Lung Cancer Screening: Promises and Challenges
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Associate Professor
Department of Internal Medicine
University of Kentucky College of Medicine

Acknowledgments

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Assistant Director, Cancer Prevention and Control, Lucille P. Markey Cancer Center

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- Patrick and Catherine Weldon Donaghue Medical Research Foundation and the Association of American Medical Colleges
- UK Lucille P. Markey Cancer Center and Center for Clinical and Translational Science (CCTS)

About the Northeast KY TLC Project

Purpose of the TLC project is to deliver a comprehensive education portfolio across a spectrum of learners in NE Kentucky about lung cancer screening and tobacco cessation and impact outcomes through implementation research in SCRMC ambulatory system.

Our initial focus group work considered health providers as the most trusted source for lung cancer screening and tobacco cessation information.
Low-Dose CT for Lung Cancer Screening

Promises

Challenges

Agenda

- Lung Cancer Epidemiology
- Evidence regarding Lung Cancer Screening
- Shared Decision Making for Lung Cancer Screening
- Comments and Questions

Epidemiology of Lung Cancer

United States

&

Kentucky
# LEADING CAUSES OF KENTUCKY DEATHS, 2013

<table>
<thead>
<tr>
<th>Cause</th>
<th>Deaths</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>10,085</td>
<td>1st</td>
</tr>
<tr>
<td>Heart Diseases</td>
<td>9,971</td>
<td>7th</td>
</tr>
<tr>
<td>Respiratory Diseases</td>
<td>3,187</td>
<td>1st</td>
</tr>
<tr>
<td>Unintentional Injuries</td>
<td>2,513</td>
<td>5th</td>
</tr>
<tr>
<td>Stroke</td>
<td>1,990</td>
<td>9th</td>
</tr>
<tr>
<td>Alzheimer's Disease</td>
<td>1,462</td>
<td>9th</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>1,187</td>
<td>12th</td>
</tr>
</tbody>
</table>

**KY Life Expectancy at birth**: 75.1 years  
**Nat’l Rank**:


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## Cancer Statistics 2015

### Estimated Deaths

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Males</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung &amp; bronchus</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Prostate</td>
<td>9%</td>
<td>0%</td>
</tr>
<tr>
<td>Colon &amp; rectum</td>
<td>8%</td>
<td>5%</td>
</tr>
<tr>
<td>Pancreas</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Liver &amp; intrahepatic bile duct</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Leukemia</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Esophagus</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Uterine corpus</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Hodgkin lymphoma</td>
<td>0%</td>
<td>3%</td>
</tr>
<tr>
<td>All Cancers</td>
<td>90%</td>
<td>90%</td>
</tr>
</tbody>
</table>

### Percentage Distribution of Cancer Deaths

CA CANCER J CLIN 2015;65:5–29

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### Trends in Death Rates: Joining Females for Selected Cancers, United States, 1930 to 2008

CA: A Cancer Journal for Clinicians Volume 63, Issue 1, 17 JAN 2013
5-year survival rates

• 99% for prostate cancer
• 90% for breast cancer
• 65% for colon cancer
• 18% for lung cancer

American Lung Assoc. Lung Cancer Fact Sheet

Lung Cancer Survival by Stage

Kentucky Annual Cancer Deaths 2008-2012

<table>
<thead>
<tr>
<th>Site</th>
<th>KY Deaths/100k</th>
<th>KY Deaths/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung and bronchus</td>
<td>70.9</td>
<td>3,442</td>
</tr>
<tr>
<td>Colon</td>
<td>18.1</td>
<td>858</td>
</tr>
<tr>
<td>Breast</td>
<td>22.6</td>
<td>604</td>
</tr>
<tr>
<td>Pancreas</td>
<td>11.0</td>
<td>529</td>
</tr>
<tr>
<td>Prostate</td>
<td>21.5</td>
<td>373</td>
</tr>
<tr>
<td>Liver</td>
<td>5.5</td>
<td>273</td>
</tr>
<tr>
<td>Ovary</td>
<td>7.5</td>
<td>200</td>
</tr>
</tbody>
</table>

