LUNG CANCER SCREENING

The Evidence for LDCT

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Disclosures

No financial disclosures

Chair NCCN Lung Cancer Screening Panel

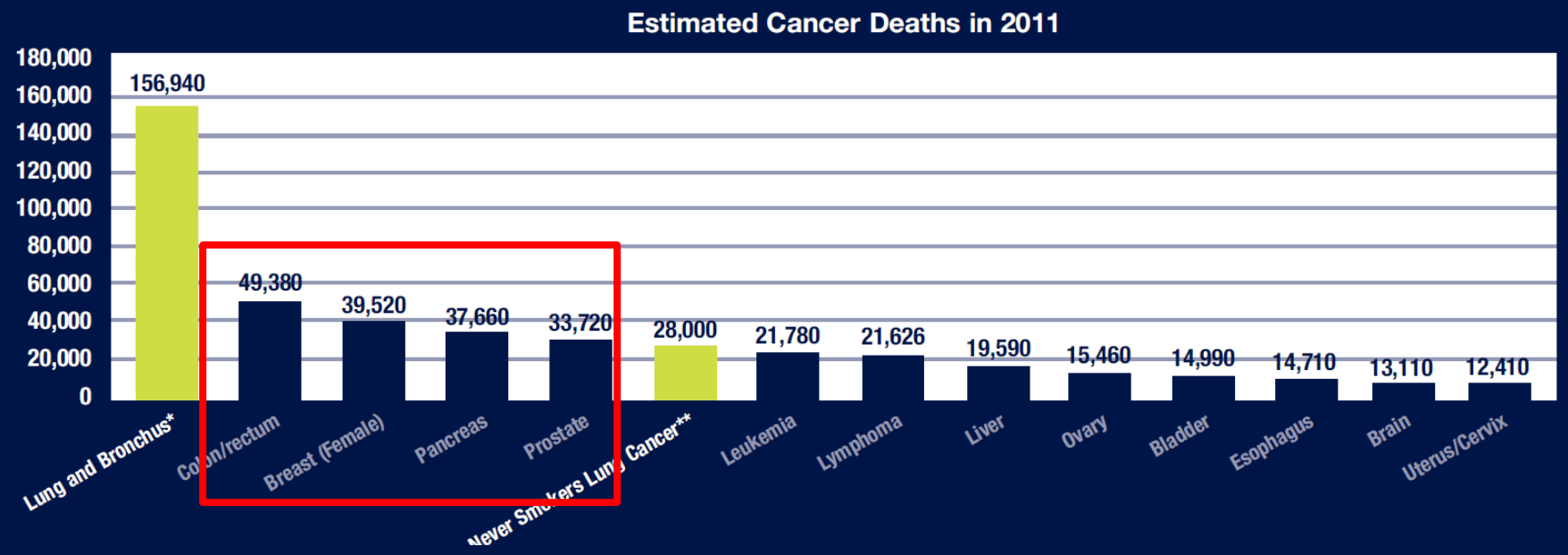
Vice-Chair NCCN Non-Small Cell Lung Cancer Guidelines Panel

Co-Chair, American Cancer Society National Lung Cancer Roundtable

Which is the following is true regarding insurance coverage for lung cancer screening?

1. There is no coverage for lung cancer screening.
2. Medicare covers screening for high-risk patients.
3. Private insurers cover screening for high risk patients.
4. Both Medicare and private insurers cover screening for high-risk patients.
5. Medicare and private insurers cover all patients for screening.

Lung Cancer is the Leading Cause of Cancer Death in Every Ethnic Group



Lung Cancer is the Second Leading Cause of all Deaths in the United States

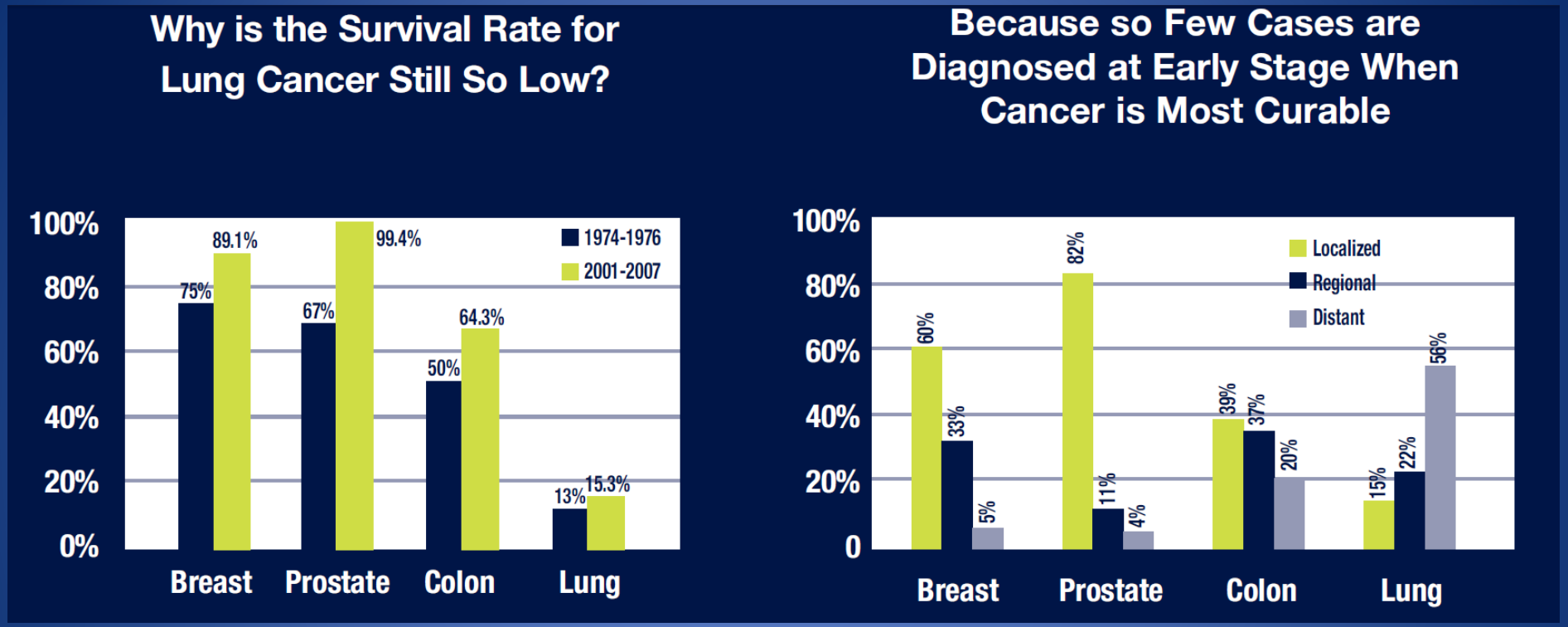
Actual Deaths in 2009

Heart disease 598,607	Breast cancer: 41,115	Homicide 16,591
Lung cancer 158,105	Suicide 36,547	Ovarian cancer 14,513
Lower respiratory disease ...*137,082	Pancreatic cancer 35,872	Bladder cancer 14,315
Stroke: 128,603	Septicemia 35,587	Brain cancer 14,192
Accident: 117,176	Liver disease 30,444	Esophageal cancer 13,916
Alzheimers: 78,889	Prostate cancer 28,154	Kidney cancer 13,027
Diabetes: 68,504	Leukemia 22,697	Stomach cancer 11,139
Colorectal cancer 52,462	Lymphoma 21,626	HIV/AIDS 9,424
Pneumonia 50,774	Parkinson's disease 20,552	Melanoma 9,254
Kidney disease 48,714	Liver cancer 19,311	Lip/oral cancers 7,913

* Includes COPD, emphysema, asthma, bronchitis

Source: National Center for Health Statistics; http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_04_tables.pdf

Cancer Screening – Early Detection



Cancer screening coverage

- Breast
- Prostate
- Colon

Lung cancer disparities

- Elderly
- Low socioeconomic group
- Racial
- “Self-inflicted” disease

LUNG CANCER SCREENING
Background

Previous studies have established lower stage distribution, and improved resectability and survival
BUT not lower mortality

No randomized trial has had an appropriate control
Randomized control trial very difficult to perform
Previous trials have had increased incidence in screened groups - ? Overdiagnosis, length, or lead time bias

NCCN® Practice Guidelines in Oncology – v.1.2010

Non-Small Cell Lung Cancer

LUNG CANCER PREVENTION AND SCREENING

At the present time, the NCCN panel does not recommend the routine use of screening CT as standard clinical practice (category 3). Available data are conflicting and thus, conclusive data from ongoing clinical trials are necessary to define the benefits and risks….

National Lung Screening Trial

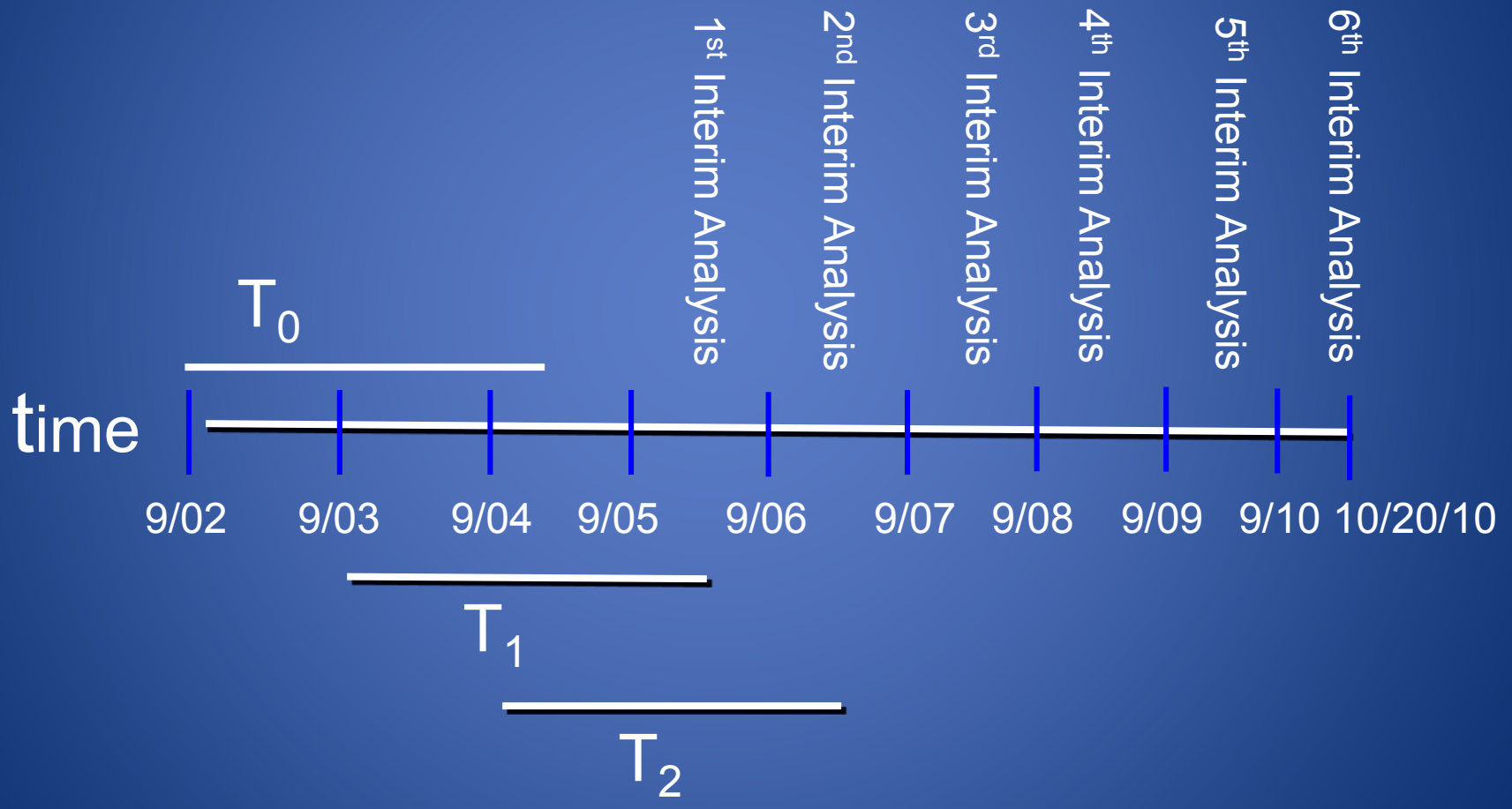
Primary aim: to determine whether lung cancer screening using low-dose helical CT reduces lung cancer-specific mortality relative to screening with chest radiographs in a high-risk cohort.

National Lung Screening Trial (NCI)

- Study design: Randomized controlled trial
- Interventions: 3 screenings performed over 2 years:
- 1º Outcome: Lung cancer mortality assessed after 5 years of follow-up
- Major eligibility criteria:
  - Age 55 to 74 years
  - A cigarette smoking history of at least 30 pack-years
  - Current cigarette smokers and former smokers who quit within 15 years of randomization
- Enrollment: 53,454 participants at 33 sites
  - 90% statistical power to detect a 20% reduction in lung cancer mortality
  - Secondary endpoint of all cause mortality

National Lung Screening Trial NEJM 2011

NLST Timeline



National Lung Screening Trial Results

Lung Cancer Specific Mortality

Trial Arm	Person Years (py)	Lung Cancer Deaths	Lung Cancer Mortality per 100,000 py	Reduction in Lung Cancer Mortality (%)	95% CI	p Value
LDCT	144,103	356	247	20.0	6.8 to 26.7	0.004
CXR	143,368	443	309			

All Cause Mortality

Trial Arm	Person Years (py)	Deaths	All-cause Mortality per 100,000 py	Reduction in All-cause Mortality (%)	95% CI	p Value
LDCT	167,389	1877	1121	6.7	1.2 to 13.6	0.02
CXR	166,382	2000	1202			

National Lung Screening Trial NEJM 2011

Conclusion

Screening with low dose chest CT conclusively reduces mortality from lung cancer in high risk patients.

