What is Quality Implementation of Lung Cancer Screening?

Thoughts on Optimizing Community-Based Implementation

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LDCT for Lung Cancer Screening

Promise

Challenge

IMPLEMENTATION
Objectives

1) Recognize importance of delivering quality lung cancer screening

2) Examine elements of quality lung cancer screening

3) Consider approaches to advancing the science and practice of lung cancer screening
Where do we go from here?

IMPLEMENTATION
Translating the NLST (and NELSON)
Implementing Lung Cancer Screening

Lung Cancer Screening Uptake 2010 (Pre-Policy)

Lung Cancer Screening Uptake 2015 (Post-Policy)

(Jemal & Fedewa, 2017; Huo, Shen, Volk, & Shih, 2017)
WHY SO LOW?

- **New**, translation takes time!

- **Field of Dreams Fallacy:**
  “If you build it, they will come.

- **Awareness:**
  Community
  Organizations
  Healthcare systems
  Clinicians
  Screening-Eligible Individuals!!

- **Our Approach:**
  Fear Appeal
  Stigma Appeal
  Rational Appeal

- **Screening Perspective/People**
Adherence: Another Threat to Lung Cancer Screening

**Implementation Issue**

Rates of adherence in the NLST included 95% in the LDCT arm and 93% in the CXR arm (crucial to identifying the 17/20% relative LC mortality reduction)

Anecdotal reports of program adherence as low as 20% to annual screening

**Tools/Strategy:** Engaging 🌟 Empathic 🌟 Feasible
LCS targets a unique population that likely requires substantial engagement efforts to achieve optimal outcomes.
Lung Cancer Screening: An Ongoing Case Study in Clinical and Translational Science

We are here
Implementation science seeks to understand the barriers and facilitators that influence successful implementation of effective interventions.

Implementation Science is needed to facilitate high quality lung cancer screening program development.
Translational Degradation (Acceleration)

- **T3 translation from RCT to community implementation**
  - Resources (e.g., high quality engagement efforts)
  - Expertise (e.g., image reading and nodule follow-up)
  - Effort (e.g., rigorous participant follow-up)
  - Motivation (e.g., desire to improve outcomes)

- “Hopefully, we will never do lung cancer screening as poorly as we do it today.”
  - Constant opportunities for improvement
  - Need for frameworks
  - Need for metrics
  - Need for evaluation systems
  - Need strong desire to improve patient outcomes
Serious Threats to Translation

- Pervasive, persistent, and toxic lung cancer stigma
- Time, Effort, and Resources to *Adapt* NLST
- Radiologic Assessment (reliable and valid reads)
- Navigation/Engagement (Adherence)
- Suboptimal or unfettered screening

Under-Screening  
Goldilocks Screening  
Over-Screening
What is Quality Implementation of LCS?

- I don’t know (for sure).
- Nobody knows (for sure).
- However, we must start somewhere, so here goes...
Primary Sources of Information to Inform Quality Implementation of Lung Cancer Screening
Rational Model of Lung Cancer Screening

- Identify High Risk Candidates
- Conduct Lung Cancer Screening
- Identify Pulmonary Nodules
- Perform Follow-Up Diagnostics
- Diagnose Lung Cancer Early
- Treat Early Stage Lung Cancer
- Reduce Lung Cancer Mortality
The National Lung Screening Study

OBJECTIVE:
• Compare whether screening with low-dose helical CT scan vs chest x-ray reduces lung cancer-specific mortality in participants who are at high risk for developing lung cancer.

Prospective randomized controlled trial
Screening for 3 consecutive years with either CXR or low-dose chest CT

- High Risk Subjects
  - Randomize
  - Experimental Group CT
  - Control Group CXR

Time
0 1 2 3 4 5 6 7 8 9 10 11 years

Final: 10/2010

https://clinicaltrials.gov/ct2/show/NCT00047385
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

**Figure 1.** Cumulative Numbers of Lung Cancers and of Deaths from Lung Cancer.

The number of lung cancers (Panel A) includes lung cancers that were diagnosed from the date of randomization through December 31, 2009. The number of deaths from lung cancer (Panel B) includes deaths that occurred from the date of randomization through January 15, 2009.

**NLST (2011) NEJM, 365, 395-409.**
Adherence to Annual LDCT

Where is the effect of lung cancer screening?

- By year 1?
- By ear 2?
- By year 3?