http://statecancerprofiles.cancer.gov/
Kentucky Annual Deaths

<table>
<thead>
<tr>
<th>Cause</th>
<th>KY Deaths/100k</th>
<th>KY Deaths/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung CA</td>
<td>70.9</td>
<td>3442</td>
</tr>
<tr>
<td>Stroke</td>
<td>41.7</td>
<td>1990</td>
</tr>
<tr>
<td>Diabetes</td>
<td>24.1</td>
<td>1187</td>
</tr>
<tr>
<td>Drug OD</td>
<td>23.7</td>
<td>1019</td>
</tr>
<tr>
<td>Colon CA</td>
<td>18.1</td>
<td>858</td>
</tr>
<tr>
<td>Traffic Fatalities</td>
<td>15.2</td>
<td>700</td>
</tr>
<tr>
<td>Breast CA</td>
<td>22.6</td>
<td>604</td>
</tr>
<tr>
<td>Firearm deaths</td>
<td>13.9</td>
<td>600</td>
</tr>
</tbody>
</table>

Risk Factors for Lung CA

- **Smoking** linked to about 90% of lung cancers.
  - Smokers are 15-30 times more likely to get lung cancer or die from lung cancer.
- **Secondhand Smoke** 7,300 people die from lung cancer due to secondhand smoke every year.
- **Radon**
- **Other Substances**: Examples include asbestos, arsenic, diesel exhaust, and silica and chromium.
- **Pulmonary Fibrosis**: risk increased about 7x
- **Personal or Family History of Lung Cancer**
- **HIV infection**
- **Radiation Therapy to the Chest**: Cancer survivors who had radiation therapy to the chest are at higher risk.
- **Diet**
  - Smokers who take beta-carotene supplements have increased risk.
  - Antioxidants, cruciferous vegetables, phytoestrogens may reduce risk, but have not been successful in high-risk patients.
  - High Carb diets linked to higher risk (Ca Epi Bio Prev. Mar 2016)
Lung Cancer Epidemiology

- Lung cancer incidence rate (2009-2013)
  - USA: 74.5 (men) 53.4 (women)
  - Kentucky: 118.3 (men) 80.2 (women)

- Lung cancer mortality rate (2009-2013)
  - USA: 57.8 (men) 37.0 (women)
  - Kentucky: 90.5 (men) 54.8 (women)

- Adult smoking rate (2015)
  - USA: 19.7% (men) 15.3% (women)
  - Kentucky: 26.2% (men) 25.2% (women)

http://www.americashealthrankings.org/kct/Smoking

Lung Cancer Incidence in Kentucky

Lung Cancer Mortality in Kentucky
Lung Cancer Screening: The Evidence

Why Lung Cancer Screening?

✓ Common cause of morbidity/mortality
✓ Identifiable high-risk target group (smokers)
✓ Lengthy pre-clinical phase of disease
✓ Effective therapy with early diagnosis
✓ Sensitive screening test available (LDCT)

(Cole & Morrison, 1980; Patz, Goodman, & Bepler, 2000)

Past Lung Cancer Screening Studies

Randomized Controlled Trials
- Northwest London Mass Radiography Service  CXR Frequency
- Memorial-Sloan Kettering Study  CXR+SC
- Johns Hopkins Study  CXR+SC
- Czechoslovakian Study  CXR+SC
- Mayo Lung Project  CXR+SC
- Prostate, Lung, Colorectal, Ovarian (PLCO)  CXR+SC

Overall Results
- No study demonstrated a mortality reduction
- Challenges: efficacious Tx, specificity issues → false positives, cost
- Some methodological limitations hindered analysis
**Table 1. Randomized Controlled Trials of Computed Tomography Screening for Lung Cancer**

<table>
<thead>
<tr>
<th>Study</th>
<th>LDCT (n)</th>
<th>LDCT (n)</th>
<th>LDCT (n)</th>
<th>LDCT (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Objective</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To determine if LDCT screening could reduce lung cancer specific mortality relative to CXR.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>53,454 participants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 annual screens: randomized to either LDCT or CXR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligibility Criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>55 to 74 years of age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>at least 30 pack-years history of cigarette smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Former smokers must have quit within the past 15 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
National Lung Screening Trial

