Lung Cancer Screening:

Maximizing Gain ... and “Dealing with Pandora’s Box”

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Lung Cancer
Mortality: The Reality

- Leading cause of cancer death
- U.S. 2015 estimate 158,040 deaths
- 5-year survival ~17% at best

1. Cessation “Front”
2. Screening
   (Lung: Low Dose CT Scanning)

Goal: Early Surgical (or Radiotherapy-) Elimination of disease
Challenge: Early metastatic aggression

Why a Screening Program?

Other Considerations and **Screening**:

- Advanced stage at diagnosis is common
  (only about 30% stage I-II)

- Lung cancer screening may detect earlier-stage disease
  (when resection or curative radiation can achieve >50% long-term cure)

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**Principles of Screening**

- Diagnose disease early in asymptomatic patients.
- Detect diseases that respond better to early vs late treatment.
- Ensure the benefits of treating the small number of patients who will receive a disease diagnosis outweigh the harms associated with screening a large number of healthy individuals.
Low-dose CT: The NLST – Some Facts

A Randomized Trial: NEJM August, 2011: NLST (USA)

Screened 53,454 patients (2002-2004 enrollment with f/u thru 2009)

LDCT vs CXR yearly X3 in Hi Risk Population:

Heavy current or former smokers age 55 – 74 with any use within last 15yrs; and >30 pack-yrs use

“Low Dose” CT? Approx 1/5 amount of gamma irradiation as conventional diagnostic chest CT

Lung Cancer Mortality and Screening Trial Success:

20% relative reduction in mortality

NNS: Number needed to screen w/ LDCT to prevent 1 lung cancer death: 320

Overall Mortality:
LDCT group: significant reduction: 6.7%

AT WHAT COST??
Study Findings: Low-dose CT versus Chest X-ray screening

53,454 current and former smokers were randomly assigned to be screened once a year for 3 years with low-dose CT or chest X-ray. Here's what happened after an average of 6.5 years:

<table>
<thead>
<tr>
<th>Benefit: How did CT scans help compared to chest X-ray, an ineffective screening test?</th>
<th>Low-dose CT</th>
<th>Chest X-ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 in 1,000 fewer died from lung cancer</td>
<td>18 in 1,000</td>
<td>versus</td>
</tr>
<tr>
<td>5 in 1,000 fewer died from all causes</td>
<td>70 in 1,000</td>
<td>versus</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Harm: What problems did CT scans cause compared to chest X-ray?</th>
<th>Low-dose CT</th>
<th>Chest X-ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>223 in 1,000 more had at least one false alarm</td>
<td>365 in 1,000</td>
<td>versus</td>
</tr>
<tr>
<td>18 in 1,000 more had a false alarm leading to an invasive procedure, such as bronchoscopy, biopsy, or surgery</td>
<td>25 in 1,000</td>
<td>versus</td>
</tr>
<tr>
<td>2 in 1,000 more had a major complication from invasive procedures</td>
<td>3 in 1,000</td>
<td>versus</td>
</tr>
</tbody>
</table>

Possible patient thoughts/considerations in discussing screening:

“I as a patient appreciate 3 or 4 less deaths in every 1000 screenings – I might be one of the saves!”

“I don’t want to be among 39% with a Positive Test! ...invasive testing, and possible complications!?”

“I just don’t care to know ... Leave me alone!”
NLST “Translation”
Critiques/Concerns

• Healthy-volunteer effect (bias results: more favorable since patients actively seek out care/diagnostic testing)

• Surgical expertise in centers was excellent
  How is this a problem ?? Not reflective of nation-wide average…

• Hi rate of false positive results
  Must deal with heavy nodule follow-up

• Radiation Effects?
  Difficult to measure effects of (low-level) Rad. -- follow-up needed
Diagnostic Rates and Procedures in the Screened Groups

Diagnosis of Lung Cancer:

LDCT group: **1060** w/ lung cancer: **649** after (+) screen, **347** after screening phase completed (70% diagnosed at early-stage I or II)

