>
</table>

*Non-Small Cell Lung Cancer*
Potential LCS-eligible Population in VHA

2.8 Million Primary Care Patients
- Aged 55 – 80 years
- Without certain cancers
- Without life expectancy < 6 months

~890,000 Patients Meeting Smoking Criteria
- Current smoker & ≥30 pack-year history
- Former smoker & quit <15 years ago

~750,000 Patients Potentially to be Offered LCS
- Did not have other medical exclusions
- Provider assessed appropriate for LCS
The purpose of a budget impact analysis was to answer the question, “What is the cost of conducting one round of LDCT LCS?”

Analysis conducted from a health care system perspective

The analysis accounted for:

- Screening enrollment costs (staff time)
- Cost of performing LDCT scans (procedure costs and staff time)
- Cost of follow-up and tracking (procedure costs + staff time)
Budget Impact Analysis

- The estimated cost for an initial round of screening all patients meeting guideline criteria, from a health care system perspective, was between $531 million to $908 million in the 11 months following the initial screening, assuming that all patients could be screened at once.
Results from Qualitative Interviews

Facility Resources
- Need for careful coordination of facility resources and staff
- Between radiology, primary care, pulmonary medicine, oncology services, and other disciplines.

LCS Coordinator
- Critical role in tracking, follow-up, facilitating communication between patients and providers
- In coordinating services involved in lung cancer screening

Tracking System
- Need a robust system-wide tracking system and registry
- Assist in follow-up of individuals who are receiving lung cancer screening

Primary Care
- Time and effort to screen and assessment patients
- Assist with informed decision-making, and coordinate follow-up care for positive findings
Lessons Learned: Staff and Tools

• Systematic identification of patients eligible for LCS necessitates **dedicated LCS coordinators**
  – Shared decision making, tracking, communication with primary care, radiology, oncology, pulmonary and others

• A standardized protocol for local **nodule tracking is necessary**; a national tracking system would be ideal
  – Central database or registry that communicates with electronic medical record and tracking system
  – Support needed for technical and clinical updates and maintenance
Lessons Learned: Implementation

• Lung cancer screening should be discussed only with patients who meet screening criteria. Patients should understand the small likelihood of benefit and the larger likelihood of harm.

• The level of commitment to LCS among providers (e.g., based on perception of strength of evidence) was variable in this project, creating a barrier to change.

• A strong partnership is needed between services including clinical informatics, Radiology, and Primary Care.
Lessons Learned: Resources

• Significant **resources** would be needed to implement a systematic approach to lung cancer screening
  – Radiology resources (staff, CT machines, maintenance)
  – Multidisciplinary team (radiology, oncology, surgery, pulmonary)
  – Information Technology support of tracking system and electronic tools
  – Primary care clinical staff time for initial training, shared decision making, follow up of findings, annual screening
Lessons Learned: Central Coordination

• A designated national LCS management team to provide ongoing guidance, support, and oversight is crucial
  – A system-wide implementation would require a significant, long-term investment to stand up an entire program
  – Communication and system-wide implementation of updates: LungRADS, changes in screening guidance, coding, etc.
  – A smaller-scale implementation would still require support to establish guidance and protocols
Conclusions

• Implementing a lung cancer screening program in VA involves a complex program of care to coordinate services and track findings.

• Approximately two-thirds of the individuals screened in this project had abnormal findings, some of which required tracking and clinical follow up.
Conclusions

• If a proactive program of lung cancer screening is implemented in a health care system, resource needs will be significant.

• Smoking cessation is the most important intervention to prevent the incidence of lung cancer and to decrease the morbidity and mortality associated with lung cancer.
Questions?