• Additional Results
  – Positive Screens
    • LDCT: 39% had 1+ pos. screen
    • CXR: 16% had 1+ pos. screen
  – False positive results:
    – 96.4% CT group, 94.5% CXR group
    – >90% of these resulted in further testing, most often further imaging


National Lung Screening Trial

• Lung Cancer Diagnosis
  – 1060 lung cancers in CT group (645/100,000)
  – 941 lung cancers in CXR group (572/100,000)
  – Ratio = 1.13
• Stage 1A and B Disease
  – 63% in CT group vs. 47.6% in CXR group
• Mortality
  – 356 deaths from lung cancer in the CT group
  – 443 deaths from lung cancer in the CXR group
  – Significant (20% reduction) in the CT group (P=0.004)
  – Reduced all-cause mortality by 6.7% (P=0.02).


National Lung Screening Trial

• Primary Results
  – 20% relative reduction in lung cancer mortality with LDCT
  – 6.7% reduction in all-cause mortality with LDCT
• Additional Results
  – Positive/False Positive Screens
    • LDCT: 39% had 1+ pos. screen
    • CXR: 16% had 1+ pos. screen

**NLST Sites Above/Below US Lung CA Incidence**

<table>
<thead>
<tr>
<th>Location</th>
<th>Incidence Rate</th>
<th>Incidence Rate</th>
<th>5-Year Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washington DC</td>
<td>(59.6)</td>
<td>(65.7)</td>
<td></td>
</tr>
<tr>
<td>Detroit MI</td>
<td>(69.1)</td>
<td>(69.1)</td>
<td></td>
</tr>
<tr>
<td>Marshfield WI</td>
<td>(61.7)</td>
<td>(67.1)</td>
<td></td>
</tr>
<tr>
<td>Honolulu HW</td>
<td>(47.7)</td>
<td>(67.1)</td>
<td></td>
</tr>
<tr>
<td>Rochester MN</td>
<td>(55.4)</td>
<td>(61.7)</td>
<td></td>
</tr>
<tr>
<td>Madison WI</td>
<td>(69.7)</td>
<td>(67.1)</td>
<td></td>
</tr>
<tr>
<td>San Diego CA</td>
<td>(48.0)</td>
<td>(77.5)</td>
<td></td>
</tr>
<tr>
<td>Nashville TN</td>
<td>(77.5)</td>
<td>(77.5)</td>
<td></td>
</tr>
<tr>
<td>Salt Lake City UT</td>
<td>(28.6)</td>
<td>(28.6)</td>
<td></td>
</tr>
<tr>
<td>Philadelphia PA</td>
<td>(64.6)</td>
<td>(64.6)</td>
<td></td>
</tr>
<tr>
<td>New Orleans LA</td>
<td>(73.0)</td>
<td>(78.6)</td>
<td></td>
</tr>
<tr>
<td>Youngstown OH</td>
<td>(71.6)</td>
<td>(71.6)</td>
<td></td>
</tr>
</tbody>
</table>

**Incidence Rate for Kentucky**

<table>
<thead>
<tr>
<th>County</th>
<th>Annual Incidence</th>
<th>Average Annual Rate</th>
<th>Period</th>
<th>Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kentucky</td>
<td>97.5</td>
<td>4,773</td>
<td>2008-12</td>
<td>falling -2.3</td>
</tr>
<tr>
<td>Floyd County</td>
<td>153.4</td>
<td>74</td>
<td>2008-12</td>
<td>stable -4.5</td>
</tr>
<tr>
<td>Perry County</td>
<td>150.8</td>
<td>52</td>
<td>2008-12</td>
<td>stable -7.5</td>
</tr>
<tr>
<td>Martin County</td>
<td>150.0</td>
<td>20</td>
<td>2008-12</td>
<td>stable -4.1</td>
</tr>
<tr>
<td>Leslie County</td>
<td>142.4</td>
<td>20</td>
<td>2008-12</td>
<td>stable 7.7</td>
</tr>
<tr>
<td>McCreary County</td>
<td>140.7</td>
<td>28</td>
<td>2008-12</td>
<td>stable 12.1</td>
</tr>
<tr>
<td>Powell County</td>
<td>137.3</td>
<td>21</td>
<td>2008-12</td>
<td>stable 16.3</td>
</tr>
</tbody>
</table>

