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# Low-Dose CT for Lung Cancer Screening: Promises and Challenges

Jamie L. Studts, PhD

Timothy Wm. Mullett, MD

Michael A. Brooks, MD

University of Kentucky College of Medicine

Lucille P. Markey Cancer Center

# Low-Dose CT for Lung Cancer Screening

**Promises**

**Challenges**



**IMPLEMENTATION**

# Agenda

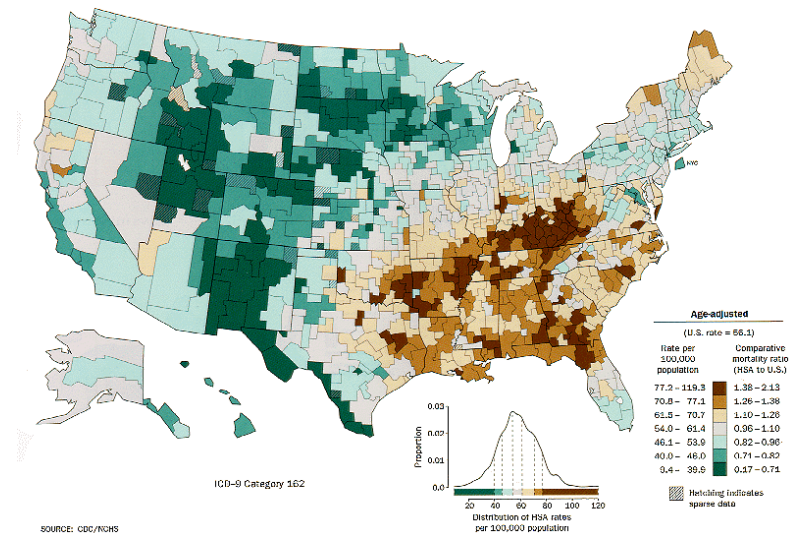
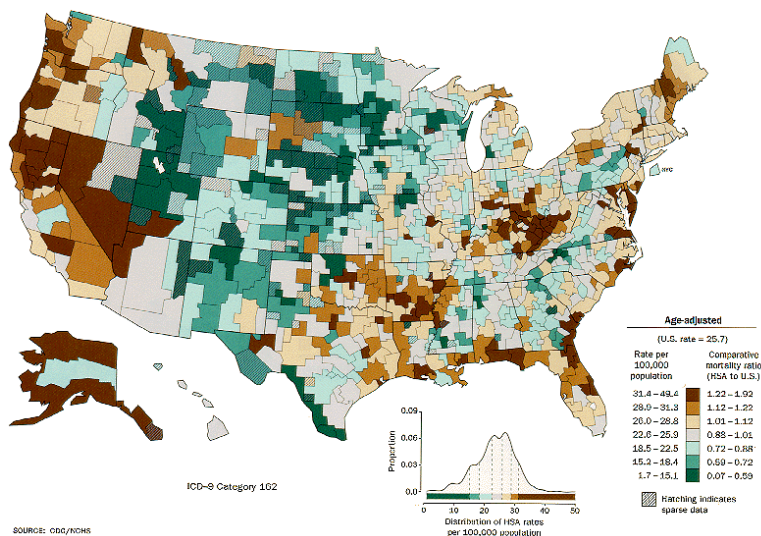
- Lung Cancer Epidemiology
- Evidence regarding Lung Cancer Screening
- Shared Decision Making for Lung Cancer Screening
- Comments and Questions