National Lung Screening Trial NEJM 2011

Benefits of Guidelines for Screening or Preventive Services

- Especially important to identify “at risk” population
- Identification of benefits and harms
- Uniformity of evaluation and management protocols
- Avoidance of over-testing
  - Lack of knowledge by provider
  - Anxiety of patient
  - Financial incentives
- Identification of requisite specialization
- Guide correct entry points to treatment (and mitigate potential of over treatment)

National Comprehensive Cancer Network®

NCCN Member Institutions

NCCN Guidelines Program

50 multidisciplinary panels with 26-30 experts per panel

62 Clinical Practice Guidelines in Oncology updated continuously

Cover continuum and all modalities of cancer care

Accepted as standard for clinical care and policy in oncology in United States

Basis for insurance coverage policy and quality evaluation

6.7 million copies downloaded in 2015 to 180 countries

Advantages of NCCN Guidelines for Lung Cancer Screening

- Wide breadth of expertise and specialties, including layperson
- Not led by a medical specialty society
  - Non-partisan
  - No perceived or real conflict of interest
- Evidence and consensus based
  - Evidence where evidence exists
  - Consensus of experts to help fill in gaps in evidence for practical application
- Considered full spectrum of risk factors for lung cancer, not just NLST inclusion criteria
- Annual updates
  - Prompt revisions responsive to new evidence
  - Corrections, improvements, and revisions based on institution feedback

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JNCCN

JNCCN.org

Journal of the National Comprehensive Cancer Network

Lung Cancer Screening

Douglas E. Wood, George A. Eapen, David S. Ettinger, Lifang Hou, David Jackman, Ella Kazerooni, Donald Klippenstein, Rudy P. Lackner, Lorriana Leard, Ann N. C. Leung, Pierre P. Massion, Bryan F. Meyers, Reginald F. Munden, Gregory A. Otterson, Kimberly Peairs, Sudhakar Pipavath, Christie Pratt-Pozo, Chakravarthy Reddy, Mary E. Reid, Arnold J. Rotter, Matthew B. Schabath, Lecia V. Sequist, Betty C. Tong, William D. Travis, Michael Unger and Stephen C. Yang

J Natl Compr Canc Netw **2012;10:240-265**

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NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Lung Cancer Screening

Version 1.2016

NCCN.org

NCCN Guidelines for Patients® available at www.nccn.org/patients

Continue

NCCN Guidelines Version 1.2016 Panel Members
Lung Cancer Screening

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Thoracic surgery
Internal medicine
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Pathology
Epidemiology
Patient advocacy

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† Medical oncology	Þ Internal medicine
& Epidemiology	¥ Patient advocacy
ϕ Diagnostic radiology	≠ Pathology
Ξ Pulmonary medicine	* Writing committee

NCCN Guidelines Panel Disclosures

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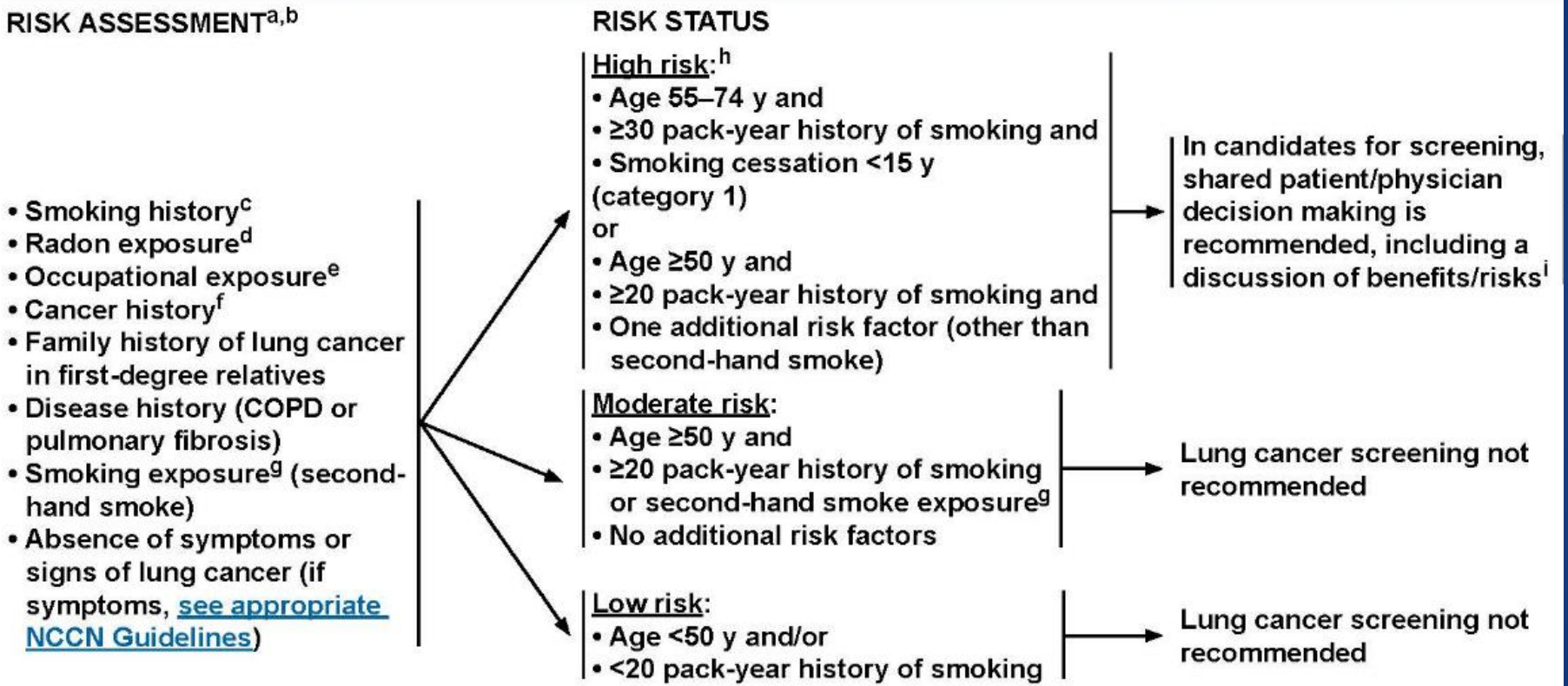
Lung Cancer Screening



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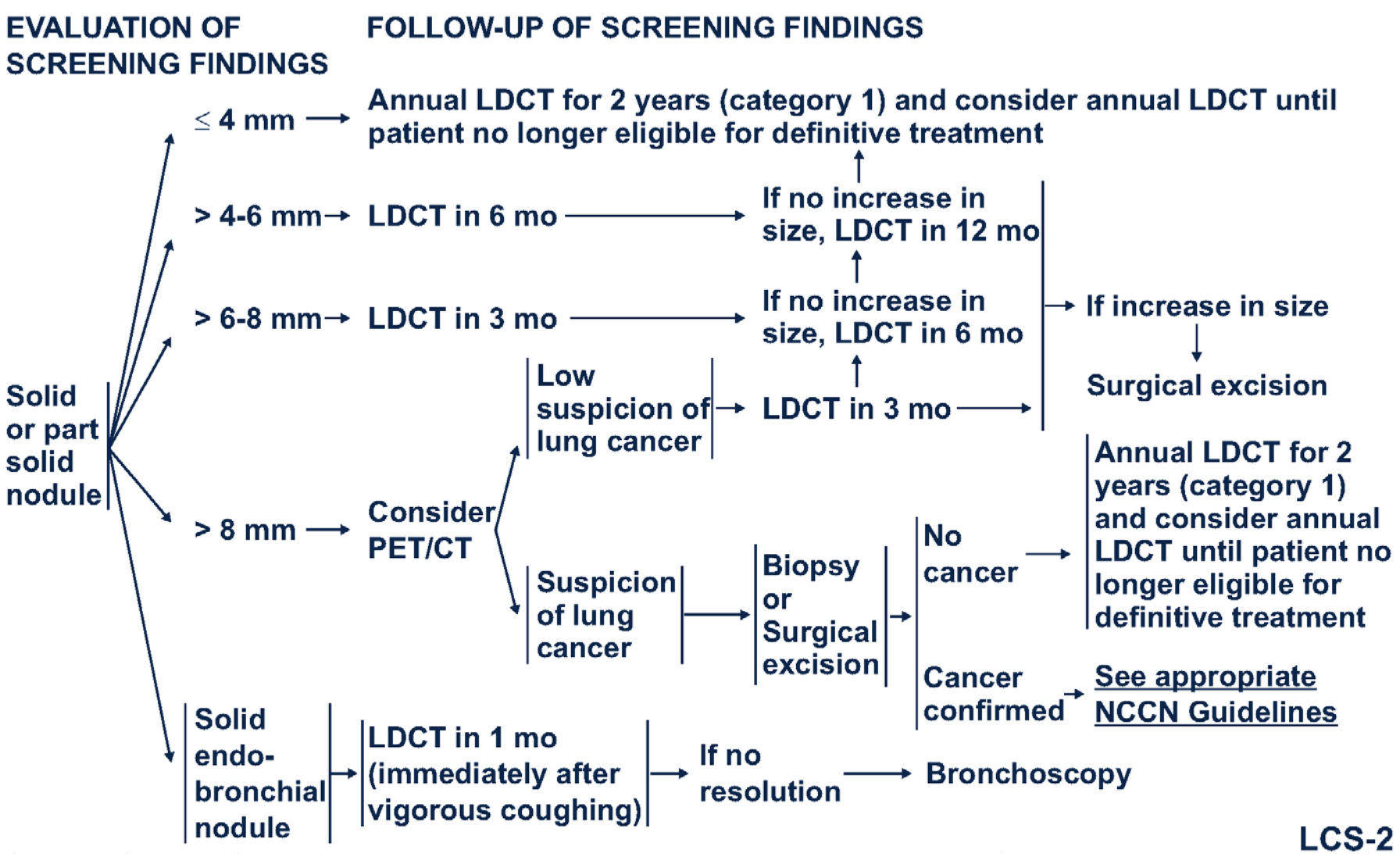


LCS-2

ORIGINAL RESEARCH | Annals of Internal Medicine

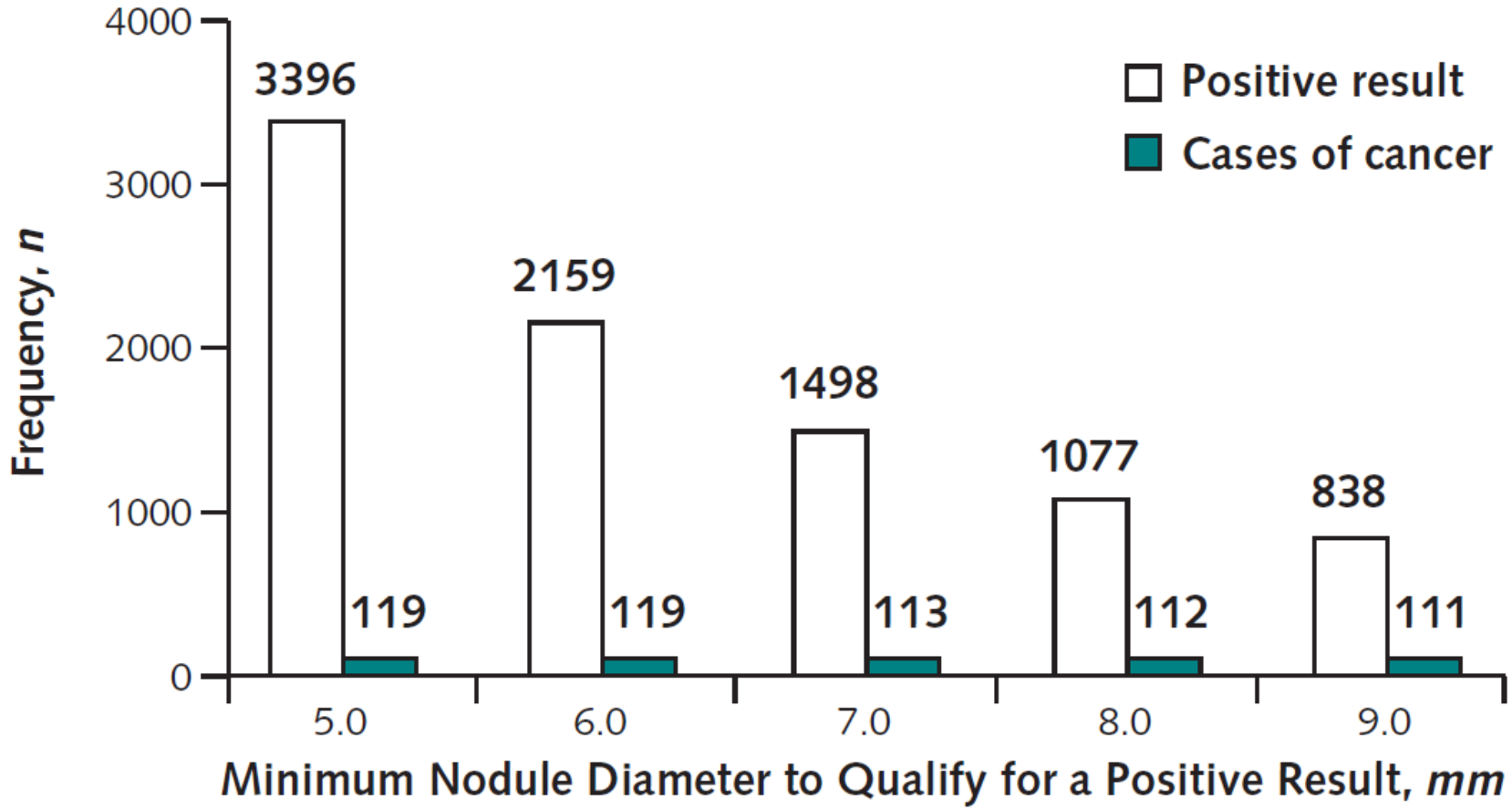
Definition of a Positive Test Result in Computed Tomography Screening for Lung Cancer

A Cohort Study

Claudia I. Henschke, PhD, MD; Rowena Yip, MPH; David F. Yankelevitz, MD; and James P. Smith, MD, for the International Early Lung Cancer Action Program Investigators*

Ann Intern Med. 2013;158:246-252.

Figure. **Frequency of a positive result and cases of lung cancer diagnosed within 12 mo of baseline enrollment.**



Henschke C., et al. *Ann Intern Med*. 2013; 158-246-252.

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Lung Cancer Screening

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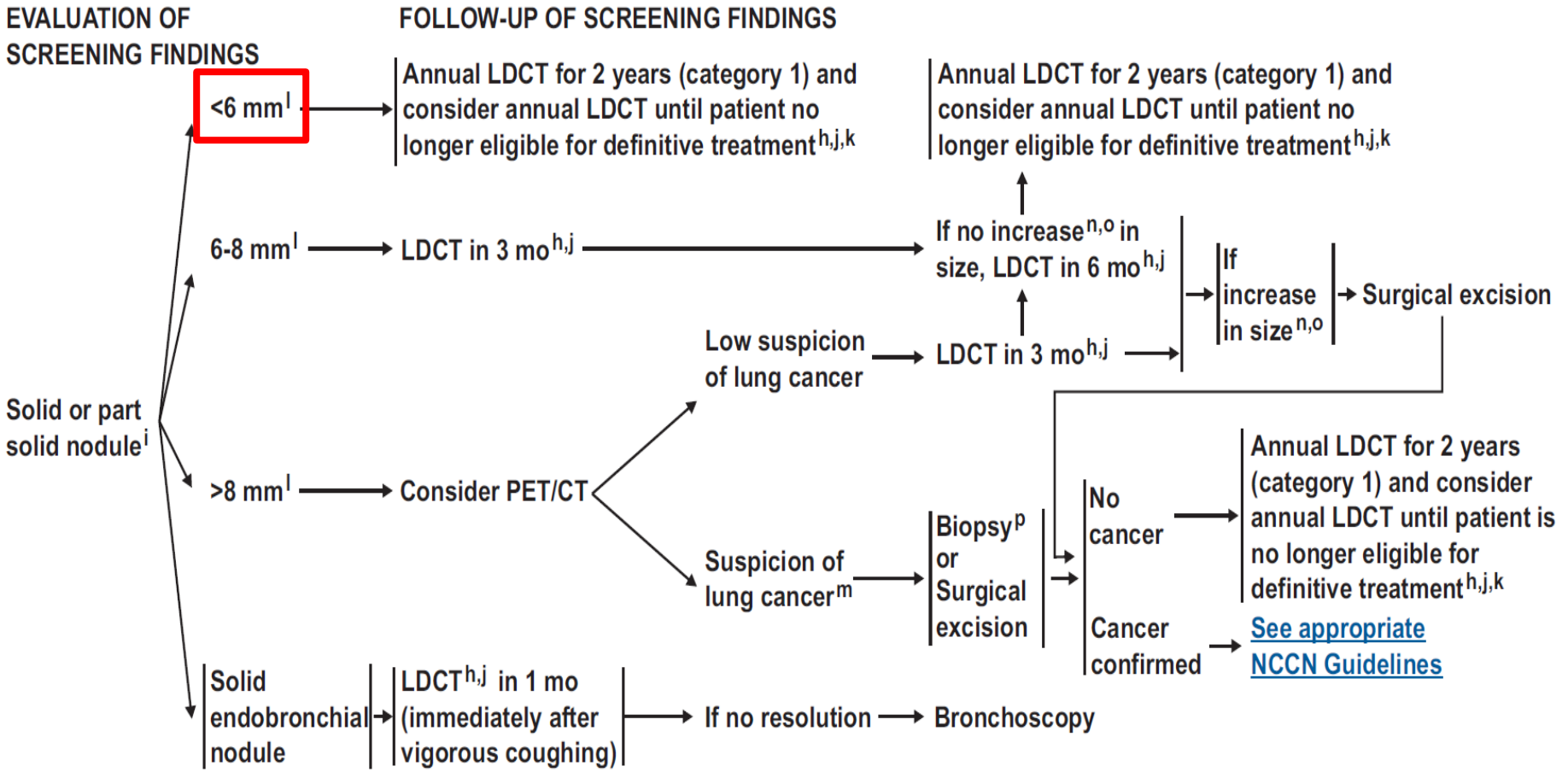