**National Lung Screening Trial (NLST)**

In Summary, for those who received a CT scan:
- 9.8% saw no benefit
- 0.5% were helped by preventing death
- 22% were helped by false positive (normal scan)
- 3.5% were harmed by undergoing a surgical procedure
- 0.8% were harmed by suffering a complication of surgery

In Other Words:
- 1 in 211 were helped (prevented death)
- 1 in 4 were harmed (false positive CT scan)
- 1 in 30 were harmed (unnecessary surgery)
- 1 in 101 were harmed (surgical complication)

http://www.thennt.com/ct-scans-to-screen-for-lung-cancer/
Population Impact of NLST (LDCT)

- Data from NLST was applied to the population to estimate the number of lung cancer deaths that could be averted by LDCT screening
- 8.6 million Americans eligible for LDCT per NLST
  - 5.2m American men/3.4m American women
- Results
  - 12,250 lung cancer deaths averted each year
  - 8,990 American men/3260 American women
  - 7.6% of all American lung cancer deaths each year
  - (Ma et al., 2013, Cancer)

Kentucky Annual Cancer Deaths 2008-2012

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<tr>
<td>Prostate</td>
<td>21.5</td>
<td>373</td>
</tr>
<tr>
<td>Liver</td>
<td>5.5</td>
<td>273</td>
</tr>
<tr>
<td>Ovary</td>
<td>0.076 x 3442 = 262</td>
<td>200</td>
</tr>
</tbody>
</table>

http://statecancerprofiles.cancer.gov/

Generalizability/Eligibility Data

- Assessed variation in efficacy, false positive rates, and lung-cancer deaths prevented according to quintile of LC risk.
- Results
  - Benefit increased with risk
  - FP rate decreased with risk
  - 60% (Q1-3) accounted for 88% of prevented deaths and 64% of false positive results
  - 20% at lowest risk (Q1) accounted for only 1% of prevented deaths

(Kovalchik et al., 2013, Targeting of low-dose CT screening according to the risk of lung-cancer death, NEJM)
Cost-Effectiveness of LDCT Screening in the National Lung Screening Trial (NLST)

- Examination of mean life-years, quality-adjusted life-years (QALYs), costs per person and incremental cost-effectiveness ratios (ICERS) for LDCT, CXR, and no screening.

- Cost Per Person
  - $0 No screen
  - $469 CXR
  - $1,631 LDCT

- ICERs for LDCT
  - $52,000 per life-year gained (95% CI: $34,000 to $106,000)
  - $81,000 per QALY gained (95% CI: $52,000 to $186,000)

(Black et al., 2014, NEJM, 371, 1793-1802)

USPSTF Final Guidelines for Lung Cancer Screening

The Task Force recommends annual screening for lung cancer using low-dose computed tomography (LDCT) in individuals at high risk for lung cancer based on age and smoking history.

Grade B

(Posted July 29, 2013)
(Affirmed December 31, 2013)

GRADE B: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

(Humphrey et al., 2013, Annals of Internal Medicine, online)
(Moyer et al., 2013, Annals of Internal Medicine, online)

USPSTF Final Guideline for Lung Cancer Screening

- High Risk Status/Eligibility
  - age 55 through 80 years old, and
  - have a history of heavy smoking (30 p/y+), and
  - are either current smoker or quit within 15 years
  - other minor criteria and considerations

- Points from Draft to Final Guideline
  - upper age criteria extended (up to 80)
  - specifically calls for integration of tobacco cessation
  - specifically calls for shared decision making

(Humphrey et al., 2013, Annals of Internal Medicine, online)
(Moyer et al., 2013, Annals of Internal Medicine, online)

USPSTF Final Guideline for Lung Cancer Screening

Shared Decision Making
- "The decision to begin screening should be the result of a thorough discussion of the possible benefits, limitations, and known and uncertain harms.

Tobacco/Smoking Cessation
- "All persons enrolled in a screening program should receive smoking cessation interventions."
- "Because many persons may enter screening through pathways besides referral from primary care, the USPSTF encourages incorporating such interventions into the screening program."