# Epidemiology of Lung Cancer

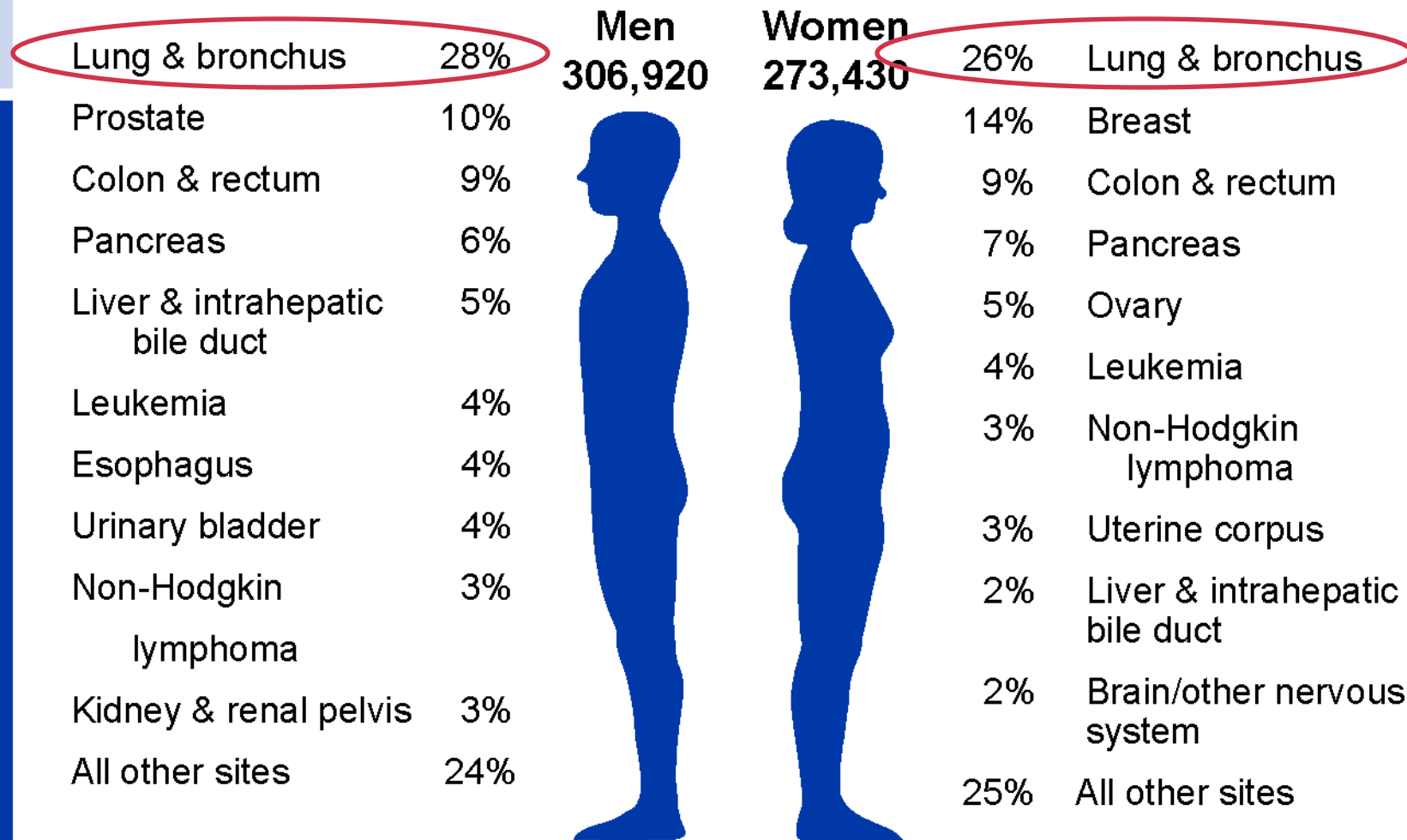
United States

Kentucky

Kentucky River Area Development District



# Estimated Cancer Deaths in the US in 2013



# Lung Cancer Epidemiology

- Lung cancer **incidence** rate
  - USA 84.4 (men) 55.7 (women)
  - Kentucky: 130.1 (men) 79.5 (women)
  - KR-ADD 165.2 (men) 103.2 (women)
- Lung cancer **mortality** rate
  - USA: 67.4 (men) 40.1 (women)
  - Kentucky: 103.0 (men) 56.1 (women)
  - KR-ADD 130.0 (men) 69.9 (women)
- Adult **smoking rate** (2012)
  - USA 21.2%
  - Kentucky 28.3%
  - KR-ADD 33.6%

American Cancer Society (2013). *Cancer facts and figures – 2013 & Kentucky Cancer Registry*

Note: All rates are per 100,000. Rates are age-adjusted to the 2000 U.S. Standard Million Population.