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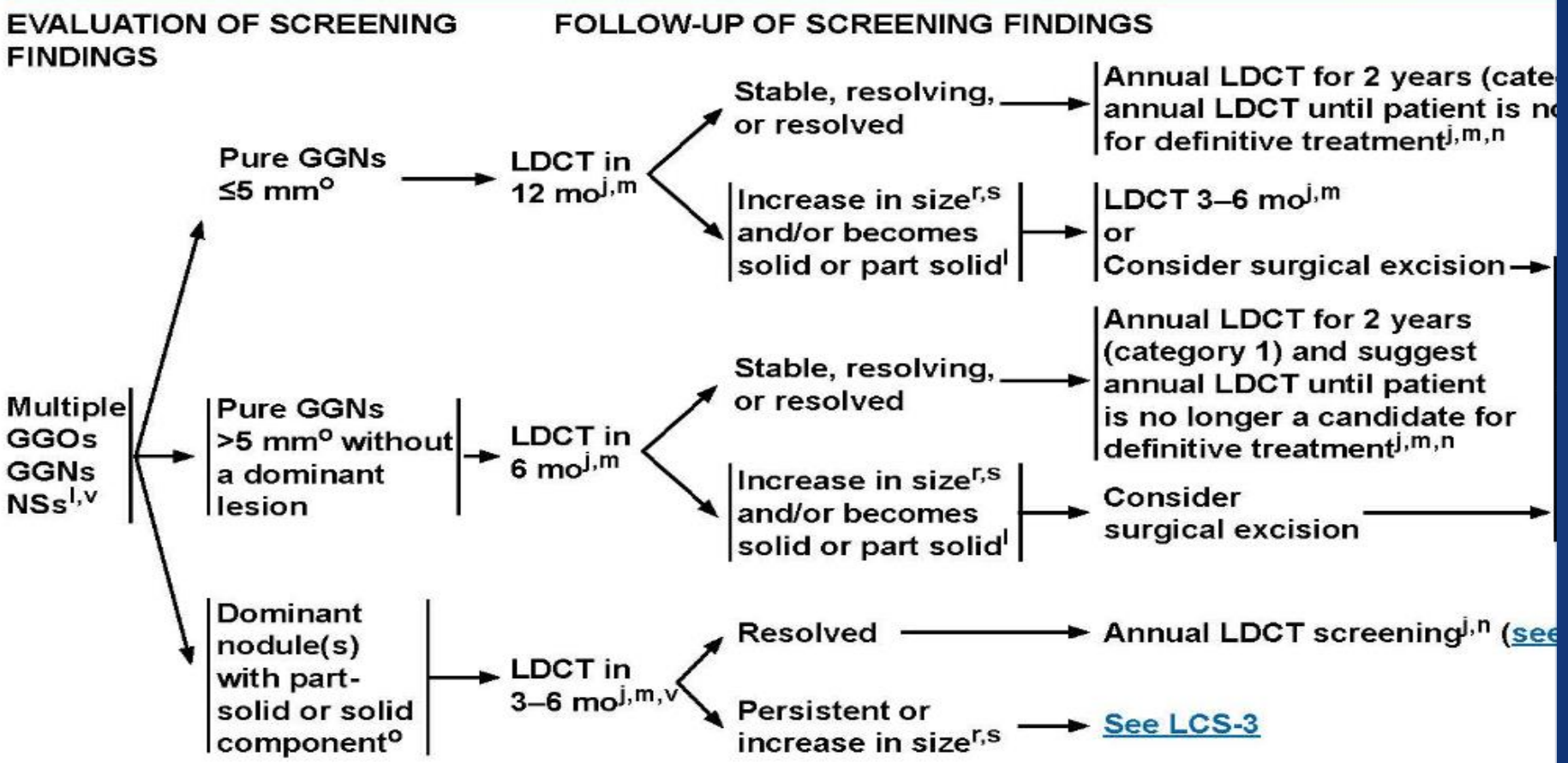

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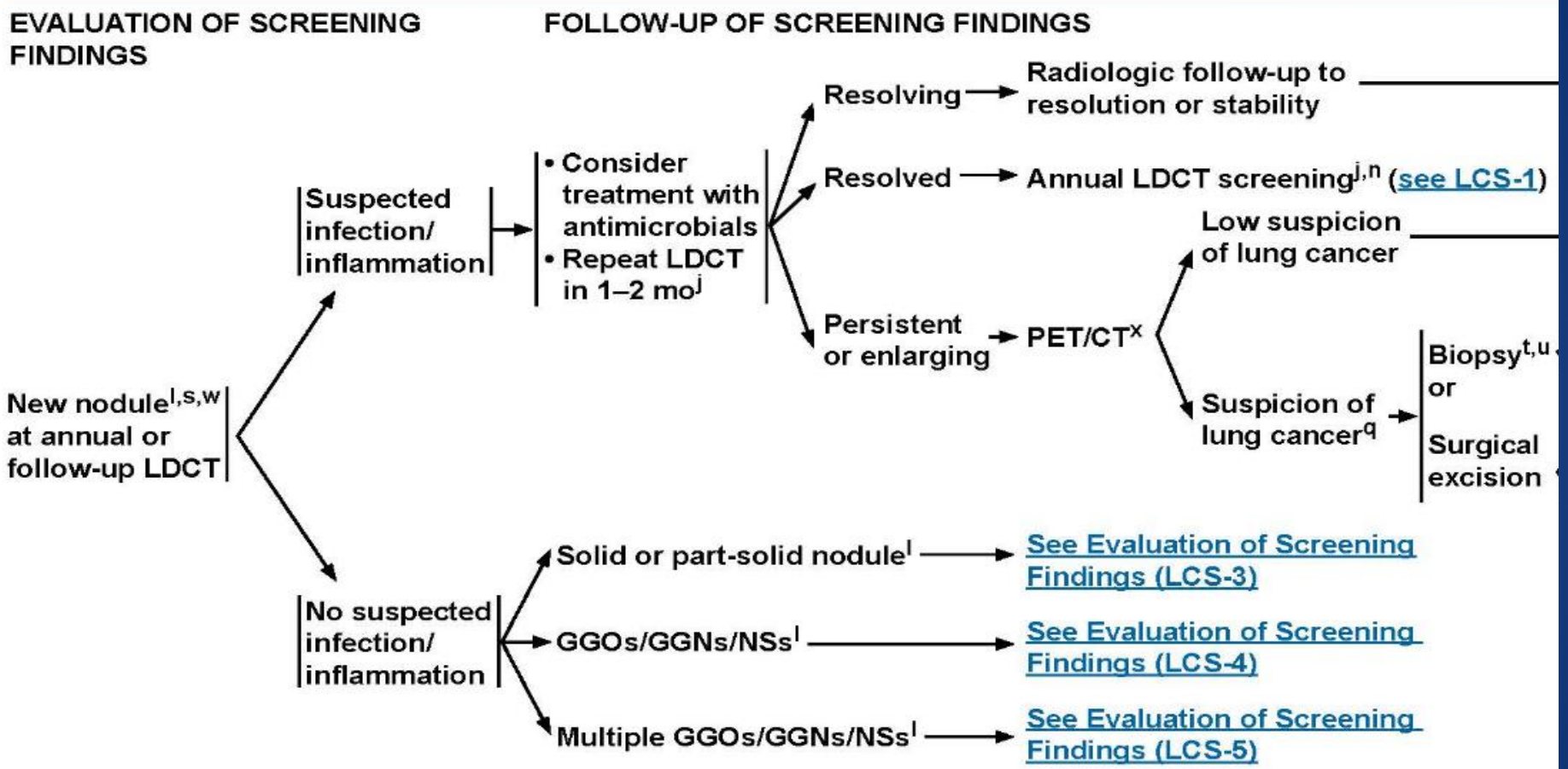

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Lung Cancer Screening

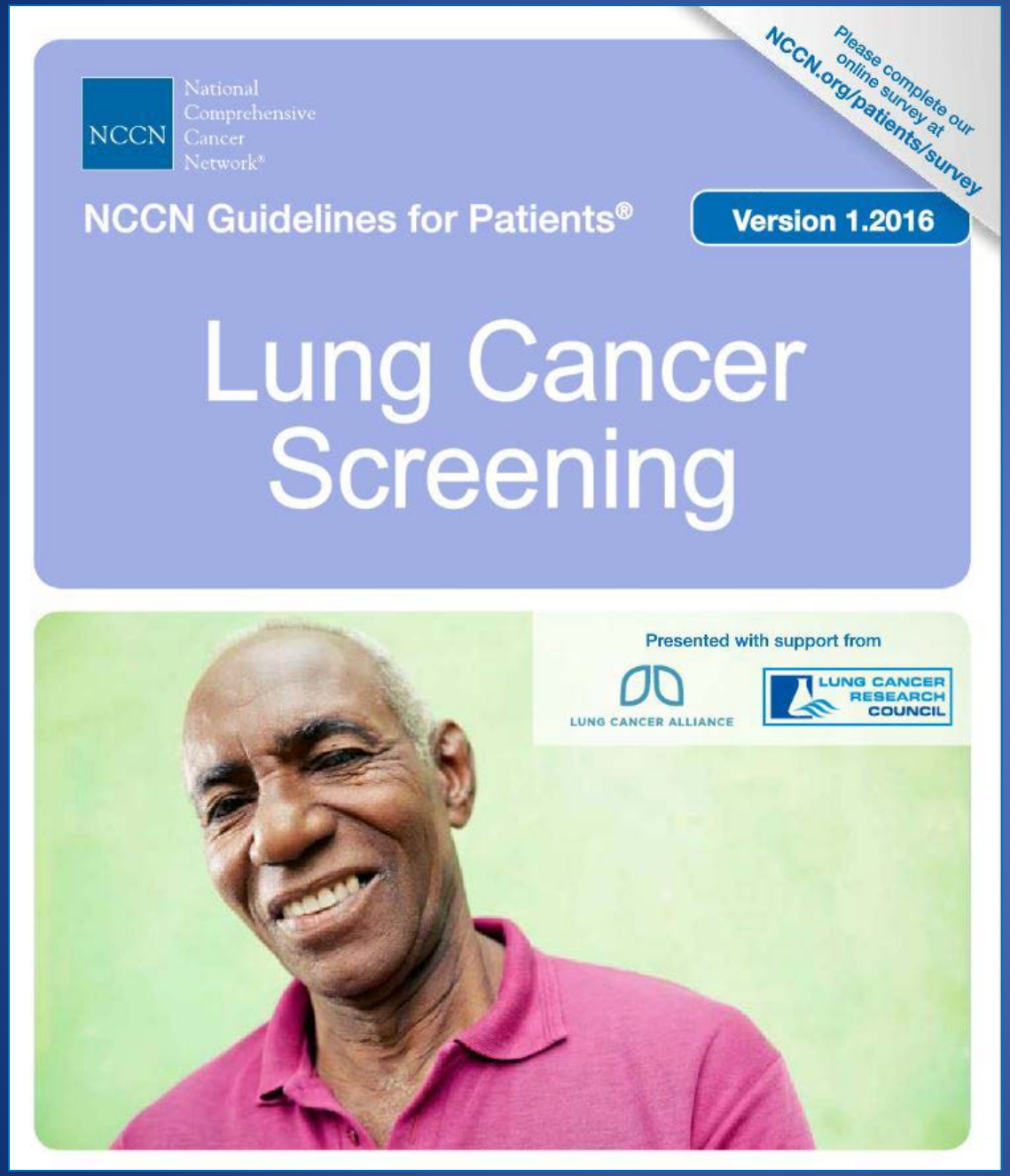
RISKS/BENEFITS OF LUNG CANCER SCREENING*

RISKS

- Futile detection of small aggressive tumors or indolent disease
- Quality of life
  - Anxiety of test findings
- Physical complications from diagnostic workup
- False-positive results
- False-negative results
- Unnecessary testing and procedures
- Radiation exposure
- Cost
- Incidental lesions

BENEFITS

- Decreased lung cancer mortality[1]
- Quality of life
  - Reduction in disease-related morbidity
  - Reduction in treatment-related morbidity
  - Improvement in healthy lifestyles
  - Reduction in anxiety/psychosocial burden
- Discovery of other significant occult health risks
  severe but silent coronary artery disease, early re
  pole of kidney, aortic aneurysm, breast cancer)



Available online at NCCN.org/patients

U.S. Preventive Services Task Force

USPSTF Home ■ Resource Links ✉ E-mail Updates

You Are Here: U.S. Preventive Services Task Force > Topic Index > Screening: Lung Cancer > Draft Recommendation Statement

Draft Recommendation Statement

Note: This draft Recommendation Statement is not the final recommendation of the U.S. Preventive Services Task Force. This draft is distributed solely for the purpose of pre-release review. It has not been disseminated otherwise by the USPSTF. It does not represent and should not be interpreted to represent a USPSTF determination or policy.

This draft Recommendation Statement is based on an evidence review that was published on July 30, 2013 (available at http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanart.htm).

The USPSTF makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service, and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decisionmaking to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

This draft Recommendation Statement was available for comment from July 30 until August 26, 2013 at 5:00 PM ET. A fact sheet that explains the draft recommendations in plain language is available here.

Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement DRAFT

Summary of Recommendation and Evidence

The U.S. Preventive Services Task Force (USPSTF) recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in persons at high risk for lung cancer based on age and smoking history.

This is a Grade B recommendation.

THE WALL STREET JOURNAL.

OPINION

Medicare's Puzzling Refusal to Cover Lung-Cancer Screening

We know screening can save thousands of lives every year. But it's not provided to the group most likely to benefit.

By DOUGLAS E. WOOD And ELLA A. KAZEROONI

June 17, 2014 7:11 p.m. ET

If you could save thousands of lives, would you do it?

That's the question Medicare officials are now considering—whether to approve lung-cancer screening for Medicare beneficiaries, which we estimate could save 14,000 lives each year in that group alone. Most patients are discovered with lung cancer at a stage already too late for a cure, and cancer screening for early detection has been recommended for other common cancers for decades. The procedure has turned thousands of people into survivors rather than victims.

The American Association of Physicists in Medicine
The Academy of Radiology Research
American Association for Thoracic Surgery (AATS)
The American Board of Radiology (ABR)
The American Board of Radiology Foundation
American College of Surgeons' Commission on Cancer
American Roentgen Ray Society (ARRS)
American Society for Radiation Oncology (ASTRO)
Association of University Radiologists (AUR)
Blanchard Valley Hospital, Findlay, Ohio
The Fleischner Society
Global Institute of Public Health, New York University
Henry Ford Medical Group
Hollings Cancer Center
Houston Methodist Hospital
International Association for the Study of Lung Cancer
International Early Lung Cancer Action Program
Lahey Hospital and Medical Center
Mary Horrigan Connors Center for Women's Health
Massachusetts General Hospital
Montefiore Einstein Center for Cancer Care
National Council of Asian Pacific Islander Physicians
National Comprehensive Cancer Network (NCCN)
National Jewish Health Lung Cancer Screening CT Program
Oakland University
William Beaumont School of Medicine
Penn Lung Center of the University of Pennsylvania
Prevent Cancer Foundation
Quantitative Imaging Biomarkers Alliance (QIBA)
Radiological Society of North America (RSNA)
Society of Chairs of Academic Radiology Departments
Society of Computed Body Tomography and Magnetic Resonance
Society of Thoracic Radiology (STR)
Tobacco Exposure Program at City of Hope Medical Center
The University of Chicago
University of Michigan Comprehensive Cancer Center
Upstate Medical University
WellStar Medical Group.

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ose Computed Tomography (LDCT)

cer with Low Dose Computed

COMMENT

Need a PDF?