Adherence is a VITAL element of lung cancer screening.

- Community Engagement
- Person-Centered LCS
“Annual screening with chest radiographs did not reduce lung cancer mortality compared with usual care.”

(Oken et al., 2011, JAMA)
Lung Cancer Screening Programs

National Framework for Excellence In Lung Cancer Screening and Continuum of Care
Lung Cancer Alliance

THE PATIENT EXPERIENCE

Community Outreach: Lung Cancer Screening, Smoking Cessation

Multi-Disciplinary Lung Cancer Clinic

Nurse Navigation

Survivorship Program

Pulmonary Medicine, Thoracic Surgery, Medical Oncology, Radiation Oncology, Pathology, Radiology

CLINICAL TRIALS
American College of Surgeons Community Cancer Program
The USPSTF 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**: 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.

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

(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.

- **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) http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfact.pdf
Other Considerations: Implementing a Lung Cancer Screening Program

Eligibility Considerations
- Importance of eligibility criteria (e.g., generally healthy NLST sample)
- Screening to be discontinued after 15 years of not smoking

Smoking Cessation Counseling
- Integration in primary care AND lung cancer screening program

Shared Decision Making
- Benefits vary by risk, and screening cannot prevent most lung cancer deaths
  “The decision to begin screening should be the result of a thorough discussion of the possible benefits, limitations, and known and uncertain harms.”

Standardizing LDCT Screening and Follow-Up of Abnormal Findings
- Diagnostic accuracy, diagnostic systems (Lung-RADS)
- Management of nodules and treatment of malignancy
- Development of a registry to monitor implementation

(Moyer et al., 2014, Annals of Internal Medicine)
National Comprehensive Cancer Network
Lung Cancer Screening Guidelines

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Lung Cancer Screening

Frequently Reviewed And Updated

Extrapolates from High Quality Evidence
NCCN Lung Cancer Screening Guideline

Strengths
- Extensive lung cancer risk assessment algorithm
- Detailed nodule assessment and follow-up
- Rigorous discussion of benefits and potential harms
- Frequently reviewed/revised

Comments
- Extension of Eligibility
  Group 1: Traditional Eligible
    Category 1 Evidence
  Group 2: Expansion Group
    Lower age (50)
    Lower smoking exposure (20 py)
    Additional risk factors
    Category 2A Evidence

The 10 Pillars of Lung Cancer Screening

(Fintelman, et al., 2015, Radiographics, 35, 1894-1904)
The 10 Pillars of Lung Cancer Screening

1) Eligibility
2) Education
3) Exam Ordering
4) Imaging Acquisition
5) Image Review
6) Communication
7) Referral Network
8) Quality Improvement
9) Reimbursement
10) Research/Frontier

(PRE-Screening)

(PERI-Screening)

(POST-Screening)

(Throughout Screening)

(Fintelman, et al., 2015, Radiographics, 35, 1894-1904)
Implementing Lung Cancer Screening

1) INTRODUCTION
2) EVIDENCE BASE FOR LUNG CANCER SCREENING
3) ELIGIBILITY, CLINICAL PRACTICE GUIDELINES, MODELING
4) INSURANCE COVERAGE OF LUNG CANCER SCREENING
5) SHARED DECISION MAKING
6) CHALLENGES TO IMPLEMENTATION OF LUNG CANCER SCREENING PROGRAMS
7) OVERCOMING IMPLEMENTATION CHALLENGES
8) SCREENING PROGRAM CAPACITY
9) STRUCTURING LUNG CANCER SCREENING PROGRAMS
10) ENSURING THE QUALITY OF LUNG CANCER SCREENING
11) SMOKING CESSION AND LUNG CANCER SCREENING
12) VALUE AND EFFICIENCY IN LUNG CANCER SCREENING

Components of High-Quality Lung Cancer Screening? 
The National Consensus

1. Who is Offered Lung Cancer Screening
2. How Often and How Long to Screen
3. How the Scan is Performed
4. Lung Nodule Identification
5. Structured Reporting
6. Lung Nodule Management Algorithms
7. Smoking Cessation
8. Patient and Provider Education
9. Data Collection

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 screening with...
  - Determination of eligibility
  - Documentation of an SDM consultation
  - Documentation of adherence/screening counseling
  - Tobacco cessation intervention

Centers for Medicare and Medicaid Services

- **Beneficiary Eligibility**
  - Minor differences (e.g., age)
  - Substantial differences (e.g., process: documentation, SDM, counseling on adherence, and tobacco treatment)

- **Reading Radiologist Eligibility**
  - Board certification or board eligibility with the American Board of Radiology or equivalent organization;
  - Documented training in diagnostic radiology and radiation safety;
  - Involvement in supervision/interpretation of 300 chest computed tomography in the past 3 years;
  - Documented participation in CME in accordance with current ACR standards; and
  - Furnish lung cancer screening with LDCT in a radiology imaging facility that meets criteria below.

