VHA Demonstration Project for Lung Cancer Screening Using Low-Dose Chest CT Screening

ATS
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(1) San Francisco VA
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Disclosures for JKB

• Co-site director for lung cancer screening program at SFVAMC
• Helped organize this VA Interest Group Meeting
Goals of talk

• Describe the implementation of the VA’s 8-site Demonstration Project for Lung Cancer Screening
• Show preliminary data, as of 3/30/2015, from the 8 sites, as well as current updated data from one site (SFVAMC)
• Compare data from VA’s Demonstration Project to those from National Lung Screening Trial
• Suggest resources that would be needed to broaden availability of lung cancer screening within the VA
Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

The National Lung Screening Trial Research Team*
Methods (NLST)

Eligibility:

• 55 - 74 years of age
• 30 PY’s smoking or quit within past 15 years
• [9 million Americans would meet inclusion criteria]

53,454 persons enrolled

• 26,722 randomized to low dose-CT
• 26,732 randomized to CXR as control

Period of enrollment: 8/02 – 4/04

• Screening : 8/02 – 9/07
• Data collection: through 12/09
• Median F/U: 6.5 years
Screenings (NLST):

3 screenings:
   T0, T1, T2 at 1 year intervals

Positive test result =
   • Low dose CT scan: non-calcified nodule measuring at least 4mm in any diameter
   • Chest x-ray: any noncalcified nodule or mass
   • Either: adenopathy, effusions could be called positive
# NLST Results

<table>
<thead>
<tr>
<th></th>
<th>Low Dose CT</th>
<th>Chest X-ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive screening exams</td>
<td>24%</td>
<td>7%</td>
</tr>
<tr>
<td>False positive exams</td>
<td>96%</td>
<td>95%</td>
</tr>
<tr>
<td>Participants with ≥1 positive</td>
<td>39%</td>
<td>16%</td>
</tr>
<tr>
<td>exam</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung cancers diagnosed</td>
<td>645 cases/100,000 person-years</td>
<td>572 cases/100,000 person-years</td>
</tr>
<tr>
<td>Lung cancer mortality</td>
<td>247 deaths/100,000 person-years</td>
<td>309 deaths/100,000 person-years</td>
</tr>
<tr>
<td></td>
<td><strong>20% relative reduction</strong></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>7% relative reduction (due to</td>
<td>Comparison</td>
</tr>
<tr>
<td></td>
<td>lung cancer mortality reduction)</td>
<td></td>
</tr>
<tr>
<td>Number needed to screen for</td>
<td>320</td>
<td>NA</td>
</tr>
<tr>
<td>3 years to prevent 1 death</td>
<td></td>
<td></td>
</tr>
<tr>
<td>over 7 years</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lung cancers in NLST by time of detection using LDCT scans

<table>
<thead>
<tr>
<th>Screening Round</th>
<th>Total Population</th>
<th>Number of New Lung Cancers</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Chest CT (T0)</td>
<td>26,309</td>
<td>270</td>
</tr>
<tr>
<td>Second Chest CT (T1)</td>
<td>24,715</td>
<td>168</td>
</tr>
<tr>
<td>Third Chest CT (T2)</td>
<td>24,102</td>
<td>211</td>
</tr>
<tr>
<td>After 3 CTs</td>
<td></td>
<td>367</td>
</tr>
</tbody>
</table>
Early Detection with Low-Dose Chest CT Scans in NLST

<table>
<thead>
<tr>
<th>Stage</th>
<th>Positive Screening Test (N=649)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA</td>
<td>329/635 (51.8)</td>
</tr>
<tr>
<td>IB</td>
<td>71/635 (11.2)</td>
</tr>
<tr>
<td>IIA</td>
<td>26/635 (4.1)</td>
</tr>
<tr>
<td>IIB</td>
<td>20/635 (3.1)</td>
</tr>
<tr>
<td>IIIA</td>
<td>59/635 (9.3)</td>
</tr>
<tr>
<td>IIIIB</td>
<td>49/635 (7.7)</td>
</tr>
<tr>
<td>IV</td>
<td>81/635 (12.8)</td>
</tr>
</tbody>
</table>

5-Year Survival:
- IA: 73%
- IB: 58%
- IIA: 46%
- IIB: 36%
- IIIA: 24%
- IIIIB: 9%
- IV: 13%