Lung Cancer Screening Status

LDCT now established with a significant mortality benefit for lung cancer screening in high risk groups (NLST inlusion 55-74, ≥30 pk/yr smoking history, ≤15 cessation)

USPSTF recommendation requires coverage as a benefit under the ACA (55-80, ≥30 pk/yr smoking history, ≤15 cessation)

Medicare now providing coverage for beneficiaries (55-77, ≥30 pk/yr smoking history, ≤15 cessation)

Probably biggest impact on lung cancer management and outcomes in our generation

Concerns about Lung Cancer Screening

Benefit overestimated

Harm underestimated

Close balance of benefits and harms

Hippocrates – “Do no harm”

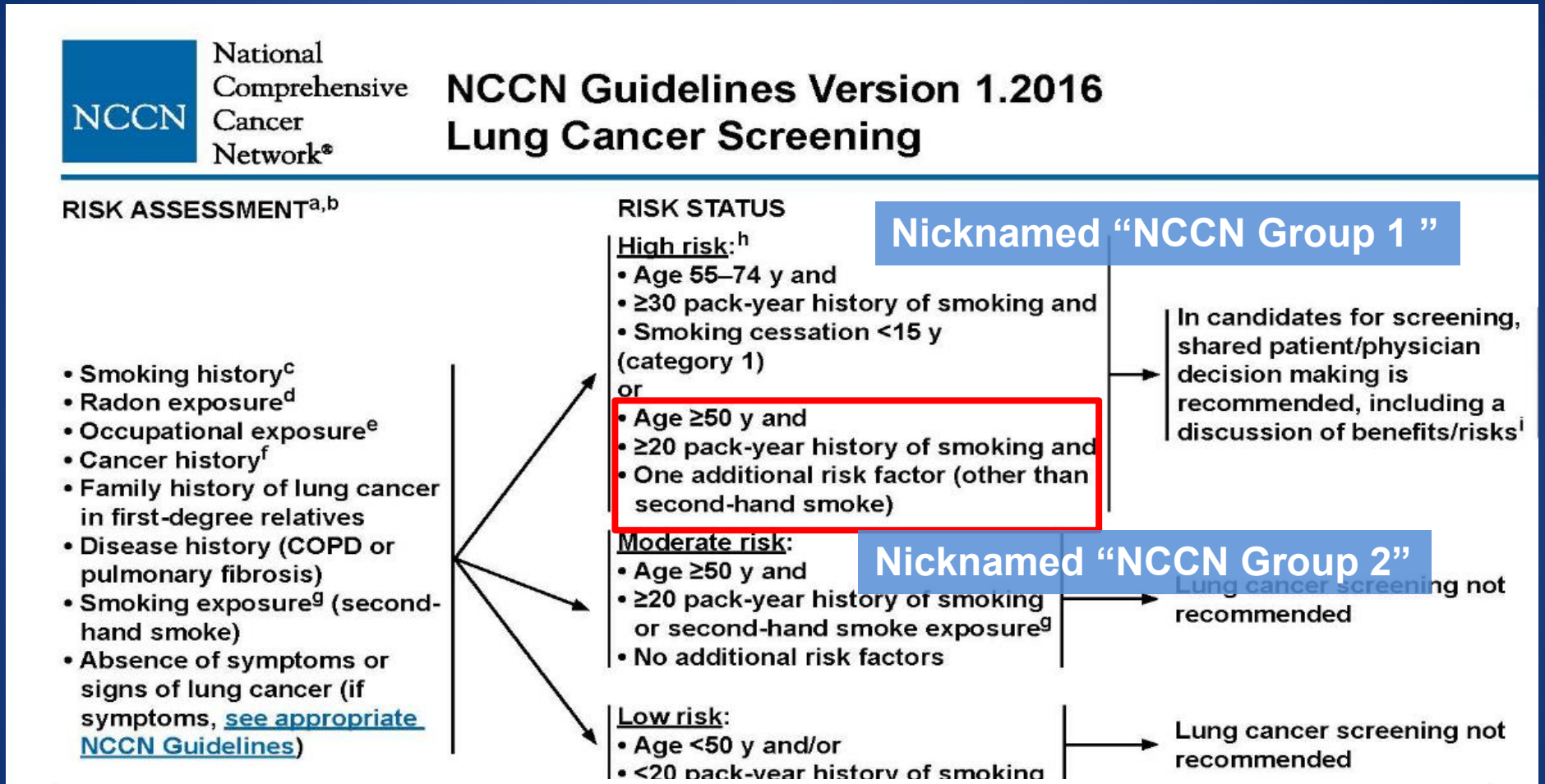
But in preventive services, harm presents in two forms:

- Unintended consequences of evaluation/treatment
- Denying preventive services from those who may benefit

Issues Debated in Lung Cancer Screening

- Does it work?
- Which patients should be screened?
  - What level of evidence?
- Minimizing harms
- Balancing unintended harms with benefit
- Lowering barriers to access

Which Patients Should be Screened?



Which Patients Should be Screened?

<u>What the NLST did do</u>:

Demonstrate a mortality reduction in patients with substantial risk factors for lung cancer

<u>What the NLST did not do</u>:

Define risk factors for lung cancer

- **NLST was a clinical trial, eligibility criteria were never meant to define the extent of "high risk" or be the basis of public policy**
- **Only considered age and smoking history**
- **No consideration of occupational/environmental exposure, cancer history, family history, other diseases**

Which Patients Should be Screened?

Key principle of NCCN Group 2 is the consideration of additional risk factors

USPSTF and CMS only considered age and smoking history (presumably on the assumption that only the NLST provides data about lung cancer risk)

Mortality benefit of patients with a certain level of lung cancer risk

- **What if we identified patients with a similar level of risk?**
- **Could they be extrapolated to have a similar level of mortality benefit?**
- **Do we know any risk factors for lung cancer other than age and smoking history?**

Which Patients Should be Screened?

NCCN position

- **Group 1 high risk patients - NLST inclusion (Category 1 recommendation)**
- **Group 2 high risk patients approximate the risk of patients included in the NLST – Category 2A “uniform consensus” from panel**

Issues Debated in Lung Cancer Screening

- Does it work?
- Which patients should be screened?
  - What level of evidence?
- Minimizing harms
- Balancing unintended harms with benefit
- Lowering barriers to access

Which Patients Should be Screened? NCCN Group 2

Evidence from randomized trial is a critical foundation

Reality that additional randomized trial data limited

- **Occupational exposure**
- **Past cancer or family history**

Is it possible to extrapolate non-randomized data regarding additional risk factors to known outcomes?

Is this more pragmatic and equitable in providing access to preventive health services?

Risk Factors for Lung Cancer
NCCN Group 2

NCCN Group 1

NLST/USPSTF/CMS

- **Age**
- **Smoking**

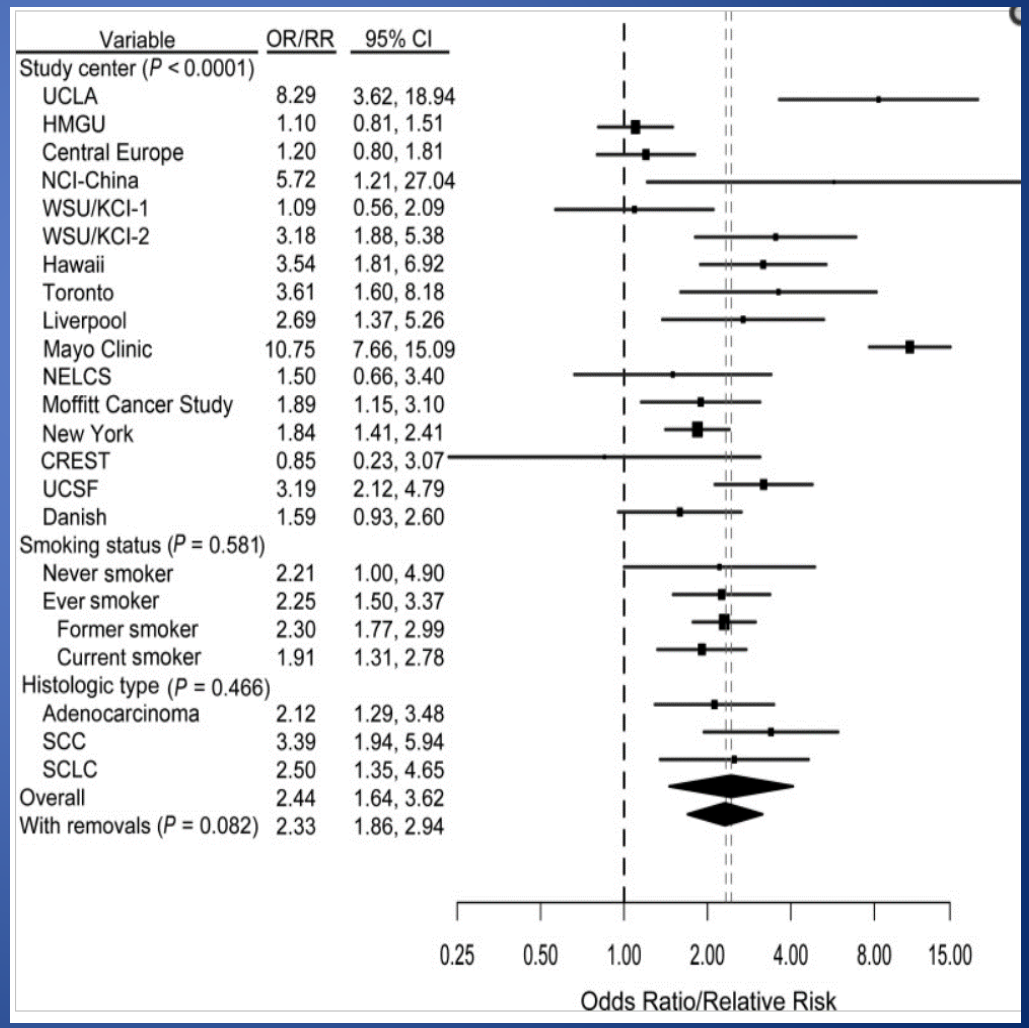
NCCN Group 2

- **Age**
- **Smoking**
- **Occupational/environmental**
  - **Asbestos, radon, silica, etc.**
- **Cancer history**
- **Family history**
- **Disease history**
  - **COPD and pulmonary fibrosis**

OXFORD JOURNALS
American Journal of EPIDEMIOLOGY

Previous Lung Diseases and Lung Cancer Risk: A Pooled Analysis From the International Lung Cancer Consortium

Emphysema odds ratio 2.3



Brenner, DR, et al. Am J Epidemiol. 2012 Oct 1; 176(7): 573–585.
Published online 2012 Sep 17. doi: 10.1093/aje/kws151

Lung Cancer Risk Assessment

	NLST	USPSTF	CMS	Brock	AATS	Bach	CLEAR	MyLungRisk	WashU
Age	+	+	+	+	+	+	+	+	+
Smoking	+	+	+	+	+	+	+	+	+
Cessation	+	+	+	+	+	+	+	+	+
Gender				+	+	+	+	+	+
Ca hist				+	+			+	+
Fam hist				+	+		+	+	+
Asbestos						+		+	+
Exposure					+		+		+
COPD				+	+		+	+	+
Educ				+	+				
BMI				+	+				
Race				+					
X-ray					+			+	

Risk Calculator Assessment

	Tammemagi	Bach	Hoggart	LLP
NCCN 1 low	0.6%	0.6%	1.8%	0.9%
NCCN 1 med	4.2%	2.3%	4.4%	2.0%
NCCN 1 high	18.9%	4.6%	5.7%	6.0%
NCCN 2 low	1.1%	0.2%	1.5%	1.3%
NCCN 2 med	4.9%	0.7%	0.1%	3.1%
NCCN 2 high	12.8%	1.7%	1.0%	6.9%

58 yo male 30 pk-yr, stopped 13 years ago, no other risk factors
65 yo male 40 pk-yr, stopped 5 years ago, family history
74 yo female 55 pk-yr, current smoker, previous cancer
50 yo female 25 pk-yr, stopped 15 years ago, previous cancer
65 yo male 25 pk-yr, current smoker, asbestos, pulmonary fibrosis
78 yo male 35 pk-yr, stopped smoking 1 year ago, previous cancer, COPD

Criticism of NCCN Group 2

“No randomized trial evidence to support”

“Extends screening to low risk individuals”

“Difficult to assess presence of risk factors”

“Need to wait for additional studies”

“Extends screening to individuals with more comorbidity”

Criticism of NCCN Group 2

“No randomized trial evidence to support”

“Extends screening to lower risk individuals”

“Difficult to assess presence of risk factors”

“Need to wait for additional studies”

“Extends screening to individuals with more comorbidity”

Decades of non-randomized data support other risk factors for lung cancer

Criticism of NCCN Group 2

“No randomized trial evidence to support”

“Extends screening to lower risk individuals”

“Difficult to assess presence of risk factors”

“Need to wait for additional studies”

“Extends screening to individuals with more comorbidity”

Criticism of NCCN Group 2

The majority concentrate on estimating risk for a 50 year-old with 20 pack-year smoking history

Most NCCN 2 patients look more like this:

72 yo with 40 pk/yr but stopped 20 years ago

78 yo with 27 pk/yr smoking and previous H&N cancer

65 yo with 20 pk/yr smoking and asbestos exposure

Criticism of NCCN Group 2

"No randomized trial evidence to support"

"Extends screening to lower risk individuals"

"Difficult to assess presence of risk factors"

"Need to wait for additional studies"

"Extends screening to individuals with more comorbidity"

Use a validated risk calculator to select eligible patients rather than NLST or NCCN 2 criteria

Risk Calculator for Patient Selection

- Benefits
  - Exclude lower risk NLST criteria individuals
  - Provide access for individuals outside of NLST inclusion
- Challenges
  - Which risk calculator?
  - Not a factor in coverage policy (nor likely to be)
  - Not practical for primary care (or EHR) assessment
  - Not relatable to patients or the public
  - Tempting to “game”, and as vulnerable to gaming as “other risk factors”

Risk Calculator for Patient Selection

Recommendation

- Do not use to “define” eligibility in guidelines or policy
- Do use to empower shared decision-making and ultimate individual choice of proceeding with lung cancer screening

Criticism of NCCN Group 2

“No randomized trial evidence to support”

“Extends screening to lower risk individuals”

“Difficult to assess presence of risk factors”

“Need to wait for additional studies”

“Extends screening to individuals with more comorbidity”

Yes, some ambiguity exists, requires judgement and shared decision-making

Criticism of NCCN Group 2

“No randomized trial evidence to support”

“Extends screening to lower risk individuals”

“Difficult to assess presence of risk factors”

“Need to wait for additional studies”

“Extends screening to individuals with more comorbidity”

More Randomized Trials?

72 yo with 40 pk/yr but stopped 20 years ago

78 yo with 27 pk/yr smoking and previous H&N cancer

65 yo with 20 pk/yr smoking and asbestos exposure

Unrealistic…..

