Lung Screening in High Risk Patients
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What's wrong with this?
- Low risk patients
- One scan for all diseases
- How often?
- No evidence
- Everything is wrong with this.

A true screening exam would need:
- Brain / neck MRI with contrast
- CT chest
- Barium swallow/Upper GI series
- Breast MRI with contrast
- Upper abdominal MRI with contrast
- Pelvic MRI with contrast
- CT colonography or Barium enema
- Extremity MRI x 4 with contrast
- Thyroid ultrasound

Virtual Check-Up™
Full Body Scanning

Virtual Check-Up

What's wrong with this?
- Low risk patients
- One scan for all diseases
- How often?
- No evidence
- Everything is wrong with this.

Tumor Doubling Time

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Doubling Time</th>
<th>% Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>14 months</td>
<td>95%</td>
</tr>
<tr>
<td>Breast</td>
<td>30 months</td>
<td>85%</td>
</tr>
<tr>
<td>Colon</td>
<td>12 months</td>
<td>90%</td>
</tr>
<tr>
<td>Lung</td>
<td>4 months</td>
<td>10%</td>
</tr>
<tr>
<td>Bladder</td>
<td>12 months</td>
<td>75%</td>
</tr>
<tr>
<td>Head &amp; Neck</td>
<td>6 months</td>
<td>60%</td>
</tr>
<tr>
<td>Rectum</td>
<td>10 months</td>
<td>80%</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>6 months</td>
<td>15%</td>
</tr>
</tbody>
</table>
### Tumor Doubling Time

<table>
<thead>
<tr>
<th>Type</th>
<th>Cases</th>
<th>Deaths</th>
<th>5yr survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>20K</td>
<td>6K</td>
<td>99%</td>
</tr>
<tr>
<td>Bladder</td>
<td>22K</td>
<td>11K</td>
<td>28%</td>
</tr>
<tr>
<td>Breast</td>
<td>159K</td>
<td>33K</td>
<td>17%</td>
</tr>
<tr>
<td>Colon</td>
<td>12K</td>
<td>6K</td>
<td>89%</td>
</tr>
<tr>
<td>Lung</td>
<td>23K</td>
<td>12K</td>
<td>17%</td>
</tr>
<tr>
<td>Rectum</td>
<td>40K</td>
<td>159K</td>
<td>7%</td>
</tr>
</tbody>
</table>

### Screening

**Pre-detectable**
- Imaging-detectable
- Nonpalpable
  - No signs/sx
- No signs/sx

**Possible detection via screening**

**Clinically detectable**
- Disability or death

**Screening too early finds nothing. Screening too late finds something already found.**

Screening too infrequently lets preclinicals turn into clinicals.

Screen only if you can “catch” preclinicals, treat them, and lower their mortality.

### The Problem

- Lung cancer is leading cause of cancer death in the US
- In 2014 (est), 159K lung cancer deaths, 224K new lung cancer diagnosis

**Medicare covers:**
- Yearly PSA, DRE
- Yearly mammography
- CBE every other year
- Yearly FOBT, Bi exams or sigmoidoscopy every 4 years, colonoscopy every 10 years (every 2 years if high risk)
The Problem

- Even never-smokers who have lung cancer form a bigger group than many other cancers. (SEER 1975-2008)

The problem: Stigma

- i.e., “Smokers knew what they were getting into.”
- Smoking is often a pediatric disease of teenagers getting hooked on a highly addictive substance
- Runners get stress fractures, the Western diet and sedentary lifestyle cause a host of issues, and certain occupations and living conditions lead to higher risk.
- Let’s focus on solutions rather than attempting to trace back the ultimate culpability of the cause of a condition. But obviously let’s also work to get patients to quit smoking!

Would screening help?

- Early stage disease dramatically improves chances of survival
- Current overall lung cancer 5-yr survival rate is 16.7% (65% for colon, 89% for breast, 98.9% for prostate)
- Over 50% of newly diagnosed patients die within 1 year
Low dose CT (LDCT) Trials

- ELCAP (Early Lung Cancer Action Project): 1990s/early 2000s
- CXR and LDCT in same patient, followed over time
- LDCT found nodules in 23% (vs 7% CXR); cancer in 2.7% (vs 0.7%)
- ELCAP studies culminate in International-ELCAP
  - 31,456 patients → 484 had lung cancer → 414 (86%) had Stage I disease and overall cure rate of 80%
- Were they just finding cancers earlier and not reducing mortality?

NLST: Double-arm RCT

- National Lung Screening Trial (NLST): NEJM Aug 2011
- 54K asymptomatic smokers aged 55-74 randomized to annual LDCT or CXR
- LDCT group had 20% less mortality (!)
- Number needed to screen: 300-320
- Lung cancer on 1st CT scan changed the...

Compare to other cancers

<table>
<thead>
<tr>
<th>Group</th>
<th>Age</th>
<th>Frequency</th>
<th>RR of cancer death</th>
<th>Number needed to screen to prevent 1 cancer death</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA: ERSPC trial</td>
<td>55-69</td>
<td>varied</td>
<td>0.80</td>
<td>1300</td>
</tr>
<tr>
<td>PSA: PLCO trial</td>
<td>55-74</td>
<td>Annual</td>
<td>1.10ns</td>
<td>N/A</td>
</tr>
<tr>
<td>Mammography</td>
<td>50-59</td>
<td>Annual</td>
<td>0.85</td>
<td>1300</td>
</tr>
<tr>
<td></td>
<td>60-69</td>
<td>Annual</td>
<td>0.68</td>
<td>380</td>
</tr>
<tr>
<td>LDCT over CXR</td>
<td>55-74</td>
<td>Annual</td>
<td>0.80</td>
<td>300-320</td>
</tr>
</tbody>
</table>

Chou: Ann Int Med 2011
Andriole: NEJM 2009
Nelson: USPTF 2009
Compare to other cancers

Cost per life year saved under $50K usually considered “cost-effective”

How has NLST affected us?