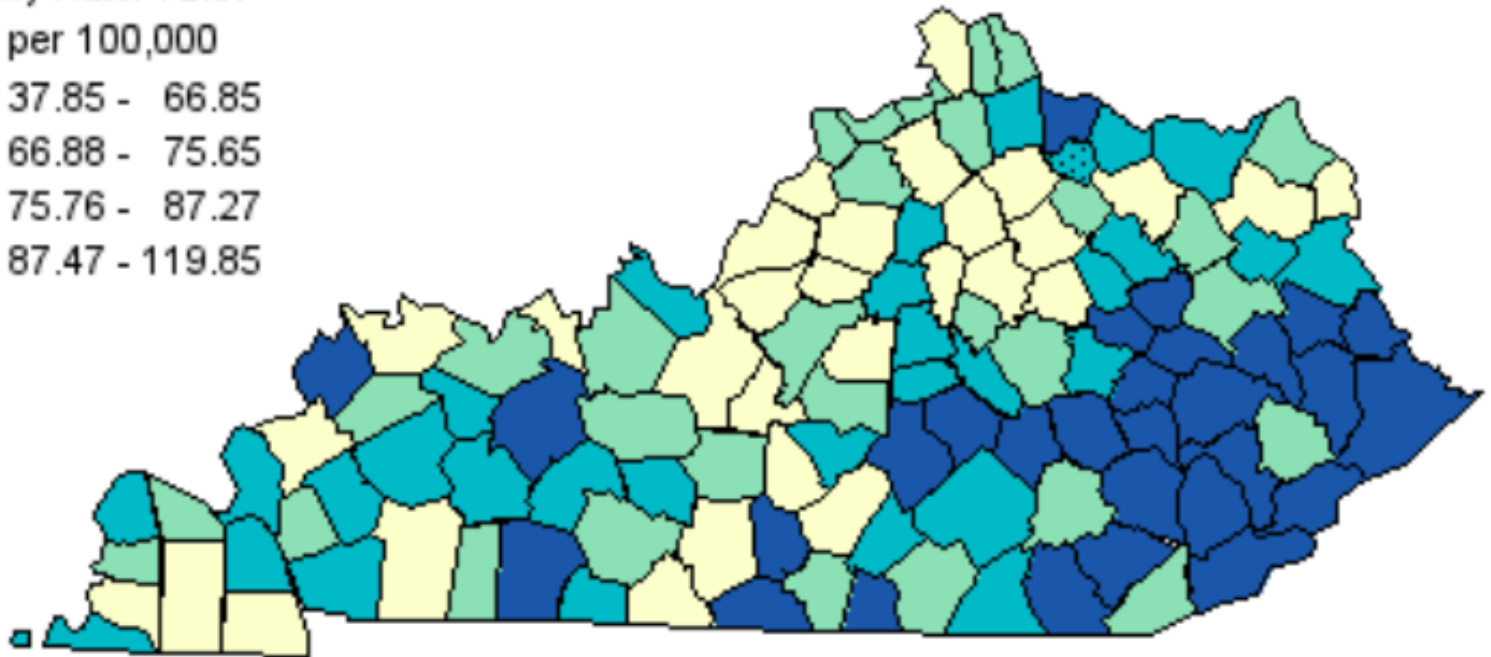
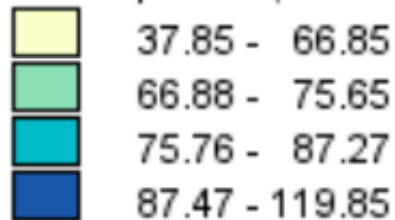
# Lung Cancer Mortality in Kentucky

## Age-Adjusted Cancer Mortality Rates in Kentucky Lung and Bronchus, 2006-2010 By County

Age-Adjusted to the 2000 U.S. Standard Million Population

Kentucky Rate: 72.57

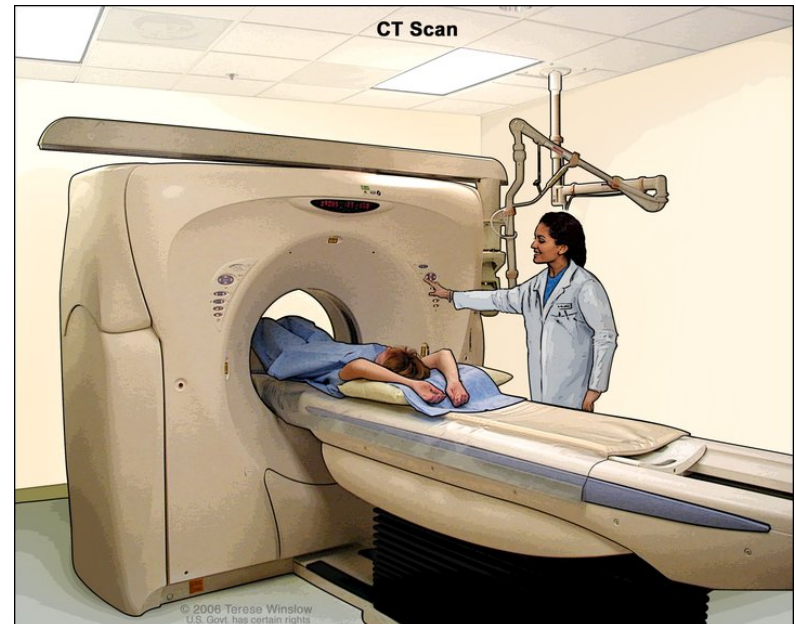
Rate per 100,000



Data accessed July 26, 2013.  
Based on data released May 2, 2013.  
Copyright (C) 2013 Kentucky Cancer Registry



# 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

- Overall Results

- No study demonstrated a mortality reduction
- Challenges: efficacious Tx, specificity issues → false positives, cost
- Some methodological limitations hindered analysis