Current data validates risk factors beyond those studied in NLST

Future data will certainly shape guidelines and coverage

Criticism of NCCN Group 2

"No randomized trial evidence to support"

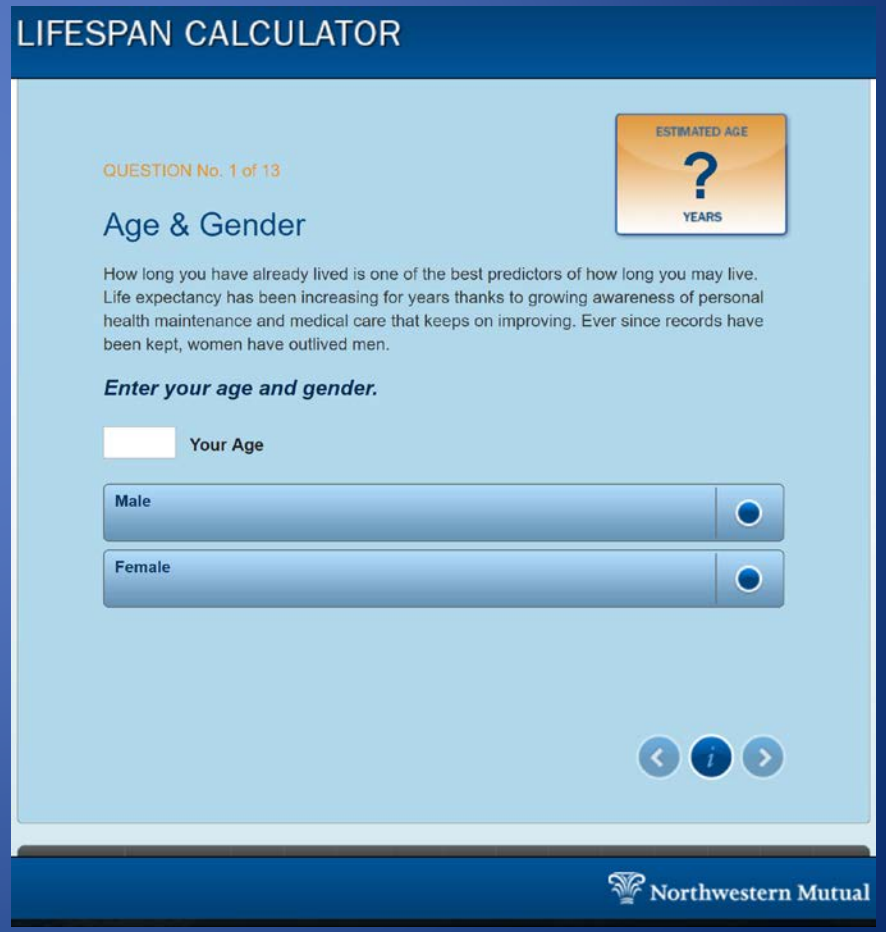
"Extends screening to lower risk individuals"

"Difficult to assess presence of risk factors"

"Need to wait for additional studies"

"Extends screening to individuals with more comorbidity"

Lower life expectancy diminishes potential benefit of screening


LIFESPAN CALCULATOR
ESTIMATED AGE
?
YEARS
QUESTION No. 1 of 13
Age & Gender
How long you have already lived is one of the best predictors of how long you may live. Life expectancy has been increasing for years thanks to growing awareness of personal health maintenance and medical care that keeps on improving. Ever since records have been kept, women have outlived men.
Enter your age and gender.
Your Age
Male
Female
Northwestern Mutual

Risk Factors for Lung Cancer

Factors Associated with Lower Life Expectancy

- **Age**
- **Smoking**
- **Occupational/environmental**
  - **Asbestos, radon, silica, etc.**
- **Cancer history**
- **Family history**
- **Disease history**
  - **COPD and pulmonary fibrosis**
- **Elderly**
- **Lower socioeconomic status**
- **Minorities**
- **Comorbidity**

Ethics of Guidelines and Coverage Policy

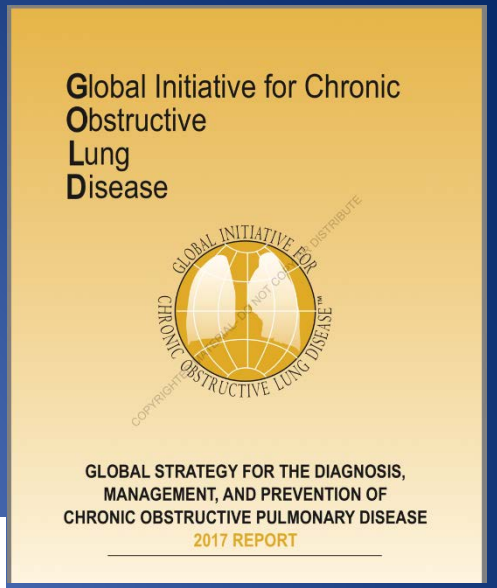
Appropriate to establish a threshold of risk for inclusion of a group or population (made up of individuals)

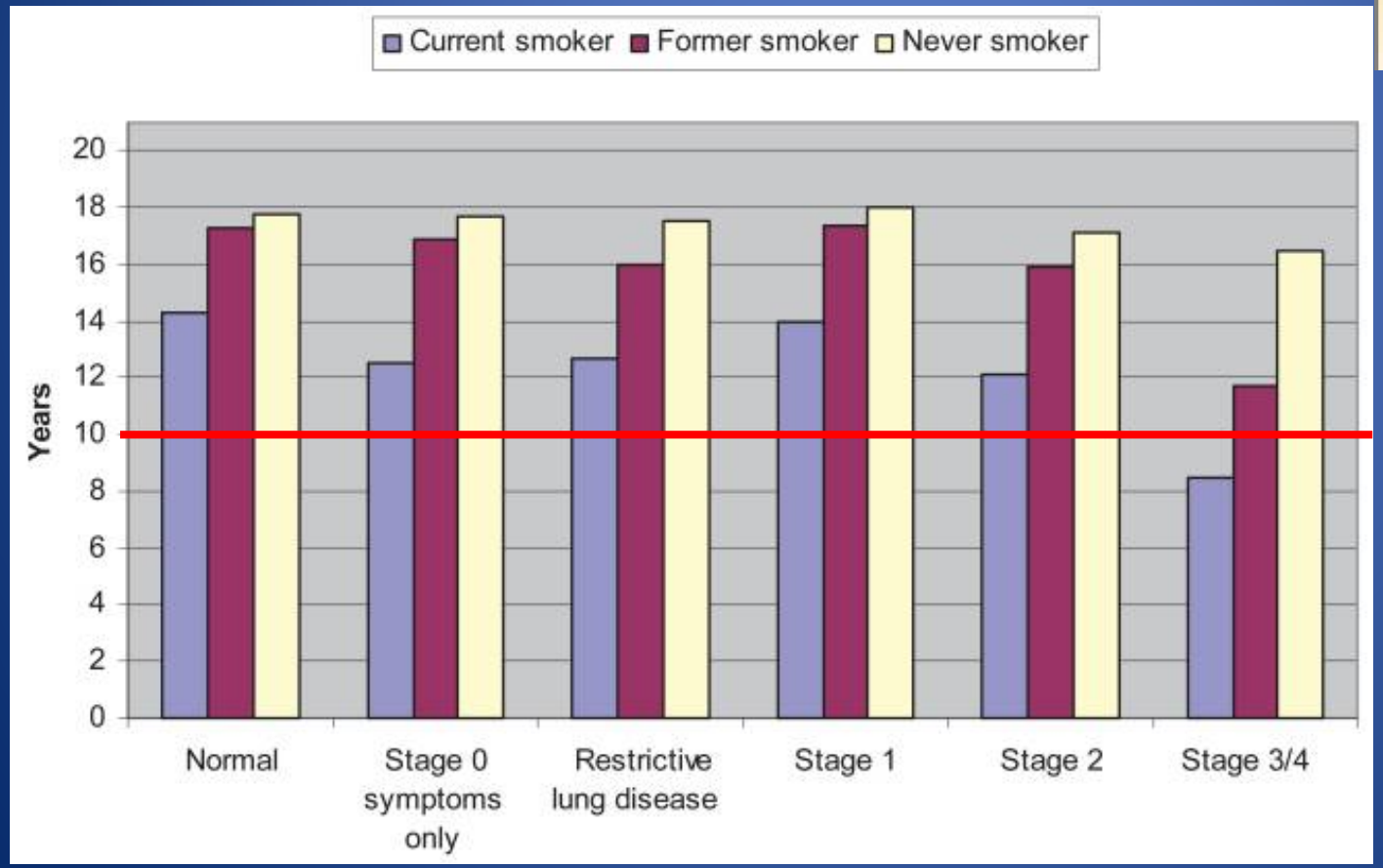
- **Recognizing ambiguity, imperfections, differences of opinion**

Challenging ethical questions when exclusion of individuals is based on actuarial estimates of life expectancy or "diminished benefit"

Ethics of Guidelines and Coverage Policy

Should patients with diabetes be denied lung cancer screening?
Should patients with COPD be denied lung cancer screening?
A history of cancer?
Asbestos exposure?
Elderly?
Minorities?


Global Initiative for Chronic Obstructive Lung Disease
GLOBAL STRATEGY FOR THE DIAGNOSIS, MANAGEMENT, AND PREVENTION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE
2017 REPORT


Current smoker
Former smoker
Never smoker
Years
0
2
4
6
8
10
12
14
16
18
20
Normal
Stage 0 symptoms only
Restrictive lung disease
Stage 1
Stage 2
Stage 3/4

Asbestos exposure increased risk of death, odds ratio 1.15
Occurs 20-40 years after exposure
Two years lower actuarial survival

58 yo male 30 pk-yr, stopped 13 years ago, no other risk factors

Is this patient eligible for lung cancer screening under USPSTF guidelines?

A. Yes

B. No

58 yo male 30 pk-yr, stopped 13 years ago, no other risk factors

Will he have insurance coverage through his private insurer with no copay?

A. Yes

B. No

58 yo male 30 pk-yr, stopped 13 years ago, no other risk factors

What would you estimate his lung cancer risk?

A. Low
B. Medium
C. High

50 yo female 25 pk-yr, stopped 15 years ago, previous bladder cancer

Is this patient eligible for lung cancer screening under USPSTF guidelines?

A. Yes

B. No

50 yo female 25 pk-yr, stopped 15 years ago, previous bladder cancer

Will she have insurance coverage through her private insurer with no copay?

A. Yes

B. No

50 yo female 25 pk-yr, stopped 15 years ago, previous bladder cancer

What would you estimate her lung cancer risk?

A. Low
B. Medium
C. High

Lower Lung Cancer Risk

58 yo male 30 pk-yr, stopped 13 years ago, no other risk factors

- Included in NLST
- Recommended by USPSTF
- Insurance coverage
- Risk 0.6%

50 yo female 25 pk-yr, stopped 15 years ago, previous bladder cancer

- Not included in NLST
- Not recommended
- No coverage
- Risk 1.1%

65 yo male 40 pk-yr, stopped 5 years ago, brother died of lung cancer

Is this patient eligible for lung cancer screening under Medicare?

A. Yes

B. No

65 yo male 40 pk-yr, stopped 5 years ago, brother died of lung cancer

What would you estimate his lung cancer risk?

A. Low
B. Medium
C. High

65 yo male 25 pk-yr, current smoker, asbestos, pulmonary fibrosis

Is this patient eligible for lung cancer screening under Medicare?

A. Yes

B. No

65 yo male 25 pk-yr, current smoker, asbestos, pulmonary fibrosis

What would you estimate his lung cancer risk?

A. Low
B. Medium
C. High

High Lung Cancer Risk

65 yo male 40 pk-yr, stopped 5 years ago, brother died of lung cancer

- Included in NLST
- Recommended by USPSTF
- Insurance coverage
- Risk 4.2%

65 yo male 25 pk-yr, current smoker, asbestos, pulmonary fibrosis

- Not included in NLST
- Not recommended
- No coverage
- Risk 4.9%

74 yo female 55 pk-yr, current smoker, previous head and neck cancer

Is this patient eligible for lung cancer screening under Medicare?

A. Yes

B. No

78 yo male 35 pk-yr, stopped smoking 1 year ago, previous H&N cancer, COPD

Is this patient eligible for lung cancer screening under Medicare?

A. Yes

B. No

Very High Lung Cancer Risk

74 yo female 55 pk-yr, current smoker, previous head and neck cancer

- Included in NLST
- Recommended by USPSTF
- Insurance coverage
- Risk 18%

78 yo male 35 pk-yr, stopped smoking 1 year ago, previous H&N cancer, COPD

- Not included in NLST
- Not recommended
- No coverage
- Risk 13%

Risk Calculator Assessment

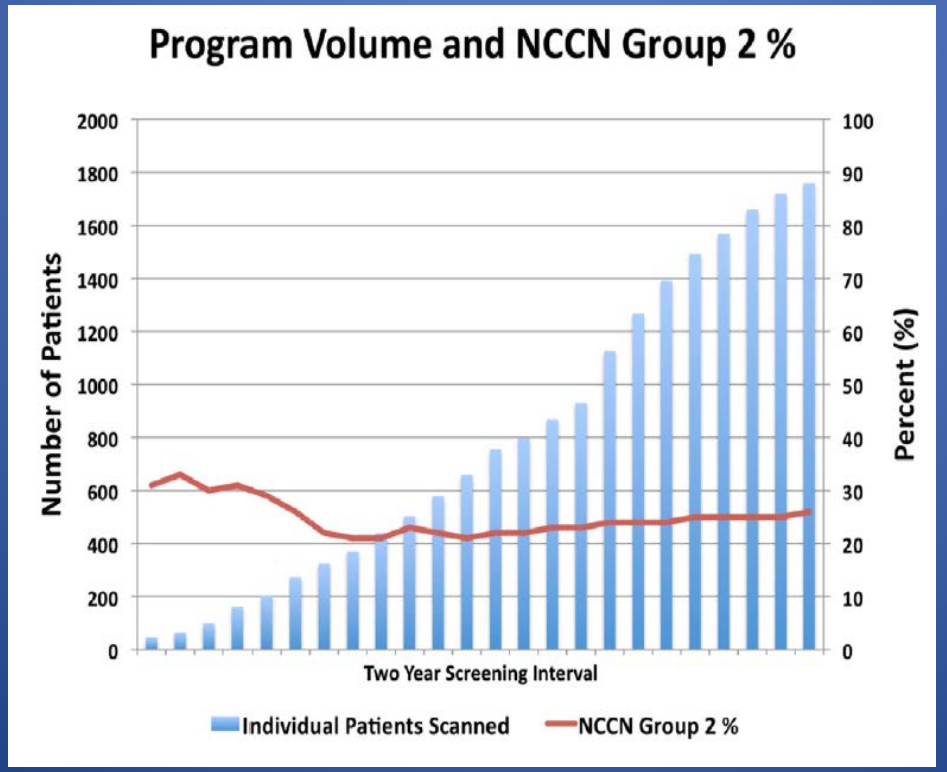
	NCCN 1	NCCN 2
Moderate	0.6%	1.1%
High	4.2%	4.9%
Very high	18.9%	12.8%

58 yo male 30 pk-yr, stopped 13 years ago, no other risk factors
65 yo male 40 pk-yr, stopped 5 years ago, family history
74 yo female 55 pk-yr, current smoker, previous cancer
50 yo female 25 pk-yr, stopped 15 years ago, previous cancer
65 yo male 25 pk-yr, current smoker, asbestos, pulmonary fibrosis
78 yo male 35 pk-yr, stopped smoking 1 year ago, previous cancer, COPD

Experience With a CT Screening Program for Individuals at High Risk for Developing Lung Cancer

Brady J. McKee, MD[a], Jeffrey A. Hashim, MD[a], Robert J. French, MD[a], Andrea B. McKee, MD[b], Paul J. Hesketh, MD[c], Carla R. Lamb, MD[d], Christina Williamson, MD[e], Sebastian Flacke, MD, PhD[a], Christoph Wald, MD, PhD[a]

J Am Coll Radiol 2015;12:192-197.



Experience With a CT Screening Program for Individuals at High Risk for Developing Lung Cancer

McKee, BJ., et al. *J Am Coll Radiol*. 2015 Feb;12(2):192-7

Table 2. Prevalence Exam Results

Result	Total Screened (n = 1,760)		NCCN Group 2 (n = 464)		NCCN Group 1 (n = 1,296)		*P* (Group 2 vs Group 1)	NLST (T0)
Total positive	481	27.3%	116	25.0%	365	28.2%	0.1	27.3%
Probably benign	412	23.4%	103	22.2%	309	23.8%	NR	NR
Suspicious	69	3.9%	13	2.8%	56	4.3%	NR	NR
Probable infection	114	6.5%	28	6.0%	86	6.6%	0.8	NR
Significant incidental findings	108	6.1%	28	6.0%	80	6.2%	0.1	10.2%

Table 4. Malignancy rate and average follow-up

Variable	Overall	Group 2	Group 1
Overall malignancy rate	23/1,328 (1.7%)	6/331 (1.8%)	17/997 (1.7%)
Average follow-up (mo)	12.5	12.1	12.7
Annualized malignancy rate	1.6%	1.8%	1.6%
Time to diagnosis (mo)	4.1	5.6	3.7
Average follow-up from diagnosis (mo)	7.8	5.3	8.6

Issues Debated in Lung Cancer Screening

- Does it work?
- Which patients should be screened?
  - What level of evidence?
- Minimizing harms
- Balancing unintended harms with benefit
- Lowering barriers to access

Minimizing Harms of Lung Cancer Screening

Limit Access

- Further narrow, or prevent widening of, eligibility criteria
- Expose fewer people to risks
- Use policy to override shared decision-making
- Disenfranchise and potentially harm others at high risk

Improve management

- Refine management algorithms to minimize false positives
- Require expertise in evaluation/treatment to optimize outcomes
- Empower shared decision-making
- Provide access to similar risk patients
- Add cost to payers
- Risk of evaluation/treatment added to new patients with less proof of benefit

LungRADS 2014

Category	Category Descriptor	Category	Findings	Management	Probability of Malignancy	Estimated Population Prevalence
Incomplete	-	0	prior chest CT examination(s) being located for comparison part or all of lungs cannot be evaluated	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed	n/a	1%
Negative	No nodules and definitely benign nodules	1	no lung nodules nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules	Continue annual screening with LDCT in 12 months	< 1%	90%
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	solid nodule(s): < 6 mm new < 4 mm part solid nodule(s): < 6 mm total diameter on baseline screening non solid nodule(s) (GGN): < 20 mm OR ≥ 20 mm and unchanged or slowly growing category 3 or 4 nodules unchanged for ≥ 3 months			
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	solid nodule(s): ≥ 6 to < 8 mm at baseline OR new 4 mm to < 6 mm part solid nodule(s) ≥ 6 mm total diameter with solid component < 6 mm OR new < 6 mm total diameter non solid nodule(s) (GGN) ≥ 20 mm on baseline CT or new	6 month LDCT	1-2%	5%
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	solid nodule(s): ≥ 8 to < 15 mm at baseline OR growing < 8 mm OR new 6 to < 8 mm part solid nodule(s: ≥ 6 mm with solid component ≥ 6 mm to < 8 mm OR with a new or growing < 4 mm solid component endobronchial nodule	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component	5-15%	2%
		4B	solid nodule(s) ≥ 15 mm OR new or growing, and ≥ 8 mm part solid nodule(s) with: a solid component ≥ 8 mm OR a new or growing ≥ 4 mm solid component	chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component.	> 15%	2%
		4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			

Annals of Internal Medicine

ORIGINAL RESEARCH

Performance of Lung-RADS in the National Lung Screening Trial

A Retrospective Assessment

Paul F. Pinsky, PhD; David S. Gierada, MD; William Black, MD; Reginald Munden, MD; Hrudaya Nath, MD; Denise Aberle, MD; and Ella Kazerooni, MD

False-positive rate

	NLST	LungRADS	Improvement w/LungRADS
Baseline	26.6%	12.8%	52%
After baseline	21.8%	5.3%	76%

Ann Intern Med. 2015;162:485-491.