January 2012: National Comprehensive Cancer Network recommends annual screening in high-risk patients

April 2012: American Lung Association


January 2013: American Cancer Society

December 2013: US Preventive Services Task Force (USPSTF) recommends screening with “B” recommendation

Some payors cover: VA, Wellpoint, Anthem SoCal, Empire BC/BS, Mass BC/BS

USPSTF as bellwether

Generally, if USPSTF recommends it → standard of care

Affordable Care Act requires private insurers to pay the entire cost of any screening recommended by USPSTF. No co-pay.

USPSTF recommends screening for patients 55-80 with 30 pack-years of smoking.
Recent MEDCAC panel

- Non-binding recommendation from MEDCAC panel to Medicare was not to cover CT lung screening (4/30/14)
- Reasoning: “Not enough evidence”

- Medicare may still decide to fund lung screening

How to screen?

1. Set up a low-dose protocol, issue reports, and let other MDs handle the results and followup

2. Create a system to attract the patient, ensure ongoing followup, and provide assistance at each critical step
**Intake form**

- Check eligibility
- Identify all lung-related risk factors
- Provide data for database
- Can use NLST or NCCN criteria for inclusion (NCCN is broader)
- USPSTF

**Low Dose Chest CT**

- 1-2 milliSieverts in dose (normal Chest CT 6-8mSv)
- Lower dose limits for evaluation of soft tissues/mediastinum
- No IV contrast
- 10-15 second scan
- <5 min start to finish

**What is the dose?**

Almost always <1.5mSv

- Handful of CXRs
- 2-3 mammograms
- 4-6 months on Earth
Reporting of CT results: “LungRads” 1 through 4

<table>
<thead>
<tr>
<th>LungRads</th>
<th>Category</th>
<th>Example</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negative</td>
<td>No findings</td>
<td>Return to annual screen</td>
</tr>
<tr>
<td>2</td>
<td>Benign</td>
<td>Calcified granuloma</td>
<td>Return to annual screen</td>
</tr>
<tr>
<td>3</td>
<td>Probably benign</td>
<td>6mm nodule</td>
<td>6 month repeat CT</td>
</tr>
<tr>
<td>4</td>
<td>Suspicious</td>
<td>Growing 7mm nodule</td>
<td>PET or biopsy</td>
</tr>
</tbody>
</table>

- Modifiers will also be added to indicate suspected infection, known lung cancer, significant non-pulmonary findings, etc.

Sample normal report

LungRADS 1N

Findings:
Lung Screening Specific (LungRADS): Negative.

Impression:
1. No findings.
2. No evidence of primary lung cancer.
3. No new or known potentially significant incidental findings.

Recommendations:

3nN

Findings:
Lung Screening Specific (LungRADS): Positive.

Impression:
1. Nodule: 4 cm solid, peripheral, ground-glass opacity.
2. Nodule: 4 cm solid, peripheral, ground-glass opacity.
3. Nodule: 4 cm solid, peripheral, ground-glass opacity.
4. Nodule: 4 cm solid, peripheral, ground-glass opacity.
5. Nodule: 4 cm solid, peripheral, ground-glass opacity.
6. Nodule: 4 cm solid, peripheral, ground-glass opacity.
7. Nodule: 4 cm solid, peripheral, ground-glass opacity.
8. Nodule: 4 cm solid, peripheral, ground-glass opacity.
9. Nodule: 4 cm solid, peripheral, ground-glass opacity.
10. Nodule: 4 cm solid, peripheral, ground-glass opacity.

Recommendations:
Follow-up L.O.C.T. scan in 3 months (or annual screen 8/20/12).
Positive results at Lahey Clinic, Burlington, MA

What counts as a false positive?

- A nodule the radiologist is pretty sure is benign, but needs a followup CT to be sure
- Unexpected pneumonia
- A renal mass suspicious for renal cell cancer
- An incidental adrenal nodule needing a followup scan
- A suspicious-looking nodule for which biopsy or a procedure or excision is recommended, but ends up being benign

Followup of positive results

- All patients will be getting yearly screen anyway
- Infection? Short-term followup 1-2 months CT
- Small nodule? Additional scan at 6 months to prove stability
Virtual Pulmonary Nodule Clinic

- "Virtual": a physical space need not be allocated
- Lung Care Coach “quarterbacks” referrals to/from PCPs, then to pulmonology as needed based on CT report

Nodule Followup Database

- CT entries would link to images, “LungRADS” links to report
- Biopsy results link to path reports
- Surgical visit would link to op note
- Letters would show letters sent to patient (date printed or emailed)

Sample patient

- Explain results
- Give contact information
- Provide opportunity to get further information
Downsides

- Cost: Baptist CT will be $35 for high-risk individuals
- Radiation exposure (less than 1mSv, comparable to bilateral mammography)
- False positives → workup and anxiety
- “Free pass” to continue smoking?

What Should You Ask?

- Eligibility criteria of your program?
- Follow Lung Cancer Alliance and/or Lung Cancer Screening Center of Excellence guidelines?
- Is the LDCT radiation dose 2mSv or lower?
- Do you have a responsible, dedicated followup system in place for lung screening patients?
- Do you have a thoracic surgeon with high volume and experience with lung cancer?
Thank you

Lung Screening Program
For people at high risk for lung cancer.

Low-dose CT, also known as chest scan, can detect lung cancer early, which is easier to treat and survival rate is better.

Formal launch date: June 30th!