# Prostate, Lung, Colorectal, Ovarian (PLCO) Trial

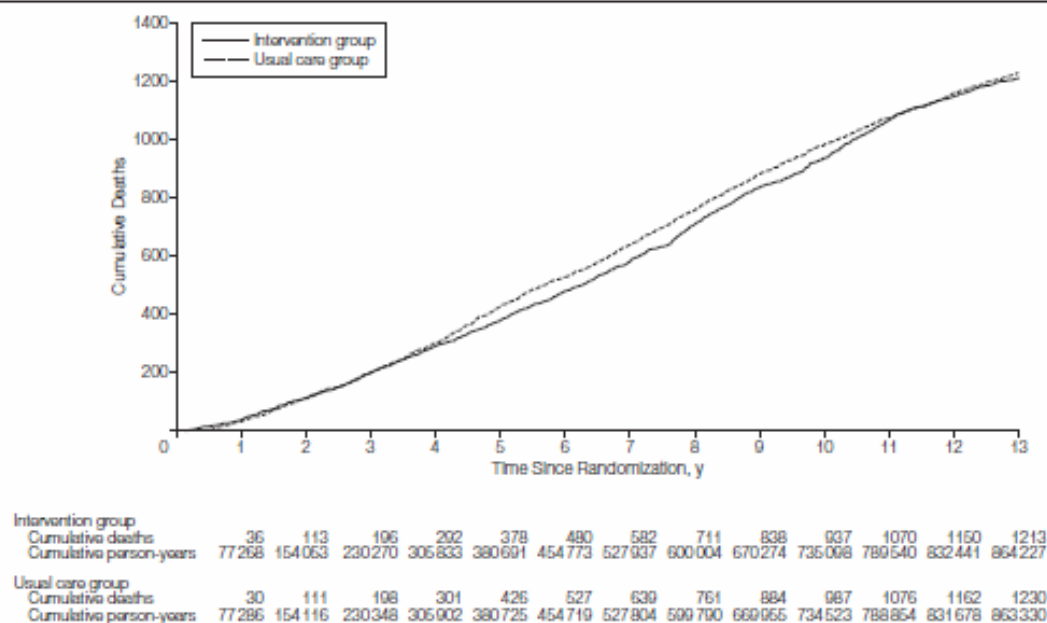


- Main Objective
  - to determine if CXR screening could reduce lung cancer specific mortality relative to usual care (UC).
- Participants
  - 154,942 participants
- Intervention
  - Baseline + Annual CXR for 3 years vs. usual care (UC)
- Eligibility Criteria
  - 55 to 74 years of age
  - No specific lung cancer risk criteria
  - However, results analyzed by NLST eligibility criteria

(Oken et al., 2011, JAMA)

# PLCO Trial Results

**Figure 3. Lung Cancer Mortality by Year**



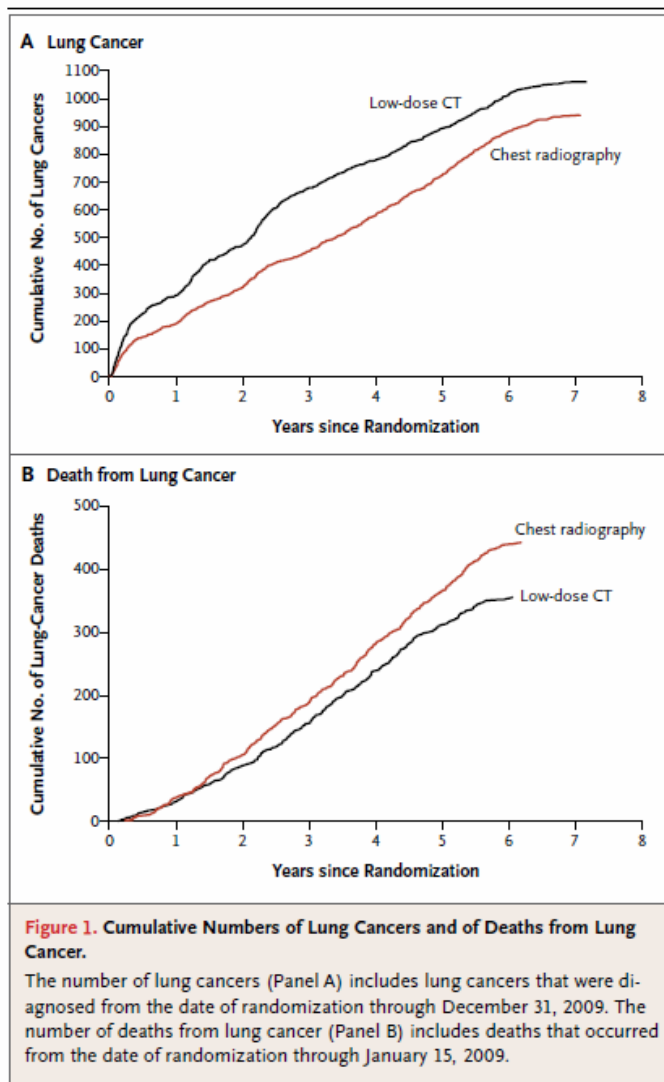
“Annual screening with chest radiographs did not reduce lung cancer mortality compared with usual care.”  
(Oken et al., 2011, JAMA)