- **Radiology Imaging Facility Eligibility**
  - Performs LDCT with appropriate volumetric CT dose index for standard size patients
  - Utilizes a standardized lung nodule identification, classification and reporting system;
  - Makes available smoking cessation interventions for current smokers; and
  - Collects and submits data to a CMS-approved registry for each LDCT lung cancer screening performed.

American Lung Association (2018)

- Section 1: Implementing a Lung Cancer Screening Program
- Section 2: Strategies for Implementation—
  Program Structure and Panel Profiles
- Section 3: Planning a Lung Cancer Screening Program
- Section 4: Before the Screening—
  Identifying Eligibility Criteria and Providing Pre-Screening Counseling
- Section 5: During the Screening—
  Reporting
- Section 6: After the Screening Study—
  Surveillance and Follow-up
- Section 7: Smoking Cessation
- Section 8: References and Bibliography
- Section 9: Resources
High Quality Lung Cancer Screening

Community Centered

Candidates & Participants
Awareness
Engagement Preparation Management

Screening Program
Education Skills Systems Support

Healthcare System
Education Systems

Monitoring Feedback

Community-Engaged

National Regulation
Challenge →→→ Opportunity

*Patient (Person) – Centered Lung Cancer Screening*

High Quality Lung Cancer Screening

- Community
- Candidates & Participants
- Screening Program
- Healthcare System
- National Regulation

$X$ $X$ $X$ $X$ $X$
Person-Centered Lung Cancer Screening

What is it?

1) Fundamentally respects patient autonomy of choice
2) Systems design that acknowledges and respects the unique context
3) Interventions tailored to meet the individual needs of participants
4) A focus on engagement over compliance (high touch endeavor)
5) Integrates comprehensive lung cancer risk reduction efforts (e.g., radon)
6) A recognized need for multilevel design (e.g., system, clinician, patient)
7) Emphasis on acceptability and feasibility of implementation
8) Seeks optimal delivery of high quality services
9) Champions multilevel and possibly multichannel communication
10) Probably many other things...
Socio-Ecological Model of Lung Cancer Screening

Public Policy

Community

Healthcare System

LCS Program Operations

LCS Program Staff

Interpersonal Social Network

Screening Candidate
Prevention and Early Detection (PD)

What does the study plan to do?

- Integrate recommendations from evidence based guidelines to promote high quality lung cancer screening in Kentucky

- Apply specific implementation strategies (i.e., resources, training, feedback) to facilitate adoption and implementation of high quality lung cancer screening programs in diverse healthcare settings

- Evaluate outcomes of lung cancer screening using implementation science
Implementing High Quality Lung Cancer Screening in Kentucky

Implementation Strategies:

✓ Audit and feedback

✓ Financial support

✓ Provider training

✓ Centralized technical assistance

✓ Supportive network of sites/Learning community
Quality Implementation of Lung Cancer Screening: The QUILS Index®

1) Screening Eligibility and Algorithm
   1) Screening Eligibility Policy
   2) Screening Frequency and Duration Policy

2) Clinical Radiology Operations
   1) LDCT Performance
   2) Lung Nodule Identification
   3) Structured Results Reporting
   4) Lung Nodule Management Algorithm

3) Interdisciplinary Team Operations
   1) Interdisciplinary Clinical Team
   2) Team Review of Radiologic Results

4) Lung Cancer Prevention Efforts
   1) Tobacco Treatment Interventions
   2) Tobacco Treatment Targets
   3) Secondhand Smoke Prevention Education
   4) Radon Prevention Education

5) Patient Education, Counseling and Support
   1) Shared Decision Making
   2) Engagement and Retention Methods

6) Community Outreach
   1) Responsible Marketing/Outreach
   2) Provider Outreach
The QUILS Index®

- **Goals/Plan:**
  Develop objective standards for LCS program evaluation
  Incorporate a process for feedback to LCS programs
  Begin with structured interviews that evaluate policy and practices and transition to objective data from common database.