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Background slides
Demonstration Project Evaluation Methods

The four-part evaluation was conducted by a Durham HSR&D team:

1) Estimating the proportion of VA patients who may be eligible for LCS in VA and their clinical experience through the screening process

2) Examining quality of clear clinical documentation and coordination of care for LCS

3) Conducting economic analyses of lung cancer screening that estimate the budgetary impact of doing an initial round of screening for all clinically-appropriate patients in VA

4) Synthesizing information on the facilitators and barriers in establishing a lung cancer screening program in VA focused on organizational-level considerations
# Evaluation Data Sources

<table>
<thead>
<tr>
<th>Medical Record</th>
<th>Quality Assurance</th>
<th>Site Reports</th>
<th>Cost Estimation</th>
<th>Qualitative Interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Data from clinical decision support tools tracking the process of implementing LCS</td>
<td>• Summary reports generated through the quality assurance process for clinical documentation</td>
<td>• Monthly site reports detailing implementation issues encountered</td>
<td>• VA’s Managerial Cost Account System data</td>
<td>• Two rounds conducted during the early and late stages of the project</td>
</tr>
</tbody>
</table>
Making a Personal Decision about Whether to Be Screened for Lung Cancer

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

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

   **Reasons to be screened or not to be screened**

   **Yes — Be screened for lung cancer:**
   1. ____________________________________________
   2. ____________________________________________
   3. ____________________________________________

   **No — Don’t be screened for lung cancer:**
   1. ____________________________________________
   2. ____________________________________________
   3. ____________________________________________

   [Scale of 0 to 10 for the importance of each reason]

2. If you checked “Unsure,” think about what you need to reach a decision.
   - I need more information about the risks and benefits of screening.
   - Review the information provided in this document.
   - List your questions.
   - Talk with your health care team.

   - I need to think more about the reasons to be screened and not to be screened for lung cancer.
   - Think about the importance you gave to the pros and cons, and the reasons behind your ratings.
   - Talk with Veterans who have been screened for lung cancer.
   - Read stories about others who have made a decision.
   - Talk with others about what matters most to you.

   - I need support from others to make a decision.
   - Discuss your thinking with a trusted person (for example, friends, family, professionals).
   - Find help to support your choice (for example, transportation, someone to come with me).

   - I am not sure about the best choice for me.
   - List anything else you need to make your decision.

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

Non-Contrast Low-Dose Chest CT for Lung Cancer Screening

Comparison: [ ] (date) [ ] (None)

Technique: [ ] (state if study is of limited quality)
[ ] (presence of LDCT)

Findings:
- Nodule: The nodule of greatest concern (usually the largest nodule that is not clearly benign) should be listed including details about its location, size, and other features (e.g., spiculation, growth, etc.) If both solid and subsolid nodules are present, the largest in each category should be listed. Any nodules with suspicious features (e.g., spiculation, growth, etc.) should also be listed. Nodules that are not specifically detailed should be referenced for a general statement, such as “Several other smaller nodules are present.”

- Average diameter:
- Density: [ ] solid [ ] ground-glass [ ] mixed solid/ground glass
- Location: [ ] hilar [ ] mediastinal
- Image: [ ] series [ ] image
- Suspicious features: [ ] spiculated border [ ] other
- Other characteristics: [ ] cavitated [ ] other
- Change in diameter: [ ] (if prior CT is available, amount and over what time)

Other lung findings: [ ]
Mediastinum: [ ]
Pleura: [ ]
Bones and soft tissues: [ ]
Visualized upper abdomen: [ ]

Impression: 1. [ ] (include imaging follow-up recommendation)
2. [ ]

- Incidental findings for which follow-up may be indicated: [ ] thyroid nodules, abdominal masses/cysts, findings, cardiac dilatation/aneurysm, infections/inflammatory/interstitial processes, other (specify)
Notes on Implementation

• There was considerable variation in implementation of lung cancer screening:
  – NCP provided implementation guidance and led the development of tools and resources for the project
  – Variations were seen in the implementation and use of clinical reminders at each facility as well as in the provider responsible for ordering the initial LDCT
Quality Assurance

• Radiology
  – Review of 63 scans that included all sites
  – Adequacy of image quality was questionable in 47.6% of scans
  – There were also important clinical differences in the interpretation of nodule identification between the reviewing expert and the site-based radiologists in 20-25% of the LDCT interpretations.

• Clinical Documentation
  – LCS Coordinator peer review
  – 100% agreement in documentation of highest risk nodules
  – 96% had documentation of patient notification of LDCT results in a timely manner