# National Lung Screening Trial



- **Main Objective**
  - to determine if LDCT screening could reduce lung cancer specific mortality relative to CXR.
- **Participants**
  - 53,454 participants
- **Intervention**
  - 3 annual screens: randomized to either LDCT or CXR
- **Eligibility Criteria**
  - 55 to 74 years of age
  - at least 30 pack-years history of cigarette smoking
  - former smokers must have quit within the past 15 years

# 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 (2011) *NEJM*, 365, 395-409.

# National Lung Screening Trial (NLST)

## In Summary, for those who received a CT scan:

- **99.5% saw no benefit**
- **0.5% were helped by preventing death**
- **23% were harmed by false positive (cancer scare)**
- **3.5% were harmed by undergoing a surgical procedure**
- **0.6% were harmed by suffering a complication of surgery**

## In Other Words:

- **1 in 217 were helped (prevented death)**
- **1 in 4 were harmed (false positive CT scan)**
- **1 in 30 were harmed (unnecessary surgery)**
- **1 in 161 were harmed (surgical complication)**

<http://www.thennt.com/ct-scans-to-screen-for-lung-cancer/>



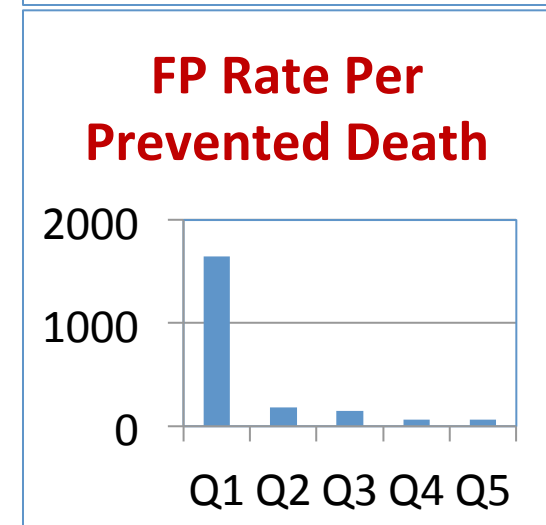
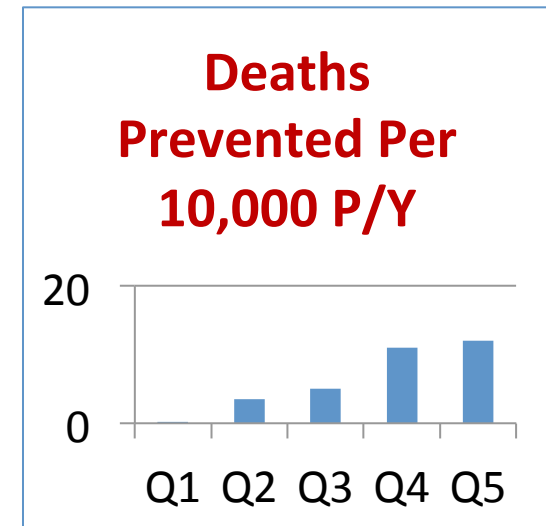
# Population Impact of NLST (LDCT)

- 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*)

# 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



# Current Lung Cancer Screening Guidelines & Recommendations

Organization	Recommendation	Year
American College of Chest Physicians/American Society of Clinical Oncology	Recommends annual low-dose CT scan screening for high-risk individuals (age 55 to 74 years with 30 pack-year history of smoking and current smoker or quit within past 15 years).	2012
American Association of Thoracic Surgery (AATS)	Recommends annual low-dose CT scan screening for high-risk individuals (age 55 to 74 years with 30 pack-year history of smoking and current smoker or quit within past 15 years) or age 50 with cumulative risk >5 percent over next five years.	2012
National Comprehensive Cancer Network	Recommends annual low-dose CT scan screening for high-risk individuals (age 55 to 74 years with 30 pack-year history of smoking or 20 pack-year history with an additional risk factor).	2011
American Cancer Society	Recommends annual low-dose CT scan screening for high-risk individuals (age 55 to 74 years with 30 pack-year history of smoking and current smoker or quit within past 15 years). Informed individual decision making before testing.	2013
US Preventive Services Task Force	<del>Evidence is insufficient to recommend for or against screening asymptomatic persons for lung cancer with either low-dose computerized tomography, chest x-ray, sputum cytology, or a combination of these tests.</del>	<del>2004</del>
Canadian Task Force on the Periodic Health Examination	Recommends against the use of chest x-ray in asymptomatic persons. Evidence is insufficient to recommend for or against screening with spiral CT in asymptomatic persons.	2003