CXR group: **941** w/ lung cancer: **279** after (+) screen, **525** after screening phase completed (57% diagnosed at early-stage I or II)

Survival

- Higher for cases diagnosed early
- Few cases diagnosed at early stage

![Stage at Diagnosis and 5-Year Relative Survival Chart]

- Localized (confined to primary site)
- Regional (spread to regional lymph nodes)
- Distant (cancer has metastasized)
- Unstaged tumors not shown
Preparatory Considerations for Lung Cancer Screening

The Task Force Recommendation on Lung Cancer Screening With Low-Dose Computed Tomography

The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in persons age 55 through 80 years with a 30 pack year history of smoking who are currently smoking or have quit within the past 15 years. Screening should be discontinued once the individual has not smoked for 15 years or develops a health problem significantly limiting either life expectancy or ability or willingness to undergo curative lung surgery.
Enter the “Pandora’s Box”...

- Risk:Benefit “trap” in a fragile/sick population?

- “New findings” on CT – “follow-up and what next…?”

- Many risks beyond tobacco exposure: Family history, Asbestos, COPD... **Screen?**
Resources: “The Elements”

People:

Screening:
- Pulmonary
- Radiology
- Primary Care

Downstream Services:
- Pulmonary/Interventional Radiology
- Interventional Radiology/Interventional Cardiology
- Cardiothoracic Surgery
- Radiation Oncology
- Medical Oncology

Screening Intake
- Qualification: USPHTF Tob/Age criteria
- No terminal illness or recent CT scans

Nodule Protocol
- Referral from Pulm or Primary Care
- General flow through system with Algorithm

LungRADS
- Database/program – Radiology software
- Dictation templates, Intake forms, patient letters

Tumor Board
- Multidisciplinary Meeting: Dx-Stage, Treatment

Research
- Can we “Enrich” who’s at risk?
- Improve specificity ??
- Patient Risk Calculator scores
- Other Nodule data
- Banked blood/urine/cells

“A 3 Hour Tour…”
Early Challenges

Follow-up and Communication
- Education, psychological support
- Patient understanding of flow within system
- Consequences of Poor Quality!

Cost
- Data Entry, Scheduling, Coordinator(s)
- Consider downstream revenue (balance vs. cost)

Integration
- Build-in program into targeted CT scans in lung disease patients (e.g., COPD)
- Primary Care
- Smooth integration of sub-specialty referrals for (+) Scans

Practitioner Education
- Primary Care intake
- Primary Care follow-up of positive nodules <1cm
- Primary Care referrals to Pulmonary
  (nodules >1cm, growth, or hi-suspicion malignancy)

“The weather started getting rough…”
Comprehensive Lung Cancer Screening Program...

*When all the following criteria are met:*

- Systematic way to **identify high-risk patients** who meet screening criteria
- Patient **education materials** for shared decision making
- Clinical **coordinators** to coordinate care of patients undergoing lung cancer screening
- **Smoking cessation program** – May save more lives than the Screening Program !
- Standardized screening and **follow-up guidelines** (Radiology-LungRADS)
- Sufficient **capacity** in primary care, pulmonary, CT surgery, medical oncology
- **Tracking system**/registry for all patients in program
  (including those with nodules and incidental findings)
- Evaluation program to **monitor outcomes**
Preperatory Considerations for Lung Cancer Screening

First-thoughts on Scale and Safety in taking on a “Pilot” Effort:

Prelim West Haven VA experience (2014) – Roughly similar-size outpatient base as VA San Diego
Over initial 6 months: Approx 1100 screened; 170 had a lesion >8mm size  (Can we handle this?)

- High likelihood of intervention by Pulm/Rad/IR/Surg Svcs.
- If we “scale” our effort to 1/4 this size – Reasonable goal to safely start at Primary Care level

- To “oil” our system:
  
  **Initiated Lung Cancer Screening in Pulmonary Clinic**
  
  Integrated Nurse Manager
Team and Resources

Team:
  Pulm Section, Nurse Manager, Radiology, Primary Care  Informatics, Leadership support!