Issues Debated in Lung Cancer Screening

- Does it work?
- Which patients should be screened?
  - What level of evidence?
- Minimizing harms
- Balancing unintended harms with benefit
- Lowering barriers to access

Screening Efficiency
Number Needed to Screen

Screening mammography[1,2]	780 - 2000
Screening colonoscopy[2]	1250
Screening LDCT (in NLST)	320

1. **Gøtzsche PC, Nielsen M. Screening for breast cancer with mammography. *Cochrane Database Syst Rev*. 2011;(1):CD001877**
2. ***J Med Screen* 2001;8:125–127**

Issues Debated in Lung Cancer Screening

- Does it work?
- Which patients should be screened?
  - What level of evidence?
- Minimizing harms
- Balancing unintended harms with benefit
- Lowering barriers to access

Applying the National Lung Screening Trial eligibility criteria to the US population: what percent of the population and of incident lung cancers would be covered?

Paul F Pinsky and Christine D Berg

SEER (Surveillance, Epidemiology and End Results)
United States Census
National Health Interview Survey
Two statistical models of lung cancer risk

Proportion of those diagnosed with lung cancer that would be covered by the NLST-based eligibility criteria.

27%

J Med Screen 2012;19:154–156

Cancer

Annual Number of Lung Cancer Deaths Potentially Avertable by Screening in the United States

Jiemin Ma, PhD, MHS[1]; Elizabeth M. Ward, PhD[2]; Robert Smith, PhD[3]; and Ahmedin Jemal, DVM, PhD[1]

8.6 million Americans eligible for screening
Annual number of lung cancer deaths averted – 12,250

Experience With a CT Screening Program for Individuals at High Risk for Developing Lung Cancer

NCCN Group 2 adds 2 million eligible for screening
Additional estimate of averted lung cancer deaths ≈ 3000

Cancer 2013;119:1381-5

J Am Coll Radiol 2015;12:192-197.

THE OFFICIAL SPONSOR OF BIRTHDAYS.®

Cancer Facts & Figures 2014

Cancer Disparities

An overarching objective of the American Cancer Society's 2015 challenge goals is to eliminate disparities in the cancer burden among different segments of the US population, defined in terms of socioeconomic status (income, education, insurance status, etc.), race/ethnicity, geographic location, sex, and sexual orientation.

Lung cancer patient disparities:

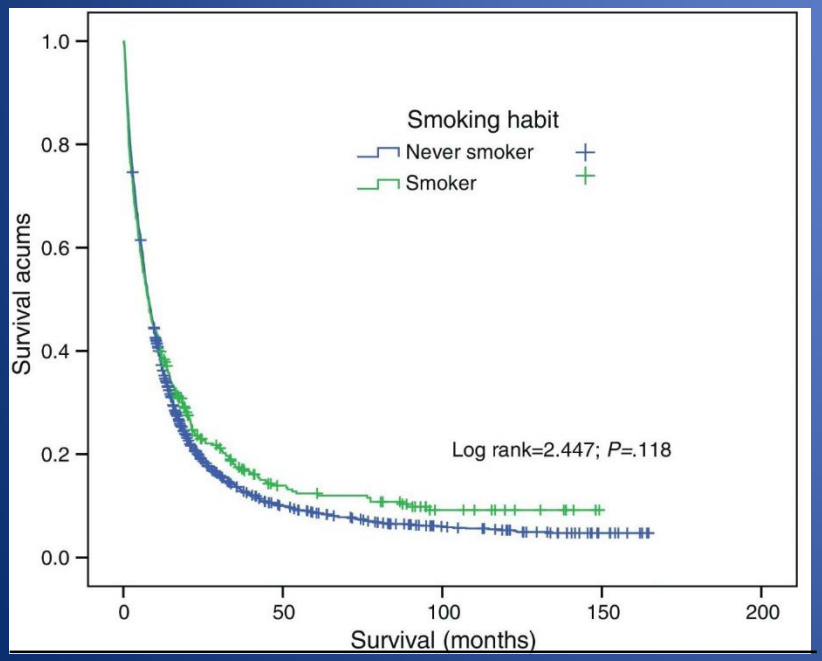
- **Older – 68% Medicare population**
- **Higher mortality amongst African-Americans**
- **Lower socioeconomic groups mortality 4-5 times greater**
- **Rural access to screening and treatment**

THE JOURNAL OF
THORACIC AND
CARDIOVASCULAR SURGERY

Balancing curability and unnecessary surgery in the context of computed tomography screening for lung cancer

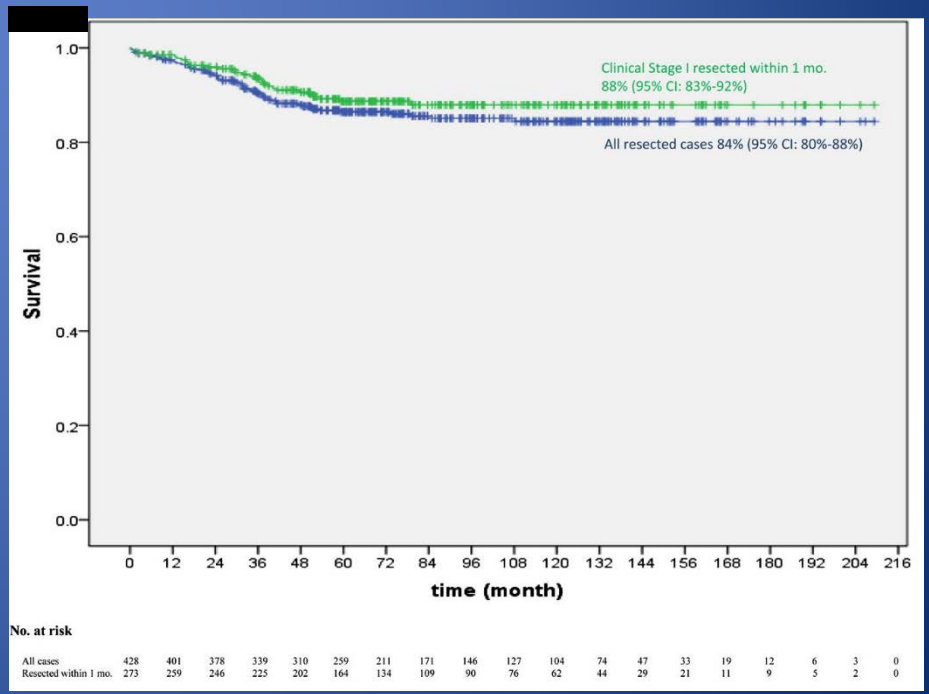
Lung Cancer Survival

Current Lung Cancer Survival



Lamelas, IP, et al. Arch Bronconeumol.2014;50:62-6

I-ELCAP



J Thorac Cardiovasc Surg 2014; 147:1619-1626.

Lung Cancer Screening Summary

- Lung cancer screening reduces mortality in a high risk population
- Randomized trial data, and USPSTF eligibility, do not consider risk factors other than age and smoking
- Non-randomized data exists to validate other risk factors
- Rigid adherence to NLST inclusion criteria
  - Ignores important data regarding lung cancer risk
  - Disenfranchises patients at legitimate risk
  - Lost opportunity of maximizing benefit of lung cancer screening
  - Violates principles of equity and elimination of health care disparities
- Data supports NCCN Group 2 as having similar risk to NLST
- Policy should extend screening to patients similar to NCCN Group 2
- Screening risk minimized by algorithmic management and multidisciplinary expertise
- Shared decision making important to balance risks and benefits

National Lung Cancer Roundtable

Mission
Create lung cancer survivors

Vision
Lower the impact of lung cancer through prevention, early detection, and optimal therapy

American Cancer Society

Values

Patient-centered	Evidence-based
Inclusive	Diverse
Proactive	Visionary

National Lung Cancer Roundtable

Support interdisciplinary communication
Enhance opportunities for collaboration
Do not duplicate effort
Identify resources, knowledge gaps, opportunities
Create synergies
Increase awareness, priority, and urgency
Accelerate the mission – to create lung cancer survivors

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Shared Decision Making for Lung Cancer Screening: Why it matters

BMS Foundation's Grantee Summit, April 9-112018.

Robert J. Volk, PhD
Department of Health Services Research
bvolk@mdanderson.org

Funding and Disclaimers

Some of the work presented here has been supported by the Patient-Centered Outcomes Research Institute (PCORI). Any findings and conclusions are solely the responsibility of the investigator and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee.

Increasing attention to shared decision making in healthcare

1982 President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research

More equal doctor-patient relationships

Advocated SDM as an ethical ideal for patient-provider relationships

2009 Institute of Medicine

Initial National Priorities for Comparative Effectiveness Research

The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

2013 Institute of Medicine

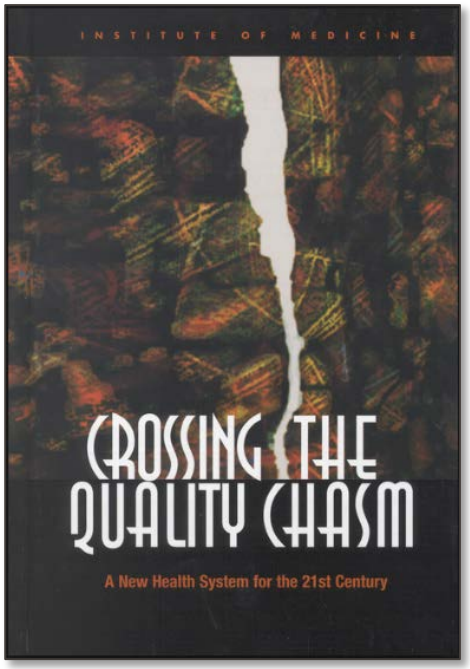
Delivering High-Quality Cancer Care

Recommendation #1: Engaged patients

Cancer care team provides patient and families with understandable information about prognosis, treatment benefits/harms, palliative care, psychosocial support, and estimates of costs of care.

- Develop information/decision aids
- Personalize information for aids
- Train care team
- Use CMS innovative payment models

Shared Decision Making – The Pinnacle of Patient-Centered Care



IOM definition of patient-centered care (2001)

"…care that is respectful of and responsive to individual patient preferences, needs, and values"

and ensures "that patient values guide all clinical decisions."

Barry & Edgman-Levitan (2012)

The most important aspect of PCC is "active engagement of patients when fateful health care decisions must be made…"

Barry & Edgman-Levitan, NEJM 2012.

Shared decision making defined

Shared decision making is a model of patient-centered care that enables and encourages people to play a role in the medical decisions that affect their health. It operates under two premises:

- First, consumers armed with good information can and will participate in the medical decision making process by asking informed questions and expressing personal values and opinions about their conditions and treatment options.
- Second, clinicians will respect patients' goals and preferences and use them to guide recommendations and treatments.

The aim of shared decision making is to ensure that patients understand their options and the pros and cons of those options and patient's goals and treatment preferences are used to guide decisions (www.ahrq.gov).

Why shared decision making matters

Increasing emphasis on patients as partners in their care

Patients want to be involved in their care (information vs “final say” authority)

Better short-term outcomes (cognitive/ affective)

Potential to impact long-term patient outcomes

Potential to decrease practice variation

Potential to decrease costs

Greater legal protection when certified patient decision aids are used (“informed consent squared”)

A better process!

It’s the right thing to do!

Classic studies in informed decision making

Classic study by Clarence Braddock and colleagues - 1993

- Audio-recorded 1057 encounters among 59 primary care physicians
- Analyzed recordings for evidence of informed decision making

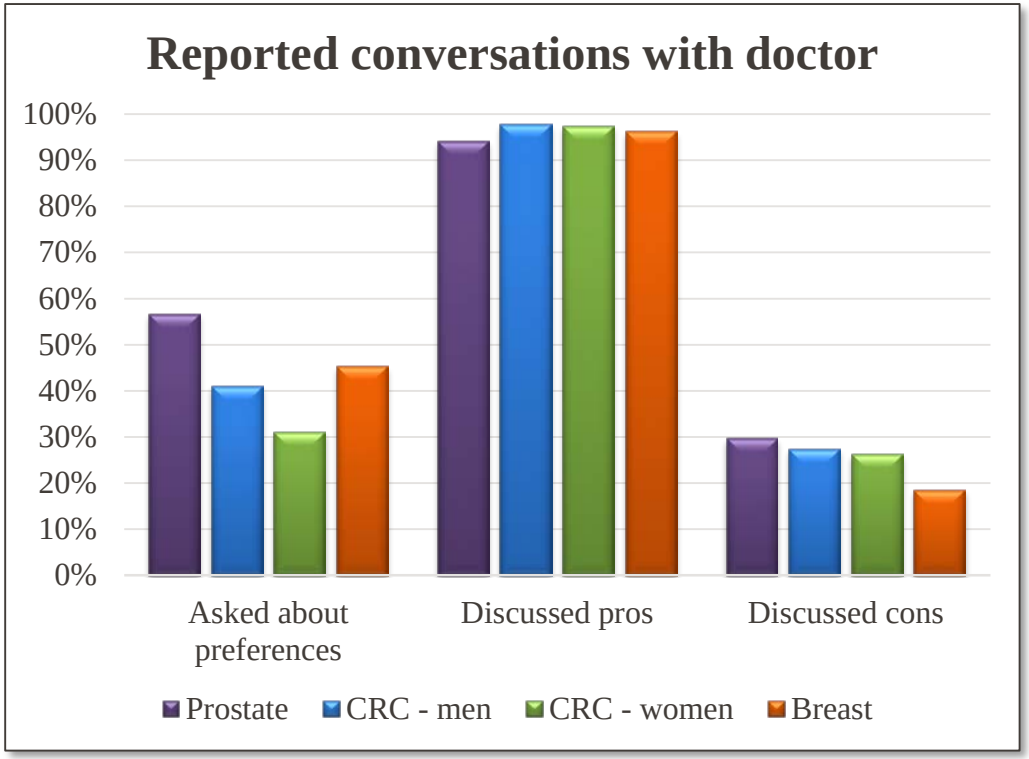
- 9% of decisions met predefined criteria for completeness
- 71% discussed nature of decision
- 21% assessed patient's preferences
- 11% discussed alternatives
- 8% discussed pros/cons
- 6% discussed patient's desired role
- < 5% discussed patient understanding

Braddock, JAMA 1999; J Gen Intern Med 1997.

Is the use of informed/shared decision making improving?

The DECISIONS Study

- 2006 – 2007
- Surveyed 1082 adults 50+ years of age from general U.S. population.
- Reported discussions about cancer screening tests.



Hoffman, Med Decis Making 2010.