(Deffenbach, & Humphrey 2013, Screening for lung cancer. *UpToDate*)

# USPSTF Draft 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

USPSTF Recommendation Grades	
Grade	Definition
A	Recommended.
B	Recommended.
C	Recommendation depends on the patient's situation.
D	Not recommended.
I statement	There is not enough evidence to make a recommendation.

(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)

<http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfact.pdf>

# 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)

<http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfact.pdf>

# 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.”

(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>

# American Cancer Society



- This guideline recommends that clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should initiate a discussion about screening with apparently healthy patients aged 55 years to 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 to the potential benefits, limitations, and harms associated with screening for lung cancer with low-dose computed tomography should occur before any decision is made to initiate lung cancer screening.
- **Smoking cessation counseling** remains a high priority for clinical attention in discussions with current smokers, who should be informed of their continuing risk of lung cancer.
- Screening should not be viewed as an alternative to smoking cessation.

# National Comprehensive Cancer Network



National  
Comprehensive  
Cancer  
Network®

- **Eligibility A (NLST Consistent)**

- Age 55 – 74 and...
- $\geq 30$  pack year smoking history
- Current smoker or quit within past 15 years

- **Eligibility B (Extension)**

- Age 50 – 74 and
- $\geq 20$  pack year smoking history, and
- One or more of the following risk factors...
  - Exposure to radon, silica, metals, diesel fumes
  - Personal history of cancer
  - COPD or pulmonary fibrosis
  - A family history of lung cancer





# LUNG CANCER ALLIANCE

- Strong advocates for screening
- “Low dose CT screening for lung cancer carried out safely, efficiently and equitably will save tens of thousands of lives a year.”
- More aligned with NCCN guidelines to broaden access to LDCT



# 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 draft “B” Grade, making way for ACA support for lung cancer screening. A final statement is expected prior to January 1, 2015.

# Lung Cancer Screening Implementation

Low-Cost Lung Cancer Screening

**\$50**  
Only

Part of a special one-year program. Price valid from May 2013 - May 2014



**"Low Dose" Lung CT Scan**  
Reduces Mortality from Lung Cancer  
You may be at risk if you are now smoking or have a history of heavy smoking.

Our Lung Health Program is a comprehensive package that includes an analysis of the lungs and coronary arteries and three personalized smoking cessation classes. All.

Coupon valid only for Lung Health Screening Program (Insurance coverage may vary) Expiration date 12/31/12

**\$100.00 off**

For more information call 203.859.4896 or visit [www.ctlungcancerscreening.com](http://www.ctlungcancerscreening.com)

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**\$150 Lung Cancer Screening**