- **Principles:**
  Iterative – The QUILS Index 1.0 is wrong (like any model)
  Bidirectional communication with LCS sites to improve QUILS Index
  Problem-solving approach to promote achievable and valuable metrics
The QUILS Index© Scoring

Program Parameters

Screening Eligibility and Screening Algorithm
1) Screening Eligibility Policy - ASPEN LUNG
2) Screening Frequency and Duration Policy - ASPEN LUNG

Clinical Radiology Operations
3) LDCT Performance - ASPEN LUNG (1 field)
4) Lung Nodule Identification - D&I site data
5) Structured Results Reporting - ASPEN LUNG
6) Lung Nodule Management Algorithm - ASPEN LUNG

Interdisciplinary Team Operations
7) Interdisciplinary Clinical Team - D&I site data
8) Team Review of Radiologic Results - D&I site data

Lung Cancer Prevention Efforts
9) Tobacco Treatment Interventions - ASPEN LUNG
10) Tobacco Treatment Targets - ASPEN LUNG
11) Secondhand Smoke Prevention Education - ASPEN LUNG (1 field)
12) Radon Prevention Education - ASPEN LUNG (1 field)

Patient Education, Counseling and Support
13) Shared Decision Making - ASPEN LUNG
14) Engagement and Retention Methods - D&I site data

Community Outreach
15) Responsible Marketing/Outreach - D&I site data
16) Provider Outreach - D&I site data

75 maximum score
The QUILS Index®:
Structured Key Informant Interview

### Lung Cancer Prevention Efforts

1. **Which option best describes your program’s approach to delivering tobacco treatment interventions?**
   - CTTS integrated into evidence-based comprehensive program (treat, track, follow) (5)
   - Integrated evidence-based comprehensive program w/o CTTS (treat/track/follow) (4)
   - Integrated evidence-based comprehensive program w/o CTTS (treat only) (3)
   - Referral to local/regional resources (e.g., quitline, cooper-clayton, etc) (2)
   - Advice to quit/Have brochures available (1)
   - None/No systematic approach (0)

2. **Which participants in your program receive evidence-based tobacco treatments?**
   - All patients at each encounter (5)
   - All patients at initial encounter only (3)
   - Only active smokers at each encounter (2)
   - Only active smokers at initial encounter (1)
   - None/Other: ______________________

3. **Which option best describes your program’s approach to second-hand smoking prevention?**
   - Counseling on importance of reducing exposure to second-hand smoke exposure (3)
   - Flyers/hand-outs regarding importance of reducing second-hand smoke exposure (1)
   - None (0)

4. **Which option best describes your program’s approach to radon prevention?**
   - Counseling on the importance of radon testing and mitigation (2)
   - Flyers/hand-outs regarding the importance of radon testing and mitigation (1)
   - None (0)
Data Sources for Evaluation

1) Team Member Interviews (Structured and Semi-Structured)
2) Program Surveys (Standardized IS Instruments)
3) Program Database Extraction (Enhanced Common Database)
Kentucky LEADS Collaborative

- Very long process
- Trial (finally) launches next week
- Preliminary/baseline results next year

Thank You

- Bristol-Myers Squibb Foundation
- National Cancer Institute
- Kentucky Lung Cancer Research Program
- University of Kentucky Markey Cancer Center
Lung Cancer Control Continuum

Prevention → Early Detection → Diagnosis → Treatment → Survivorship

Lung Cancer Stigma
Conclusions

- Large array of information, data, and perspectives to inform quality implementation of lung cancer screening.

- Defining exact “quality lung cancer screening” remains an active work in progress.

- Implementation science, harnessing many methods, is our best chance at quality implementation and achieving outcomes.

- More national and regional data as well as data sharing and collaboration will be necessary to achieve greater LC mortality reductions.

- In addition to factors directly related to lung cancer screening operations, we must consider a broader range of factors that will impact screening.

- Hoping that a Person-Center Lung Cancer Screening Approach can address a range of challenges, and I believe that the collaborative ongoing work in Maine and Kentucky will make substantial contributions to this clinical arena.
Thank You

QUILS and Answers
The QUILS Index®
QUality Implementation of Lung Cancer Screening

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Lung Cancer Screening

Professional Lenses

Primary Care Lens

Complication Lens

Oncology Care Lens

Damage Lens