American Cancer Society
- Clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should initiate a discussion about screening with patients aged 55-74 years who have at least a 30-pack-year smoking history and who currently smoke or have quit within the past 15 years. *(NLST-Consistent)*
- A process of informed and shared decision-making with a clinician related should occur before any decision is made to initiate lung cancer screening.
- Smoking cessation counseling remains a high priority.
- Screening should not be viewed as an alternative to smoking cessation.

Lung Cancer Screening Guidelines and Recommendations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Groups eligible for screening</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Academy of Family Physicians</td>
<td>Evidence is insufficient to recommend for or against screening</td>
<td>2013</td>
</tr>
<tr>
<td>American Association for Thoracic Surgery*</td>
<td>1. Age 55 to 74 years with ≥ 30-pack-year smoking history. 2. Lung cancer survivors who have completed 4 years of surveillance without recurrence and the can tolerate lung cancer treatment following screening to detect second primary lung cancer until the age of 79. 3. Age 55 to 74 years with a 20-pack-year smoking history and additional risk factors that produce a lifetime risk of developing lung cancer ≥ 3% in 5 years.</td>
<td>2012</td>
</tr>
<tr>
<td>American Cancer Society*</td>
<td>Age 55 to 74 years with ≥ 30 pack-year smoking history, who either currently smoke or have quit within the past 15 years, and who are in generally good health.</td>
<td>2015</td>
</tr>
<tr>
<td>American College of Chest Physicians*</td>
<td>Age 55 to 74 years with ≥ 30 pack-year smoking history, who either currently smoke or have quit within the past 15 years.</td>
<td>2015</td>
</tr>
<tr>
<td>American College of Chest Physicians and American Society of Clinical Oncology*</td>
<td>Age 55 to 74 years with ≥ 30 pack-year smoking history, who either currently smoke or have quit within the past 15 years.</td>
<td>2012</td>
</tr>
</tbody>
</table>
Canadian Task Force on Preventive Health Care
Age 55-74 with >30 pack year smoking history and no history of lung cancer, yearly up to three consecutive years.

“Done in settings "with expertise in early diagnosis and treatment of lung cancer"

Centers for Medicare and Medicaid Services

“The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to add a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, annual screening for lung cancer with low dose computed tomography (LDCT), as an additional preventive service benefit under the Medicare program only if the following conditions are met...”


Centers for Medicare and Medicaid Services

- Age 55-77
- Asymptomatic
- Tobacco exposure of 30+ pack/years
- Current or former smoker with 15 years
- Written order for LDCT-based lung cancer screening with...
  - Determination of eligibility
  - Documentation of an SDM consultation
  - Documentation of adherence/screening counseling
  - Tobacco cessation intervention

Lung Cancer Screening Guideline Summary

- Every recently revised guideline recommends LDCT-based screening for individuals who meet NLST eligibility criteria.
- Some guidelines offer softer recommendations for LDCT-based screening to individuals who are “near” the eligibility criteria.
- USPSTF has issued a “B” Grade, making way for ACA support for lung cancer screening, which began on January 1, 2015.
- CMS Final Coverage Determine on February 5, 2015 supported immediate coverage for LDCT-based lung cancer screening, but has notable qualifiers and practice-influencing components, including required documentation for patient counseling and shared decision making (SDM).

Lung Cancer Screening Implementation

Shared Decision Making

- What is Shared Decision Making?
- Why is it important for Lung Cancer Screening?
Lung Cancer Screening: the Need for Shared Decision Making

- Best predictor of cancer screening behavior is primary care provider recommendation.

- However, lung cancer screening needs to be approached from a different model due to the high risk/high reward nature of LDCT.

- Greater need for patient engagement in exploring potential benefits/harms and personal preferences (preference-sensitive decision).

Shared Decision Making (SDM)

**Informed decision making** occurs when an individual...

- understands what the clinical service involves, including...
  - potential benefits, harms, limitations, alternatives, & uncertainties
- has considered personal preferences, as appropriate;
- has participated in decision making at the desired level
- makes a decision consistent with those preferences...

**Shared decision making** connotes a process in which providers and patients collaborate as partners in the decision-making process.