Survival, Years
Lung Cancer Screening Demonstration Project in the VA: Timeline

- VHA tasks NCP with development of demonstration project (May 2012)
- NLST results published (June 28, 2011)
- Steering Committee formed (August 2012)
- Demonstration sites selected (February 2013)
- First sites begin screening patients (summer-fall 2013)
- USPSTF releases recommendations (December 31, 2013)
- LCSDP completed (September 30, 2015)
- CMS decides to provide LCS as one of its preventative services (Feb 2015)
Questions for VA’s Clinical Demonstration Project

• What is the uptake of screening among Veterans and their PCP’s?
• What are the outcomes in Veterans?
• Can screening be implemented in the VA with the same level of safety as in NLST?
• What additional resources would be needed to begin more wide-spread use of LDCT for screening in the VA?
Program Elements

• Full-time coordinator at each site
• Accurate identification of eligible patients from EHR
• Shared decision-making, embedded smoking cessation
• Web based tracking tool for LCS and lung nodules
• Multidisciplinary conferences for cancer/suspected cancer
What new resources did the VA provide at each site?

• **Full-time coordinator at each site**

• Accurate identification of eligible patients from EHR: clinical reminders

• Shared decision-making, embedded smoking cessation

• **Web based tracking tool for LCS and lung nodules**

• Multidisciplinary conferences for cancer/suspected ca

• ** Lots of education for site directors and coordinators**
Patient Selection Criteria for VA LCS DP*

Aged 55 – 80
Active smoking or quit < 15 years ago
At least 30 pack-year smoking history

Exclusions:
- history of lung, liver, pancreatic, or esophageal cancer
- life expectancy < 6 months for other reasons

*As per USPSTF 2013 Guidelines
Use of clinical reminders to identify patients during visits to primary care clinics

**TPY Reminder**
- On if patient 55-80
- LVN completed

**Provider Reminder**
- On if TPY criteria met
- PCP completed
Screening for Lung Cancer

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

Should I be screened for lung cancer?
You should consider being screened if you have all three of these risk factors:
- 55–80 years old
- A current smoker or a former smoker who quit less than 15 years ago
- A smoking history of at least 30 pack-years (this means 1 pack per day for 30 years or 2 packs a day for 15 years, etc.). The more you smoke and the longer you smoke, the higher your risk for lung cancer.

What is screening?
- Screening is looking for a disease before a person has any symptoms. Screening helps find lung cancer in an early, more treatable stage.
- Based on research, if a group of 1000 people were screened once a year for 3 years, 3 fewer people in 1000 would die of lung cancer after 6 years. This means that, instead of 21 people, 18 people per 1000 would die of lung cancer.

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

Are there any symptoms of lung cancer that I should watch for?
If you notice any of the following, you should contact your health care team:
- Have a new cough that doesn’t go away
- Notice a change in a chronic cough
- Cough up blood, even a small amount
- Develop shortness of breath or chest pain
- Lose weight without trying

Is there a cost for the screening?
If you are charged co-pays for your VA visits, you will be charged a $50.00 co-pay for the day you have the low-dose chest computed tomography scan (LDCT). Talk with the Lung Cancer Screening coordinator if you are charged co-pays. Scheduling the scan on the same day as another visit may decrease the total charges.
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)
[ ] (close of ICT)

FINDINGS:
Nodules: (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 listed below. If both solid and sub-solid 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 by a general statement, such as "Several other smaller nodules are present")  
NOTE: Set Diagnostic Code HB6 LUNG NODULE REQUIRES FOLLOW-UP for all patients with lung nodules that require follow-up.

Nodule:
- Average diameter: [ ] (see reverse for notes about measuring average diameter)
- Density: [solid | ground-glass | mixed solid/ground glass]
- Location: [lobe]
- Image: series #: image #
- Suspicious features: [spiculated border | other]
- Other characteristics: [cavitory | other]
- Change in diameter: [ ] (if prior CT is available, amount and over what time)

Other lung findings: [ ]

Mediastinum: [ ]
Pipe: [ ]

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, aortic dilatation/varix, infectious/inflammatory/intrathoracic processes, other (specify)]

See reverse for notes and nodule follow-up guidelines
PULMONARY LUNG CANCER SCREENING

Vet: 04/22/16. Malignancy: Pulmonary; LCS FOLLOW UP X

Subject:

INITIAL LUNG NODULE documentation.