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**LUNG  
CANCER?**

Low-Cost Lung Cancer Screening at

THE ROY AND PATRICIA DISNEY FAMILY CANCER CENTER



**LUNG CANCER SCREENING  
CAN SAVE LIVES.**

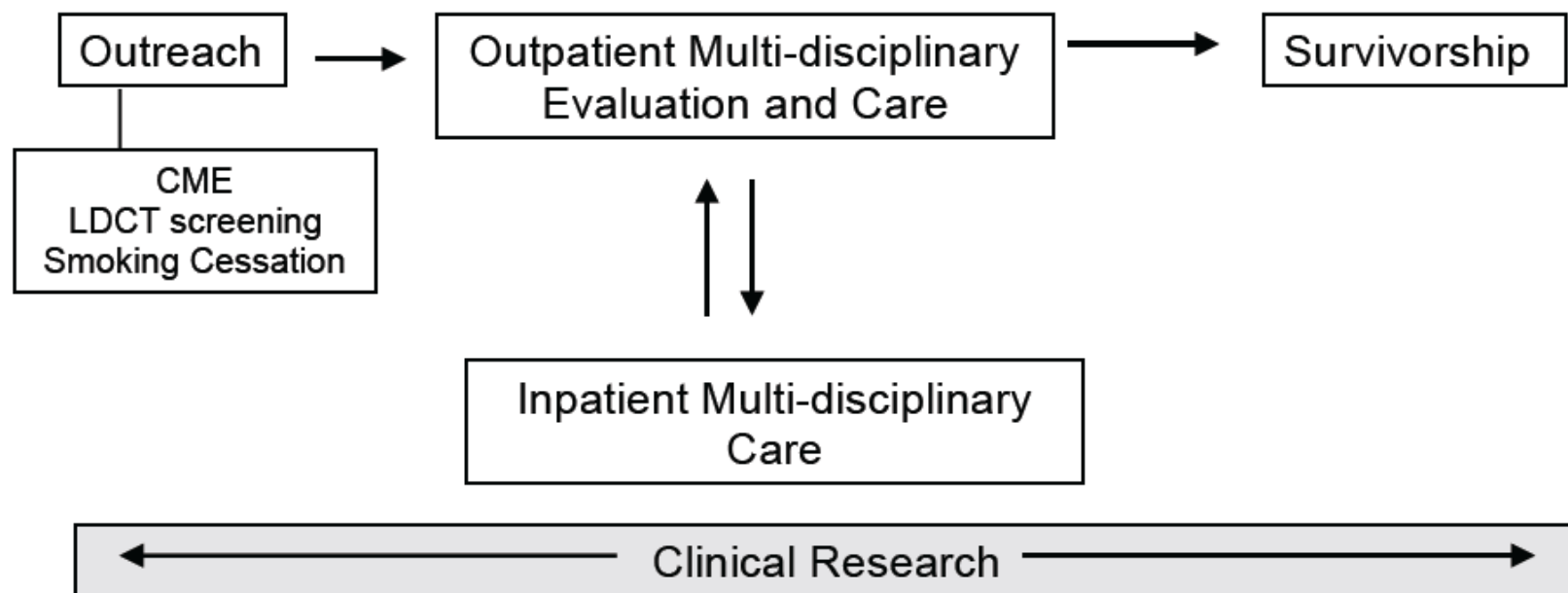
Find out if you are at risk >>



# Lung Cancer Screening Programs

## The WellStar Framework Continuum of Care in Lung Cancer Screening

### COC FRAMEWORK OVERVIEW

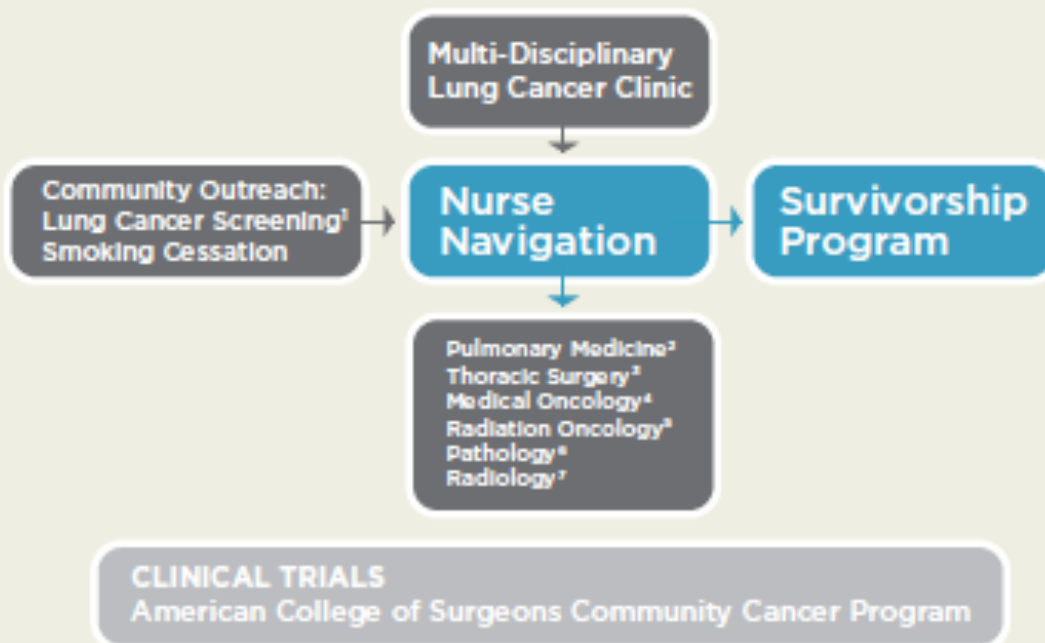


# Lung Cancer Screening Programs

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



## THE PATIENT EXPERIENCE



# Comprehensive LCS Program

- Lung Cancer Screening via LDCT
- Evidence-based Tobacco Cessation  
(*Treating Tobacco Use and Dependence*, 2008)
- Multidisciplinary Team and Management Plan
- Radon Awareness/Other Risk-reduction efforts
- ***Patient Navigation and Support***

# Role of Navigator in Lung Cancer Screening

- Maintain agnostic perspective on screening:  
***inform rather than persuade***
- Support patient engagement and informed/shared decision making
- Integrate evidence-based tobacco cessation (5A's)
- Facilitate subsequent screening, diagnostic workups, and quality lung cancer care when needed

# 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)

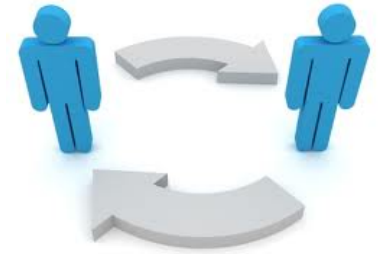
**Informed decision making** occurs when an individual...