Steps/Structure of a SDM Consultation

1. Invite the patient to participate
2. Present the decision/option(s)
3. Provide information
   - potential benefits, harms, uncertainties
   - check for understanding
4. Assist patient in evaluating decision based on goals and concerns
5. Facilitate deliberation/decision making
6. Assist with behavioral implementation

(Adapted from Informed Medical Decisions Foundation, 2012)
Discussing Potential Benefits of Lung Cancer Screening

- The USPSTF found adequate evidence that annual screening for lung cancer with LDCT in current and former smokers ages 55 to 79 years who have significant cumulative tobacco smoke exposure can prevent a substantial number of lung cancer deaths.
- The absolute magnitude of benefit depends on the population screened and the screening program used.
- Screening is not a one time test and needs to be done yearly to get the most benefit from screening.

(US Preventive Services Task Force Draft Recommendation Statement on Lung Cancer Screening)

Discussing Potential Harms of Lung Cancer Screening

- Detection of abnormalities that require additional evaluation but are not determined to be cancer (false positive results)
- Costs, loss of productivity, distress, morbidity, mortality
- Non-detection of malignant lesions (false negative results)
- Non-malignant incidental findings that require additional evaluation
- Radiation exposure (serial) could contribute to or cause cancer
- Prolonged follow-up of nodules
  - Cost, loss of productivity, distress, morbidity
- Overdiagnosis
  - treatment for lesions that would not have impacted patient's morbidity or mortality during their lifetime

(US Preventive Services Task Force Draft Recommendation Statement on Lung Cancer Screening)

RESURVE

ONLNE FIRST

Benefits and Harms of CT Screening for Lung Cancer
A Systematic Review

Risks Associated With Low-Dose Computed Tomography Screening

- False-positive and false-negative results
  - NLST CT group 40% had 1 positive CT
  - 96% were false-positive for lung cancer.
  - complications related to diagnostic evaluation of positive screening results were 1.4%
- Anxiety
- Potential unnecessary testing
- Radiation exposure
- Financial costs
- Overdiagnosis

Radiation Exposure

- LDCT exposure estimated 1.5 mSv per scan
- Total exposure estimated 8 mSv per subject
- Radiation-induced cancer 10-20 years later
- Benefit greater than risk for NLST criteria
- Risk greater than benefit for age ≤ 42

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Approx radiation dose</th>
<th>Natural background radiation for:</th>
<th>Estimated lifetime risk of fatal cancer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT-Colonography</td>
<td>10 mSv</td>
<td>3 years</td>
<td>Low</td>
</tr>
<tr>
<td>CT-Head, w/wo contrast</td>
<td>4 mSv</td>
<td>16 months</td>
<td>Low</td>
</tr>
<tr>
<td>CT-Chest</td>
<td>7 mSv</td>
<td>2 years</td>
<td>Low</td>
</tr>
<tr>
<td>CT-Lung Ca Screening</td>
<td>1.5 mSv</td>
<td>6 months</td>
<td>Very Low</td>
</tr>
<tr>
<td>DRR</td>
<td>0.1 mSv</td>
<td>10 days</td>
<td>Minimal</td>
</tr>
<tr>
<td>Mammography</td>
<td>0.4 mSv</td>
<td>7 weeks</td>
<td>Very Low</td>
</tr>
</tbody>
</table>

Discussing Uncertainty

- Involves addressing the available information and clarifying that any individual may experience different outcomes.
- Emphasize interpretation of information from patient’s perspective and how each person may weigh the potential pros and cons differently.
- Direct evidence from a large, well-conducted randomized, controlled trial (RCT) provides moderate certainty of the benefit of lung cancer screening with LDCT in this population.

(Adapted from Informed Medical Decisions Foundation, 2012)
Lung cancer screening counseling and shared decision making visit

1. Determination of beneficiary eligibility
   - Age
   - Absence of symptoms
   - "Specific calculation of cigarette smoking pack-years"
   - Number years since quit

   Documented in medical record

2. Shared decision-making, including the use of one or more decision aids, to include
   --benefits and harms of screening,
   --follow-up diagnostic testing,
   --over-diagnosis,
   --false positive rate, and
   --total radiation exposure

   Documented in medical record

3. Counseling on importance of adherence to annual LDCT, impact of comorbidities and ability or willingness to undergo diagnosis and treatment.