Do patients want to participate in medical decision making?

2002 General Social Survey

- Nationally representative sample of English-speaking adults (n=2,765).
- Asked about preferences for health care decision making, ranging from patient-directed to physician-directed.

"I prefer to leave medical decisions to my doctor"

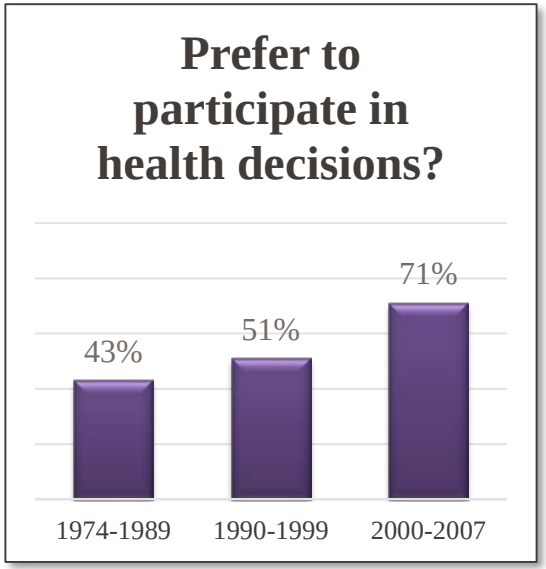
- 52% agree

(older, lower education, male, non-white, poorer health status)

"I prefer my doctor offers me choices and asks my opinions"

- 96% agree

(no ethnicity or education differences)



Increasing historically!

Levinson, J Gen Intern Med, 2005. Chewing Pt Educ Counseling 2012.

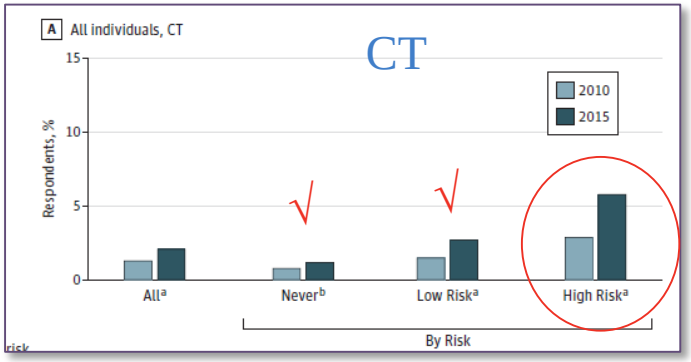
Targets for Shared Decision Making in Cancer Screening (based on recommendations in the US)

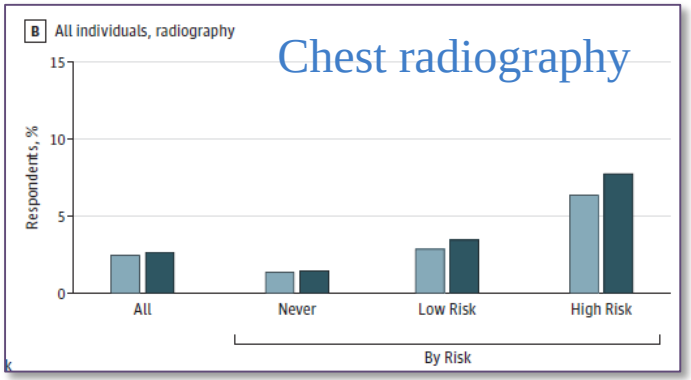
Cancer Screening	Yes/No	When to start	When to stop	What interval	Which modality
Colorectal		✓	✓		✓
Breast	?	✓	✓	✓	
Prostate	✓	✓	✓	?	
Lung	✓				

Few smokers are being screened for lung cancer

National Health Interview Survey

- Cancer Control Module
- 2010 and 2015
- Classified smokers using pack-years and smoking status
- Asked about screening of the chest for lung cancer





1. Screening with CT is low (among "eligible" smokers):
   - 2010: 2.9%
   - 2015: 5.8%
2. Some "ineligible" smokers screened.
3. Chest radiography being used for screening.
   Not effective for LCS.

Huo. Jama Intern Med 2017.

Current lung cancer screening policy in the US

United States Preventive Services Task Force

The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT):

- aged 55 to 80 years
- 30+ pack-year smoking history
- currently smoke or have quit within the past 15 years.

Screening should be discontinued:

- not smoked for 15 years, or
- develops a health problem that substantially limits life expectancy, or
- not able or willing 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.

First preventive service policy in US to require shared decision making and the use of patient decision aids!

Benefits and Harms of Lung Cancer Screening

USPSTF*	CMS
Benefits	Benefits
↓ lung cancer mortality	↓ lung cancer mortality
	↓ overall mortality
Harms	Harms
False positives	False positives
Invasive procedures	Follow-up diagnostic testing
Overdiagnosis	Overdiagnosis
Radiation exposure (cumulative)	Total radiation exposure

*Insufficient evidence about incidental findings.

CMS Beneficiary Eligibility

Written order for LDCT:

- Initial service: beneficiary receives written order during lung cancer screening and shared decision making visit from physician or qualified non-physician.
- Subsequent service: beneficiary receives written order during any appropriate visit from physician or qualified non-physician.

http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

CMS Beneficiary Eligibility

1. Determination of beneficiary eligibility:

- Age
- Absence of symptoms
- “Specific calculation of cigarette smoking pack-years”
- Number of years since quit (former smokers)

Documented in the medical record

http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

CMS Beneficiary Eligibility

2. Shared decision making, including:

- Use of 1 or more decision aids, to include…
  - Benefits, harms, follow-up diagnostic testing, over-diagnosis, false positive rate, total radiation exposure.

Documented in the medical record

http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

CMS Beneficiary Eligibility

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

Documented in the medical record

http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

CMS Beneficiary Eligibility

4. Counseling on the importance of maintaining cigarette abstinence, or furnishing information about tobacco cessation services.

Documented in the medical record

http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

CMS Beneficiary Eligibility

5. "If appropriate," furnishing a written order containing the following:

- **Date of birth**
- **Actual pack-year smoking history (a number!)**
- **Current smoking status, number of years since quit**
- **Statement that beneficiary is asymptomatic**
- **NPI of ordering practitioner**

Documented in the medical record

http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

Attention to SDM for LCS in Recommendations/Guidelines

USPSTF (2014)

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

NCCN (2015)

- Before recommending LCS, shared patient/physician decision-making is recommended so patients have a full understanding of all risks and benefits. Decision aids and risk calculators may be used to assist with decision making (for group 2).

American Cancer Society (2013)

- A process of informed and SDM with a clinician related to the potential benefits, limitations, and harms associated with LCS should occur before any decision is made to initiate screening.

American College of Chest Physicians (2013)

- Counseling should include a complete description of potential benefits and harms…It is important that these individual decisions are made rationally and not out of fear.

Attention to SDM for LCS in Recommendations/Guidelines

American Thoracic Society (2015)

- A LCS program should educate providers so they can adequately discuss the benefit and harms of screening with their patients.

American Academy of Family Physicians (2013)

- A SDM discussion between the clinician and patient should occur regarding the benefits and potential harms of LCS.

Agreement!

1. Importance of SDM.
2. Use of tools to assist with SDM.
3. Importance of clinician competencies in having SDM conversations.
   - Need for clinician training.

A little theory about how people make decisions…

Dual Processing Theory

System 1 Processing

Experiential-Automatic

- Quick
- Effortless
- Does not require deliberation before action
- Responds to loss aversion
- Overweights low probabilities

System 2 Processing

Analytic-Deliberative

- Effortful
- Cognitively demanding
- Requires active reasoning before action
- Active weighing of pros and cons
- Considers probabilities in context

Kahneman, 2011.

A SDM Model for Deliberation about LCS

Step 1: Choice Talk

Help patient understand a decision needs to be made about LCS.

- *LCS is a choice.*
- *Preferences matter.*
- *Check readiness to decide.*
- *Offer more info/detail.*

Step 2: Option Talk

Provide more detail about the LCS decision.

- *Check understanding.*
- *Clearly state options.*
- *Present information about magnitude of benefits/harms.*
- *Check understanding.*

Step 3: Decision Talk

Consider the patient's preferences and decide together about LCS.

- *Explore issues of importance.*
- *Assess readiness.*
- *Offer more info to undecided.*
- *Decision can be reviewed again later.*

Adapted from Elwyn et al, JGIM 2012.

What are patient decision support technologies?

Decision support interventions help people think about choices they face: they describe where and why choice exists.

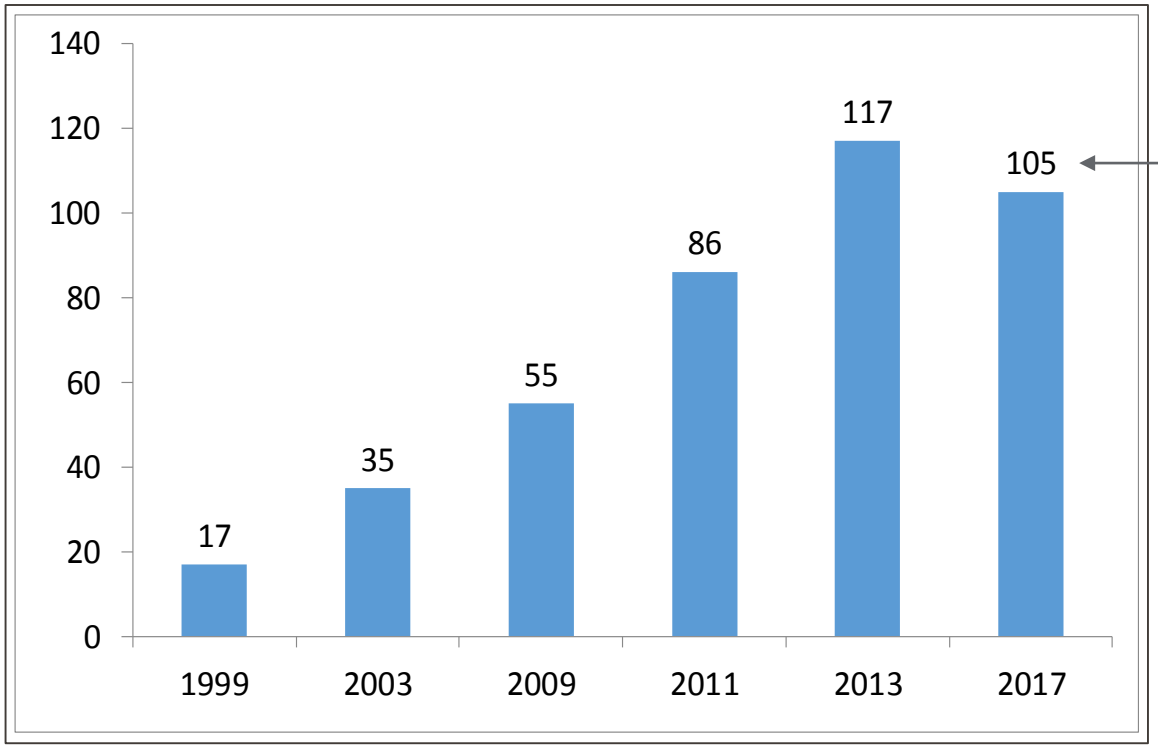
They provide information about options, including, where reasonable, the option of taking no action.

These interventions help people to deliberate, independently or in collaboration with others, about options, by considering relevant attributes.

They support people to forecast how they might feel about short, intermediate and long-term outcomes which have relevant consequences, in ways which help the process of constructing preferences and eventual decision making, appropriate to their individual situation.

Elwyn et al, Med Decis Making, 2010.

Cochrane Database of Systematic Reviews
Decision aids for people facing health treatment or screening decisions



Added 18 RCTs, and dropped 28 that compared simple vs complex aids.

- 31,043 subjects
- 10 countries
- Screening RCTs:
  - Prostate (14)
  - CRC (10)
  - Breast ca gen testing (4)

Stacey, Eisenberg Conference 2013; O'Connor, 1999; 2003; 2009; Stacey, 2011; 2013, 2017.

Cochrane Database of Systematic Reviews
Decision aids for people facing health treatment or screening decisions

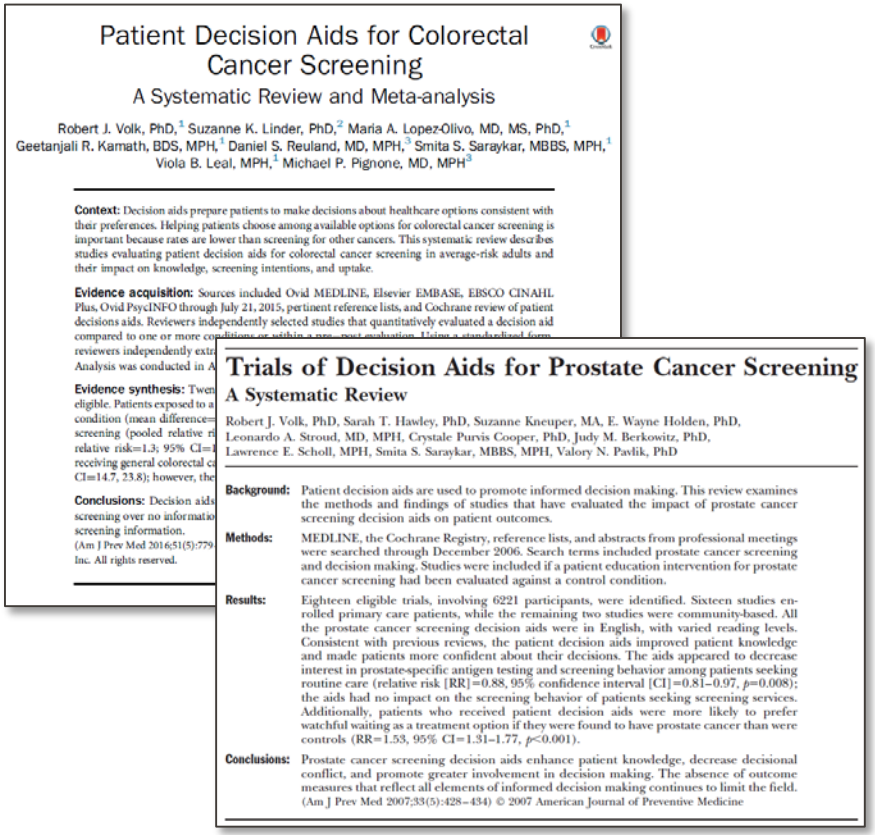
Compared to usual care, patient who use decision aids report…

- Greater knowledge (High)
- More accurate perception of outcome probabilities (Moderate)
- Greater congruence between choice and values (Low)
- Feeling more informed (High)
- Feeling clear about values (High)

- Greater participation in decision making (moderate)
- Increase consultation length by 2.6 minutes
- No impact on anxiety, health outcomes, or adverse events
- Variable impact on choice

Stacey, 2017.

Impact of cancer screening decision aids on patient choice



Patient Decision Aids for Colorectal Cancer Screening

A Systematic Review and Meta-analysis

Robert J. Volk, PhD,[1] Suzanne K. Linder, PhD,[2] Maria A. Lopez-Olivo, MD, MS, PhD,[1] Geetanjali R. Kamath, BDS, MPH,[1] Daniel S. Reuland, MD, MPH,[3] Smita S. Saraykar, MBBS, MPH,[1] Viola B. Leal, MPH,[1] Michael P. Pignone, MD, MPH[3]

Context: Decision aids prepare patients to make decisions about healthcare options consistent with their preferences. Helping patients choose among available options for colorectal cancer screening is important because rates are lower than screening for other cancers. This systematic review describes studies evaluating patient decision aids for colorectal cancer screening in average-risk adults and their impact on knowledge, screening intentions, and uptake.

Evidence acquisition: Sources included Ovid MEDLINE, Elsevier EMBASE, EBSCO CINAHL Plus, Ovid PsycINFO through July 21, 2015, pertinent reference lists, and Cochrane review of patient decisions aids. Reviewers independently selected studies that quantitatively evaluated a decision aid compared to one or more conditions or within a pre–post evaluation. Using a standardized form, reviewers independently extr
Analysis was conducted in A

Evidence synthesis: Twen
eligible. Patients exposed to a
condition (mean difference=
screening (pooled relative ri
relative risk=1.3; 95% CI=1
receiving general colorectal c
CI=14.7, 23.8); however, the

Conclusions: Decision aids
screening over no informatio
screening information.

