LDCT Lung Cancer Screening and Quitlines: New Research and Collaborations

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Patient Decision Aids for Lung Cancer Screening

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The statements presented in this work are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee. The authors declare they have no conflicts of interest.
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*Wake Forest University*
Objectives

1. Update progress on a study evaluating a patient decision aid about lung cancer screening implemented through quitlines.

2. Describe characteristics of the study participants, and baseline knowledge of lung cancer screening.

3. Invite participation in dissemination research on the products of the study with quitlines serving as partners.
Lung cancer screening: The National Lung Screening Trial

Randomized >53,000 heavy smokers to…

- Low-dose computed tomography (LDCT) or chest x-ray
- 3 annual screens
- Followed 6.5 yrs

Reduced lung cancer deaths by 16-20%.

Impact of lung cancer screening

Between 8,000 and 12,000 lung cancer deaths averted annually through screening high-risk smokers with low-dose computed tomography.

But,

rates of screening among high-risk smokers* remain low:

• 2.9% in 2010
• 5.8% in 2015

*High risk defined as pack-year smoking history of 30+, current smoker or quit within past 15 years.

**Current lung cancer screening policy**

**United States Preventive Services Task Force**

The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged **55 to 80 years** who have a **30 pack-year smoking history** and **currently smoke or have quit within the past 15 years**.

Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.

*Released December, 2013.*

**Centers for Medicare & Medicaid Services**

The evidence is sufficient to add 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.

*February 5, 2015.*
Current lung cancer screening policy

Centers for Medicare & Medicaid Services

Patient counseling and shared decision making visit

The beneficiary receives a written order including the following elements:

- Shared decision making, including the use of one or more decision aids, to include:
  - Benefits and harms of screening
  - Follow-up diagnostic testing
  - Overdiagnosis
  - False positives
  - Total radiation exposure

First preventive service policy requiring shared decision making and the use of patient decision aids!

Project Aims:

1. Update a video-based patient decision aid about lung cancer screening to reflect current eligibility criteria and evidence.

2. Compare the effectiveness of the decision aid versus standard education in promoting informed decisions about screening for lung cancer in a randomized trial of high-risk smokers recruited through tobacco quitlines.
Hypotheses:

Heavy smokers who view the decision aid (compared to those who receive the standard educational material) will:

• **Be more prepared** to make a decision about lung cancer screening
• **Feel more informed** about their decision
• **Be clearer about their values** related to the decision
• **Be more knowledgeable** about screening

We will further explore the impact of the aid on screening behaviors (intentions, PCP visits, screening completion)
Study Design

**Figure 2. Schema for the Randomized Trial.**

- **Group A Decision Aid**
  - N=200
  - Receive Decision Aid
  - 1-week follow-up assessment
    - Preparation for Decision Making Scale
    - Decisional Conflict Scale
  - 3-month and 6-month follow-up assessments
    - Knowledge
    - Screening behavior

- **Group B Educational Booklet**
  - N=200
  - Receive Educational Booklet
  - Knowledge
  - Screening intention

Tobacco quitline patients eligible for lung cancer screening
Lung Cancer Screening: Is it right for me?
Lung cancer kills more people in the United States than any other cancer.

- Are you 55 to 80 years old?
- Do you smoke or did you quit less than 15 years ago?

Help us test educational materials about lung cancer screening.

Learn the facts about lung cancer screening!
Find out if you qualify for an educational research study.
Call now: toll-free 1-844-572-0033
Email: LCSstudy@mdanderson.org
Participants will be compensated for their time and effort.
Lung Cancer Screening: Is it right for me?

- DVD format and web-enabled video
- Approx. 9 minute video
- Content:
  - Eligibility criteria
  - Overview of screening
  - Magnitude of benefits/harms (visual display)
  - Values clarification
- Messaging: Importance of smoking cessation!
- Meets certification standards
Lung Cancer Screening: Is it right for me?