Date of Initial Image with a Lung Nodule:

Date: April 21, 2016

LDCT Results

Highest risk nodule description:

Size in mm:

3mm

The following incidental findings were noted:

- Suggestive of lung infection, inflammation, or interstitial process.
- Comment: tree-in-bud inflammation
- I am notifying the Primary Care Provider for information, and for follow-up of incidental findings, if indicated.

Plan:

Interval until next LDCT scan is due:

3 months

Comment: CT 4a

Patient Notification of results:

Results letter sent to patient.
Communication to Primary Care Provider.

(remember to add the DCP as an additional signer)
National VA LCS Pilot: Preliminary Results

Initial LCS CT data only, as of March 2015: pilot ended 9/30/15
Patient flow in VA LCS DP

- Of patients being seen in PC clinics, 50% met age criteria.
- Of patient meeting age criteria, TPY reminder completed properly 61% of time.
- Of patients with properly completed TPY reminders, 32% met smoking criteria, and therefore clinical reminders were turned on.
- Of patients with properly completed TPY reminders meeting smoking criteria, PCP assessed patient for screening 28% of the time.
- Of patients assessed by PCP, 84% were deemed appropriate for screening with LDCT scans.
- Of patients deemed appropriate for LDCT scans, the scans were completed 50% of the time.

Note: data from last 6 months of VA LCS DP still are pending.
Patient flow in VA LCS DP: areas for improvement

- Of patients being seen in PC clinics, 50% met age criteria.
- Of patient meeting age criteria, TPY reminder completed properly 61% of time.
- Of patients with properly completed TPY reminders, 32% met smoking criteria, and therefore clinical reminders were turned on.
- Of patients with properly completed TPY reminders meeting smoking criteria, PCP assessed patient for screening 28% of the time.
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- Of patients deemed appropriate for LDCT scans, the scans were completed 50% of the time.

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VA DEMONSTRATION PROJECT AND SFVAMC LCS RESULTS

Results for 8-site Demonstration Project as of 3/30/2015
Results for SFVAMC as of 5/10/2016

Patients Agreed & Completed LDCT

SFVA (N=647)
(N=2,106)

Patients w/ Documented Lung Cancer
1.6% (N=34)

SFVA 2.3% (N=15)

Patients w/ Possible Lung Cancer
1.5% (N=31)

NLST 1.03%

Patients w/ Nodules to be Tracked
49% (N=1,023)

SFVA 61% (N=396)

Patients to Continue Annual LCS
48% (N=1,018)

SFVA 35% (N=227)

LDCT scans all were To (initial scans)
Screening-detected lung cancer with surgery and histologic confirmation

LD CT scan  
PET Scan  
Adenocarcinoma
Highly likely lung cancer (90-95%) but without histologic confirmation, treated with SBRT
Small, low-risk nodules to be tracked: preliminary findings in VA are similar to those of NLST

In VA LCS DP, 49% (“2 mm or greater” but 60% < 4 mm)
In NLST, 24% (“4 mm or greater” )
Complications of invasive procedures in patients with LDCT screening-detected abnormalities

In NLST, 10% had serious complications from invasive procedures.

One possible explanation: no mandated multidisciplinary conference review of high-risk findings in NLST.

In VA LCS DP, all high-risk findings were reviewed in multidisciplinary conferences. Final data are pending but it appears that there were much lower complication rates.
Questions for VA’s Clinical Demonstration Project

• What is the uptake of screening among Veterans and their PCP’s? **Among patients coming to PCP visits, if LCS were offered, 2-4% or less would have screening CT’s performed.**

• What are the outcomes in Veterans? **Probably similar to those observed in NLST.**

• Can screening be implemented in the VA with the same level of safety as in NLST? **Yes, possibly with a better level of safety than in NLST.**
What resources would be needed to offer LCS with LDCT scans more widely in the VA?

1. **IT support for database:** use Portland and/or Minneapolis experiences with their own databases

2. **Multidisciplinary review of high-risk findings:** centralize, and allow designated centers to find ways to offer screening to veterans living in rural area

3. **Adopt efficiencies so that the need for more CT scanners can be minimized:** e.g. use of biennial rather than annual screening in some patients, use of clinical prediction rules

4. **Coordinators at each site:** use training modules developed by Demonstration Project to educate existing nursing staff

5. **Change lung nodule manage algorithms from Fleischner Guidelines to Lung-RADS:** already done at 7 demonstration sites that are continuing to screen.
Lung Cancer Mortality

Estimated Cancer Deaths by Site, 2012