LDCT requirement; Challenge in blocking full-dose CT scans outside of Pilot effort

Radiology partnership and Resources:
  - Buy-in from Readers – Adoption of LungRADS LDCT scoring
  - Scanners: current status = one part-time; 2nd dedicated coming (Started: ~ 2 LDCTs/week)

**Protocol: LDCT Acquisition Parameters**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scout</td>
<td>PA to reduce breast dose</td>
</tr>
<tr>
<td>kVp</td>
<td>120</td>
</tr>
<tr>
<td>mAs</td>
<td>no more than about 25 for average size patients</td>
</tr>
<tr>
<td></td>
<td>no more than about 50 for obese patients</td>
</tr>
<tr>
<td></td>
<td>alternatively use automatically variable mA to achieve less than 3 mGy dose</td>
</tr>
<tr>
<td>Detectors</td>
<td>16 or more so study can be acquired in one breath hold</td>
</tr>
<tr>
<td>Detector collimation</td>
<td>between .625 and 1 mm</td>
</tr>
<tr>
<td>Reconstruction thickness</td>
<td>1 to 1.25</td>
</tr>
</tbody>
</table>
Individual Patient Informing/Reporting/Actions

Provider/patient Discuss in clinic
- Inform eligibility: Benefits/Risks discussion (Handout)

Should I be screened for lung cancer?
You should consider being screened if you have all three of these risk factors:

- Scan obtained: Patient informed by Pulmonary Fellow with follow-up secured.
  (Radiology Report has LungRADS score and Recommendation)

- A formal Radiology letter to provider/patient needed
  Esp. upon Primary Care Implementation

- Pulm Diagnostic Clinic referral for “Positive Lesions” with >1-2% risk
An honest discussion with patients regarding the benefits vs. harms 
“Shared Decision-making”

Different patients will have different values and risk tolerance

**Risk/Benefit:**

**SCREENED (1000 PEOPLE)**

- **BENEFITS ADDED by Screening**
  - 18 PEOPLE DIED from lung cancer in a group of 1000 people who are screened. This was 3 FEWER DEATHS from lung cancer compared to the NOT SCREENED group.

- **HARMS ADDED by Screening**
  - 365 IN 1000 PEOPLE SCREENED experienced a FALSE POSITIVE result.
  - 25 of those false positive results led to an INVASIVE PROCEDURE.
  - 3 PEOPLE developed a MAJOR COMPLICATION from the invasive procedure.

**NOT SCREENED (1000 PEOPLE)**

- 21 PEOPLE DIED from lung cancer in a group of 1000 people who were not screened. This was 3 ADDITIONAL DEATHS from lung cancer compared to the group that was screened.
Implementation

Ordering and Notification with Follow-Up:

- CPRS Order with automatic notification to Nurse Case Manager (+ ordering provider)
- Patient approved (criteria) and Protocol-entered by Radiologist → Scheduled → Scanned

- LungRADS reporting with score and recommendation on Report to Ordering Provider/Team
### LungRADS: Radiology Service/Reading and Follow-Up