1 pack a day for 30 years
or
both = 30 pack-years

2 packs a day for 15 years

18 would die from lung cancer (within 6.1/2 years)
3 fewer smokers would die from lung cancer

Benefits
- Reducing the chance of dying from lung cancer
- Finding other health problems that might be treated earlier

Harms
- Exposure to radiation
- False alarms and extra tests
- Being treated for a cancer that might never cause harm

Sources of Radiation

<table>
<thead>
<tr>
<th>Source</th>
<th>Radiation Level (milliSieverts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NY to LA Flight</td>
<td>0.01</td>
</tr>
<tr>
<td>CHEST X-RAY</td>
<td>0.90</td>
</tr>
<tr>
<td>MAMMOGRAM</td>
<td>0.45</td>
</tr>
<tr>
<td>C T SCAN</td>
<td>1.50</td>
</tr>
<tr>
<td>LIVING IN THE US</td>
<td>2.50</td>
</tr>
</tbody>
</table>
Participating Quitline Service Providers

Information & Quality Healthcare, IQH
Roswell Park Cancer Institute
OPTUM® (formerly Alere Wellbeing)
National Jewish Health®
ASHLine
Enrollment by state (n = 500 quitline patients)
## Baseline characteristics of the study participants

<table>
<thead>
<tr>
<th></th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>313 (62.6)</td>
</tr>
<tr>
<td>Male</td>
<td>187 (37.4)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>134 (26.8)</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islanders</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>White</td>
<td>358 (71.6)</td>
</tr>
<tr>
<td>Multi-race</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td>Refused to answer</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>9 (1.8)</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>491 (98.2)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>74 (14.8)</td>
</tr>
<tr>
<td>Graduated high school/GED</td>
<td>145 (29.0)</td>
</tr>
<tr>
<td>Some college/trade school</td>
<td>204 (40.8)</td>
</tr>
<tr>
<td>Graduated college or more</td>
<td>77 (15.4)</td>
</tr>
</tbody>
</table>

**Age**
Mean 61.7 years
Range 55-77

**90.9%** had some form of health insurance
## Smoking history of study participants

<table>
<thead>
<tr>
<th>Smoking history</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of years smoked</td>
<td>43.6</td>
<td>7.7</td>
<td>15 to 66</td>
</tr>
<tr>
<td>Number of cigarettes smoked per day</td>
<td>25.3</td>
<td>9.8</td>
<td>10 to 100</td>
</tr>
<tr>
<td>Pack-year smoking history</td>
<td>54.8</td>
<td>23.4</td>
<td>30 to 200</td>
</tr>
</tbody>
</table>

### Pack-year smoking history
- Median = 47.5 PY
- Upper quartile = 63 or greater PY

### How soon after awakening do/did you smoke your first cigarette?

- 5 minutes: 47.3%
- 6-30 minutes: 37.4%
- 31-60 minutes: 10.1%
- > 60 minutes: 5.2%
Knowledge of lung cancer screening at baseline

Is radiation one of the harms of LCS?

- Yes: 32.6%
- No: 18.8%
- I don't know: 48.6%

*Correct response.

Should all current and former smokers be screened for lung cancer?

- Yes: 88.4%
- No: 4.3%
- I don't know: 7.4%

How much does LCS lower chances of dying from lung cancer?

- 90%: 17.4%
- 50%: 24.4%
- 20%: 3.3%
- I don't know: 54.8%

How many people with an abnormal CT scan will have lung cancer?

- Most will: 7.9%
- About half: 21.7%
- Most will not: 8.5%
- I don't know: 61.8%

*Correct response.
Follow-up rates

1-week: 90.4%
3-months: 87.4%
6-months: 83.8%*

*Follow-up ongoing.
### Knowledge of lung cancer screening at 1-week follow-up

<table>
<thead>
<tr>
<th></th>
<th>% correct</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decision Aid (n=234)</strong></td>
<td><strong>Standard Educatio n (n=232)</strong></td>
<td></td>
</tr>
<tr>
<td>Is radiation exposure one of the harms of lung cancer screening? (yes)</td>
<td>67.7%</td>
<td>64.2%</td>
</tr>
<tr>
<td>Should all current and former smokers be screened for lung cancer? (no)</td>
<td>12.0%</td>
<td>5.2%</td>
</tr>
<tr>
<td>How much does screening for lung cancer with a CT scan lower your changes of dying from lung cancer? (about 20%)</td>
<td>25.4%</td>
<td>6.9%</td>
</tr>
<tr>
<td>How many people with an abnormal CT scan will have lung cancer? (most will not)</td>
<td>38.0%</td>
<td>9.1%</td>
</tr>
</tbody>
</table>
# Decisional conflict at 1-week follow-up