   Documented in medical record
4. Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and, if appropriate, furnishing of information about tobacco cessation interventions

LDCT – Patient Experience

- Overall, the process takes about 15 minutes or so.
- LDCT uses X-rays to scan the entire chest in about 5 to 10 seconds during a single breath-hold.
- The CT scanner looks like a donut, with the person undergoing a CT scan lying still on a table that moves through the opening in the scanner as the CT machinery rotates around the person.
- The process does NOT include any injections/is performed without contrast.

LDCT – Interpretation/Algorithm

- **Positive Screen** = findings suspicious for lung cancer
  - Non-calcified nodule(s) ≥ 4 mm in greatest transverse dimension
  - Any other suspicious finding (lobular collapse, enlarged hilar/mediastinal lymph nodes, endobronchial lesion)

- **Negative Screen** = no findings suspicious for lung cancer
  - Non-calcified nodule(s) < 4 mm or any benign calcified nodule
  - Other minor abnormality (e.g., emphysema, gallstones)
  - Abnormality requiring further evaluation (e.g., other mass)
  - No abnormality

(Aberle & Berg, NLST Team Slide Set)
Results of Initial LDCT:
Follow-up of Positive Screening Results

<table>
<thead>
<tr>
<th></th>
<th>LuCa+</th>
<th>LuCa-</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=270)</td>
<td></td>
<td></td>
<td>(N=7049)</td>
</tr>
<tr>
<td>Any Diagnostic Follow-Up</td>
<td>100.0%</td>
<td>90.0%</td>
<td>90.4%</td>
</tr>
<tr>
<td>Imaging Studies</td>
<td>95.6%</td>
<td>80.5%</td>
<td>81.1%</td>
</tr>
<tr>
<td>Percutaneous Analysis/Biopsy</td>
<td>36.3%</td>
<td>0.8%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>58.5%</td>
<td>2.2%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Surgical Procedure</td>
<td>76.7%</td>
<td>1.3%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Other Procedure</td>
<td>17.0%</td>
<td>1.8%</td>
<td>2.4%</td>
</tr>
</tbody>
</table>


LDCT: Follow-Up of Positive Screens

**Follow-Up Plan**
- 4-10 mm nodules: 3-6-mo follow-up LDCT recommended
- >10 mm or growing: immediate more aggressive eval.
  - Modified by margin, attenuation assessment

**Positive Scan Rates for LDCT**
- Screen 1: 7,193 of 26,314 = 27.3%
- Screen 2: 6,902 of 24,718 = 27.9%
- Screen 3: 4,054 of 24,104 = 16.8%
- All Screens: 18,149 of 75,136 = 24.2%

(Aberle & Berg, NLST Team Slide Set)

Checking for Understanding

“You’ve seen a lot of numbers which can be confusing. Do you have any questions? May I help you sort through them?”

OR

“I want to be sure that I’ve explained things well. Please tell me what you heard about the pros and cons of lung cancer screening.”

(Adapted from Informed Medical Decisions Foundation, 2012)
SDM Importance for LCS

- Multiple authoritative organizations strongly encourage (some mandate) shared decision making about lung cancer screening.

- The context of lung cancer screening demands a different approach to provider recommendations for cancer screening.

- Model is more akin to prostate cancer screening than other established programs.

Medscape

- Interviews of New Mexico primary care physicians about their beliefs and attitudes toward low-dose CT screening found that many were skeptical about the real-world applicability of the National Lung Screening Trial results, especially given its 95% false positive rate. [4]

- A survey of family physicians in South Carolina found that although three-quarters believed that the benefits of screening for lung cancer in patients who met Medicare criteria outweighed the harms, fewer than half had actually recommended it to more than one patient in the previous year. [5]
• The harms of repeat scans, bronchoscopy, or thoracotomy for positive findings might conceivably outweigh the potential benefits if patients who aren’t at high risk for lung cancer are screened inappropriately, or too many suspicious findings turn out to be harmless "incidentalomas" that would have been better left undetected.

• The jury is still out on whether the guidelines will end up doing more good than harm.

Conclusions

1. Results of the NLST create a unique opportunity to reduce lung cancer mortality. (Promise)

2. However, implementation of lung cancer screening needs to proceed differently than current cancer screening processes (Challenge)

3. We have a brief window to create optimal, high quality lung cancer screening programs that can fulfill the promise and meet the challenge, and SDM is a reasonable path to achieve these aims.