<table>
<thead>
<tr>
<th>Category</th>
<th>Category Descriptor</th>
<th>Category</th>
<th>Findings</th>
<th>Management</th>
<th>Probability of Malignancy</th>
<th>Estimated Population Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete</td>
<td>-</td>
<td>0</td>
<td>prior chest CT examination(s) being located for comparison part or all of lungs cannot be evaluated</td>
<td>Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>No nodules and definitely benign nodules</td>
<td>1</td>
<td>no lung nodules nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules</td>
<td>Continue annual screening with LDCT in 12 months</td>
<td>&lt; 1%</td>
<td>90%</td>
</tr>
<tr>
<td>Benign Appearance or Behavior</td>
<td>-</td>
<td>2</td>
<td>solid nodule(s): &lt; 6 mm new &lt; 4 mm part solid nodule(s): &lt; 6 mm total diameter on baseline screening</td>
<td>6 month LDCT</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Probably Benign</td>
<td>Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer</td>
<td>3</td>
<td>solid nodule(s): ≥ 6 to &lt; 8 mm at baseline OR new 4 mm to &lt; 6 mm part solid nodule(s): ≥ 6 mm total diameter with solid component &lt; 6 mm OR new &lt; 6 mm total diameter non solid nodule(s) (GGN) ≥ 20 mm on baseline CT or new</td>
<td>3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component</td>
<td>1-2%</td>
<td>5%</td>
</tr>
<tr>
<td>Suspicious</td>
<td>Findings for which additional diagnostic testing and/or tissue sampling is recommended</td>
<td>4A</td>
<td>solid nodule(s): ≥ 8 to &lt; 15 mm at baseline OR growing ≤ 8 mm OR new 6 to &lt; 8 mm part solid nodule(s): ≥ 6 mm with solid component ≥ 6 mm to &lt; 8 mm OR with a new or growing ≤ 4 mm solid component endobronchial nodule</td>
<td>chest CT with or without contrast, PET/CT and/or tissue sampling depending on the probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component</td>
<td>5-15%</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>4B</td>
<td>solid nodule(s) ≥ 15 mm OR new or growing, and ≥ 8 mm part solid nodule(s) with: a solid component ≥ 8 mm OR a new or growing ≥ 4 mm solid component</td>
<td>-</td>
<td>15%</td>
<td>2%</td>
</tr>
<tr>
<td>4X</td>
<td>Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)</td>
<td>S</td>
<td>modifier - may add on to category 0-4 coding</td>
<td>As appropriate to the specific finding</td>
<td>n/a</td>
<td>10%</td>
</tr>
<tr>
<td>Prior Lung Cancer</td>
<td>Modifier for patients with a prior diagnosis of lung cancer who return to screening</td>
<td>C</td>
<td>modifier - may add on to category 0-4 coding</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Individual Patient Reporting and Actions

- Notification and Follow-up in Pilot Program

(1) Positive report (LungRADS 2,3,4A-C: Addended to clinic note and notification by Active Diagnostic Clinic Fellow)

(2) Negative report (LungRADS 1: Addend note and “No Lung Cancer – Now What?” flyer sent to Patient)

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.

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
VASDHS Lung Cancer Screening Process Flowchart: Current State

Pulm Clinic Identifies **Qualifying Patient**

LDCT Ordered;
For Screening - Radiologist day

LDCT done with notification to Nurse Mgr
- Inform Patient
- Arrange f/u (Spreadsheet updated)
- **Positive** (2,3,4A,B,C) – Contact/see patient
- **Negative** (1) – Letter to pt w/ result

Follow-up LDCT in 1 yr
If still within screening cutoff (within 15 yrs of quitting)

If higher category LungRADS:
Sooner LDCT (3, 6mo)
Or Immediate Eval: PET/Bx/Surg

LungRADS Grade & Recommendation

 Vlad Fellow & Nurse Manager

Re-Screen Annual
Completion When out of Risk window (15 yrs Tob free)

Pulm Diagnostic Team

Workup: Malignant
(Lung Cancer, Lymphoma, ...)

Workup: Benign or Other
(Coccidioides, Sarcoid, ...)

Offer Tobacco Cessation

Planned Primary Care
To Order from Tobacco
Reminder updated by Clinician
Take-Home Points

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

• Approximately two-thirds of Veteran individuals screened have abnormal findings, some of which required tracking and clinical follow up.

• If lung cancer screening is implemented, resource needs will be significant.

• Smoking Cessation is the most important intervention to prevent lung cancer (and decrease the morbidity and mortality associated with lung cancer).

• There is ongoing discussion to formulate guidance for how a nation-wide facility such as the VA might implement lung cancer screening.

• Individual facilities may vary due to geographic risks and facility-specific expertise. Coordinator and specialty-specific downstream resources are key.
THANK YOU !