<table>
<thead>
<tr>
<th></th>
<th>% Yes</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Decision Aid (n=234)</td>
<td>Standard Education (n=232)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Know which lung cancer screening options are available?</td>
<td>38.0%</td>
<td>33.2%</td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>Know the benefits of lung cancer screening?</td>
<td>90.2%</td>
<td>78.4%</td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>Know the risks/side effects of lung cancer screening?</td>
<td>70.9%</td>
<td>44.0%</td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Clear about which benefits matter most to you?</td>
<td>75.6%</td>
<td>56.3%</td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Clear about which risks/side effects matter most to you?</td>
<td>69.2%</td>
<td>48.9%</td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Clear about which is more important to you, the benefits or risks/side effects?</td>
<td>85.9%</td>
<td>74.5%</td>
<td></td>
<td>0.01</td>
</tr>
</tbody>
</table>
Limited PCORI Funding Announcement: Dissemination and Implementation Research Results and Products in Real-World Settings

- Fund opportunities to disseminate original PCORI research
- Stimulate D&I approaches that will increase use of PCOR/CER research/products to diverse end-users
- Better understand barriers and facilitators or evidence dissemination
- Explore mechanisms for incorporating CER findings in decision making by diverse groups of stakeholders
PCORI: Dissemination and Implementation Research Results and Products in Real-World Settings

- Paper-based products for lay audiences, cultural groups, low health literacy/numeracy groups
- Electronic or web-based tools, social networking sites, health avatars,…
- Adaptation of electronic health records or decision aids attached to these systems
- Personal interactions occurring through one-on-one or group discussions, in real-world settings
We are looking for service providers and state departments of health to serve as partners in dissemination efforts.
Optimizing Effectiveness of Smoking Cessation Interventions during Low Dose CT Scanning for Lung Cancer

Principal Investigator: Paul Cinciripini, PhD

R01-CA2027078-01
National Cancer Institute

Presented by Vance Rabius, PhD
Overall objective

Test efficacy of 3 smoking cessation treatment strategies

In context of lung cancer screening

All participants receive standard care (brief advice) and randomized to:

- Integrated Care – counseling and medication provided by smoking cessation specialists within screening setting
- Quitline RX – Quitline referral + pharmacotherapy managed by LDCT medical provider
- Quitline – Quitline referral + NRT
Eligibility Criteria

**Inclusion**

- Daily smoker or non-daily with CO > 6 ppm or NicAlert Strip > 2
- Interested in treatment that might change smoking behavior
- Medically suitable for 1 or more pharmacotherapies

**Exclusion**

- Use of other smoking cessation treatment
- Medical conditions contraindicated to pharmacotherapy use
- Medical or psychiatric condition or concomitant medication that compromises safety or treatment
Treatment Arm 1 – Quitline (QL)

Counseling

- Delivered by Optum (similar to Texas Quitline)
- Five proactive counseling calls up to 50 days post-quit
- Written materials
- Interactive online program (Web Coach)

Pharmacotherapy

- Nicotine patch provided in 4 week installments up to 12 weeks contingent on 1 or more contact with QL
Treatment Arm 2: Quitline – RX (QL-RX)

Counseling (Same as QL)
- Delivered by Optum
- Five proactive counseling calls up to 50 days post-quit
- Written materials
- Interactive online program (Web Coach)

Pharmacotherapy
- NRT (single or dual), Varenicline or Bupropion as determined by provider
- Provided in 4 week installments for up to 12 weeks with 1 or more contact with QL
- Managed by LDCT provider
Treatment Arm 3: Integrated Care (IC)

**Counseling (Specialized)**
- 4-8 motivation and problem solving counseling sessions ~ 30 minutes each
- Master's level licensed psychological counselors - specialty training in smoking cessation and mental health
- Cognitive behavioral therapy e.g., stressors, mental health concerns, tobacco withdrawal
- Consultation with program psychiatrist to manage acute and/or severe psychiatric symptoms

**Pharmacotherapy**
- Individualized pharmacotherapy (NRT, Varenicline, Bupropion, Combination Therapy)
- Provided in 4 week installments for up to 12 weeks contingent on 1 or more contact with IC
- Managed by IC medical providers
Assessment

Screening: 6 week, 12 week (EOT)
6 month follow-up

- PHQ: Current Mental Health Conditions
- FTND
- Demographic, Health & Smoking Questionnaires
- AUDIT: Alcohol abuse
- Motivation:
  - TSAMS
  - Contemplation Ladder
  - I/E Motivation Scale
Primary Outcome

- Continued, prolonged, point prevalence based on SRNT recommendations
- Timeline follow back

- Biochemical verification
- Saliva cotinine level of <15 ng/ml
- For patients still using NRT, CO <4ppm

Smoking Abstinence

Primary outcome
7-day point prevalence abstinence
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