- **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



# 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.

# 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/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

# 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.

# 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)  $\geq 4$  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



# Results of Initial LDCT: Follow-up of Positive Screening Results

	<b>LuCa+</b>	<b>LuCa-</b>	<b>Total</b>
	<b><u>(n=270)</u></b>	<b><u>(n=6,779)</u></b>	<b><u>(N=7,049)</u></b>
• Imaging Studies	100.0%	90.0%	90.4%
• Percutaneous Analysis/Biopsy	36.3%	0.8%	2.2%
• Bronchoscopy	58.5%	2.2%	4.3%
• Surgical Procedure	76.7%	1.3%	4.2%
• Other Procedure	17.0%	1.8%	2.4%

(NLST, 2013, NEJM, 368, 1980-1991)

# 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%

# 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?”*



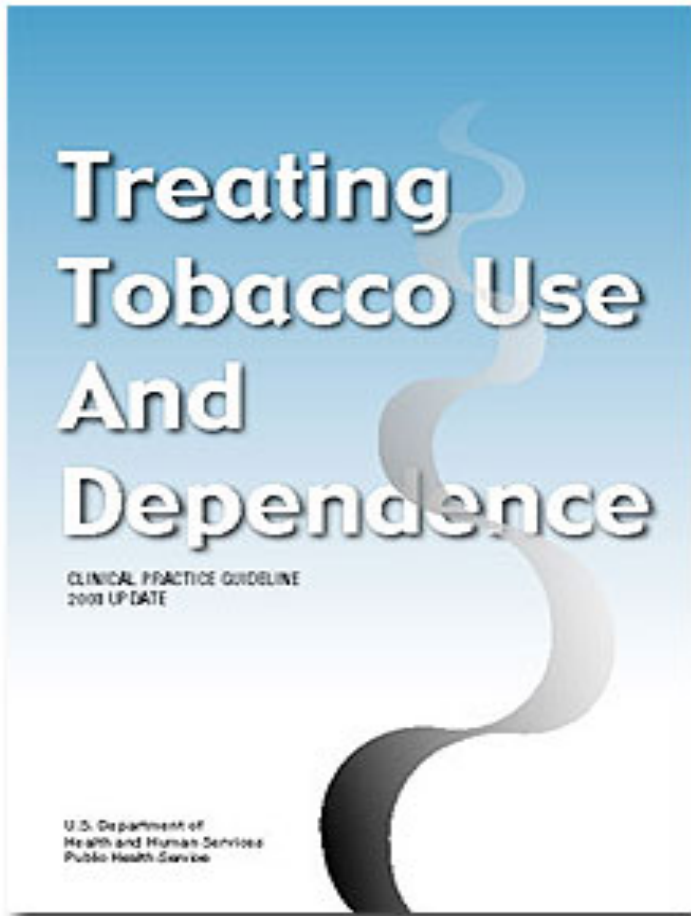
**OR**

*“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.”*

# SDM Importance for LCS

- Multiple authoritative organizations strongly encourage 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.

# Treating Tobacco Use and Dependence: Clinical Practice Guideline (USPHS, 2008)



- Assists in identifying and assessing tobacco users and in delivering effective tobacco dependence interventions
- Provides strategies and recommendations for clinicians
- Offers a detailed description of the 5 A's of treating tobacco dependence
- Identifies 10 key findings that clinicians should use with patients

# 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.

# Colleagues, Collaborators, and Support

## University of Miami

- Margaret M. Byrne, PhD
- Richard Thurer, MD

## University of Pittsburgh

- Mark Roberts, MD

## Maine Medical Center

- Paul Han, MD

## University of Kentucky

- Tim Mullett, MD
- Michael Brooks, MD
- Mark Dignan, PhD, MPH
- Susanne Arnold, MD
- Eric Bensadoun, MD

## Marcum & Wallace Hospital

- Rondall Gobel, MD
- Jim Thacker, Navigator
- Sharon Whitaker
- William Witt, MD
- Elizabeth Walling
- Susan Starling, CEO



# Thank You

Please take a moment to  
complete the brief survey.

## Comments & Questions



# MedPage Today Survey Question

- ***Should CT-based screening be recommended for ALL smokers?***
  - 2,582 responses
  - 44 narrative comments
    - Blaming
    - Useless
    - Over-endorsement