(Am J Prev Med 2016;51(5):779–
Inc. All rights reserved.

Trials of Decision Aids for Prostate Cancer Screening

A Systematic Review

Robert J. Volk, PhD, Sarah T. Hawley, PhD, Suzanne Kneuper, MA, E. Wayne Holden, PhD, Leonardo A. Stroud, MD, MPH, Crystale Purvis Cooper, PhD, Judy M. Berkowitz, PhD, Lawrence E. Scholl, MPH, Smita S. Saraykar, MBBS, MPH, Valory N. Pavlik, PhD

Background: Patient decision aids are used to promote informed decision making. This review examines the methods and findings of studies that have evaluated the impact of prostate cancer screening decision aids on patient outcomes.

Methods: MEDLINE, the Cochrane Registry, reference lists, and abstracts from professional meetings were searched through December 2006. Search terms included prostate cancer screening and decision making. Studies were included if a patient education intervention for prostate cancer screening had been evaluated against a control condition.

Results: Eighteen eligible trials, involving 6221 participants, were identified. Sixteen studies enrolled primary care patients, while the remaining two studies were community-based. All the prostate cancer screening decision aids were in English, with varied reading levels. Consistent with previous reviews, the patient decision aids improved patient knowledge and made patients more confident about their decisions. The aids appeared to decrease interest in prostate-specific antigen testing and screening behavior among patients seeking routine care (relative risk [RR]=0.88, 95% confidence interval [CI]=0.81–0.97, p=0.008); the aids had no impact on the screening behavior of patients seeking screening services. Additionally, patients who received patient decision aids were more likely to prefer watchful waiting as a treatment option if they were found to have prostate cancer than were controls (RR=1.53, 95% CI=1.31–1.77, p<0.001).

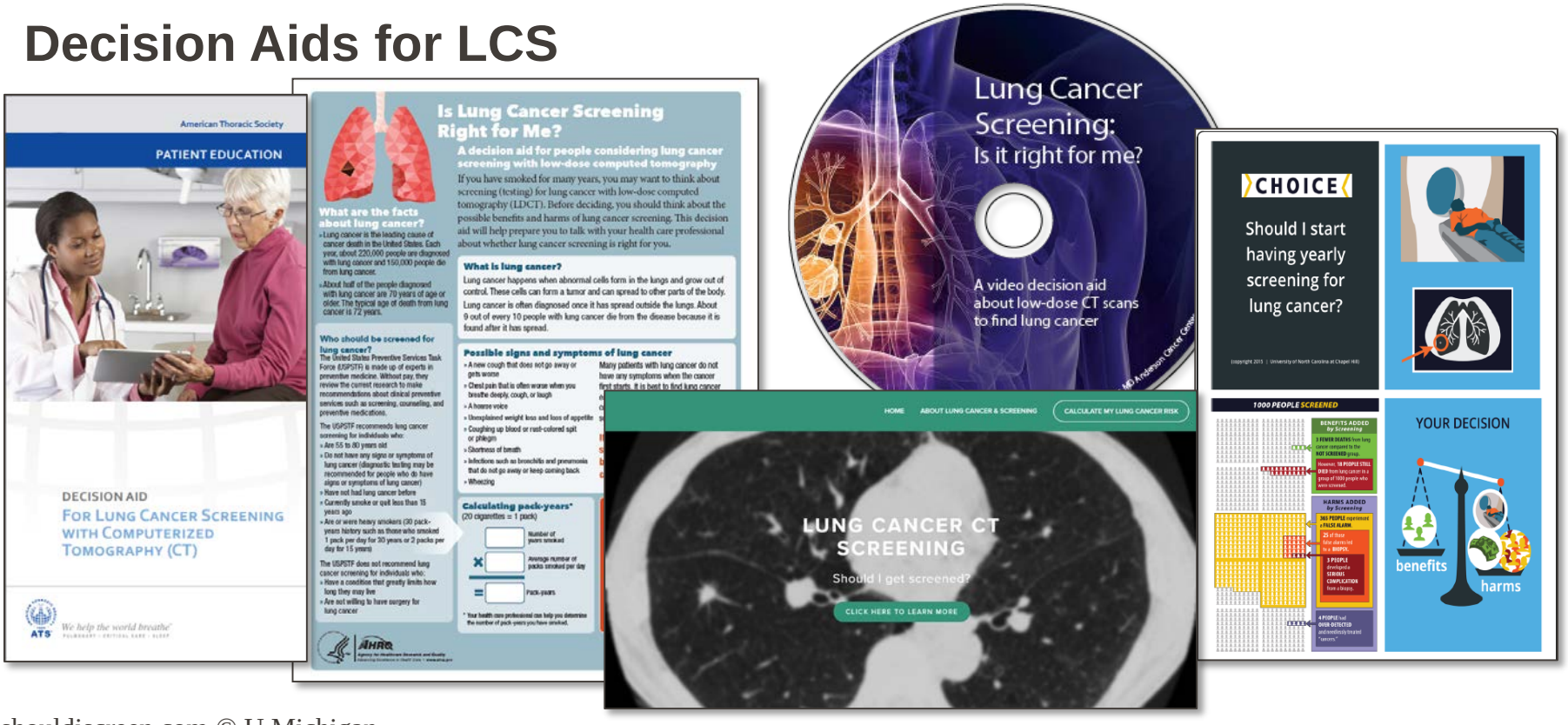
Conclusions: Prostate cancer screening decision aids enhance patient knowledge, decrease decisional conflict, and promote greater involvement in decision making. The absence of outcome measures that reflect all elements of informed decision making continues to limit the field.

(Am J Prev Med 2007;33(5):428–434) © 2007 American Journal of Preventive Medicine

Cancer screening aid	Impact on screening behavior compared to usual care
Prostate cancer screening	Reduction 12%
Colorectal cancer screening	Increase 30%
Lung cancer screening	Unknown (probably increase)
Breast cancer screening (“younger” women, “older” women)	Unknown
Other cancer screening	Unknown

Volk 2007, 2017.

Decision Aids for LCS



shouldiscreen.com © U Michigan
https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/home.html
CHOICE: Reuland, BMC MIMD, 2018.
https://www.thoracic.org/patients/patient-resources/resources/decision-aid-lcs.pdf

The International Patient Decision Aid Standards (IPDAS) Collaboration

Established in 2003, to enhance the quality and effectiveness of patient decision aids by establishing a framework for improving their content, development, implementation, and evaluation.

Processes and products:

- **IPDAS checklist** (2003-2006) – a tool for developers and adopters of decision aids (long and short versions)
- **IPDAS instrument** (2006-2009) – tool for quantitatively evaluating the quality of patient decision aids
- **Minimal standards** (2009-2013) – minimal set of standards for certification
- **Updated the evidence** (2011-2013)
- **Reporting standards** (released at ISDM 2017)

Volk, BMC Medical Informatics & Decision Making, 2013.

Advancing the science of patient decision aids

International Patient Decision Aid Standards (IPDAS) Collaboration

- Established in 2003, to enhance the quality and effectiveness of patient decision aids by establishing a framework for improving their content, development, implementation, and evaluation.

Editorial

Table 1 Achievements of the International Patient Decision Aid Standards (IPDAS) Collaboration

	Product	Description
2003–2006	IPDAS Checklist	Internationally approved criteria for determining the quality of patient decision aids
2006–2009	IPDASi Instrument	Instrument for rating the quality of patient decision aids
2009–2013	IPDAS Minimum Standards	An abbreviated set of essential criteria for certification of patient decision aids
2011–2013	Updated evidence underlying the IPDAS Checklist	Update on the conceptual and theoretical evidence underlying the 12 dimensions for addressing the quality of patient decision aids
2014–2017	SUNDAE Checklist	Reporting standards for patient decision aid evaluation studies

Adapted with permission from D Stacey (see http://ipdas.ohri.ca/resources.html for additional details).
SUNDAE, Standards for UNiversal reporting of patient Decision Aid Evaluations.

Volk, Coulter, BMJ Quality & Safety, 2018.

State Certification Efforts

Healthier Washington initiative on Shared Decision Making

Authorizing legislation provides a heightened protection from liability for failure to provide informed consent when a shared decision making process with certified patient decision aids is used.

Washington State Health Care Authority has developed certification criteria for patient decision aids following the IPDAS standards.

18 criteria (8 additional criteria for screening/testing).

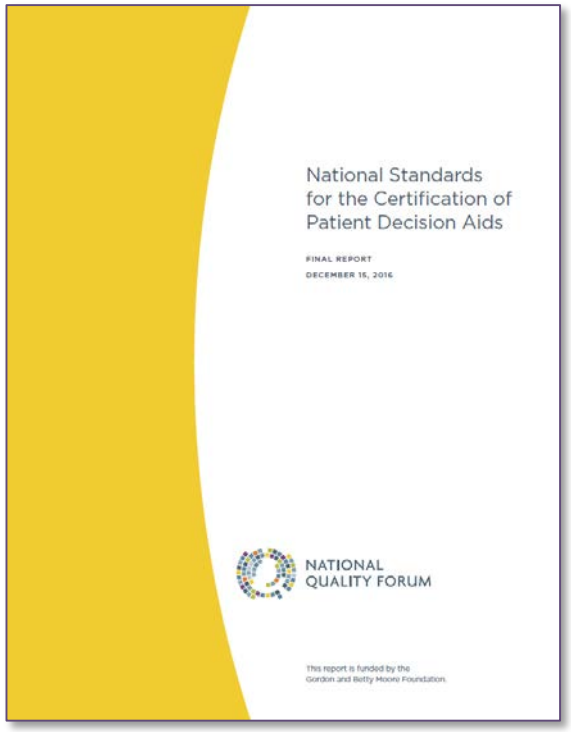
A certification process has also been developed.

Launched April 2016.

- First topic area is maternity and labor/delivery decision aids.

http://www.hca.wa.gov/hw/Pages/shared_decision_making.aspx

National Certification Efforts

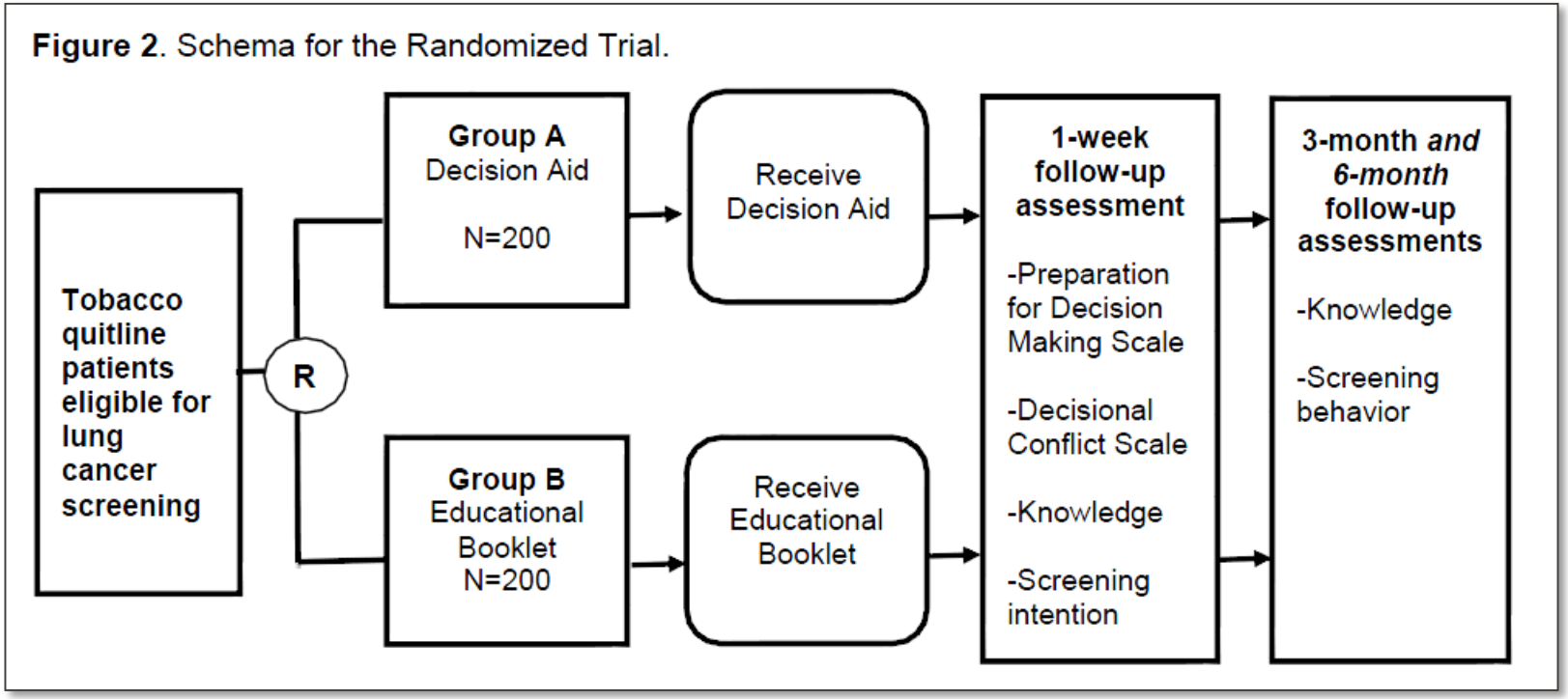


National Quality Forum Certification Standards

- Eligibility (7 criteria)
- Certification (12 criteria)
- Screening and Diagnostic Testing (6 criteria)

Promoting Informed Decision Making about Lung Cancer Screening (PCORI Contract CER-1306-03385)

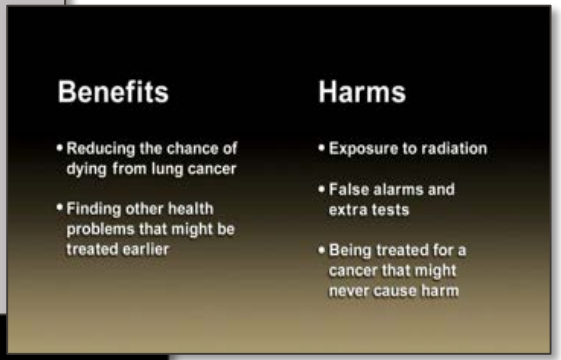
Figure 2. Schema for the Randomized Trial.

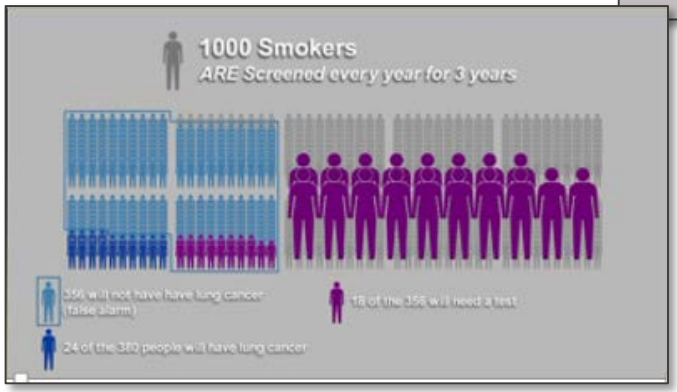


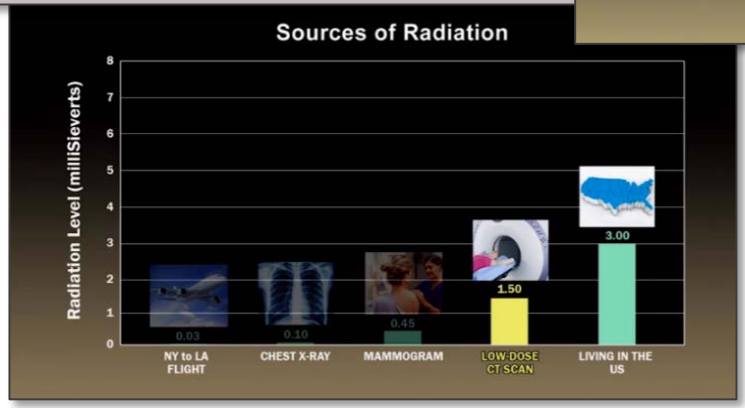
Lung Cancer Screening: Is it right for me?

- 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

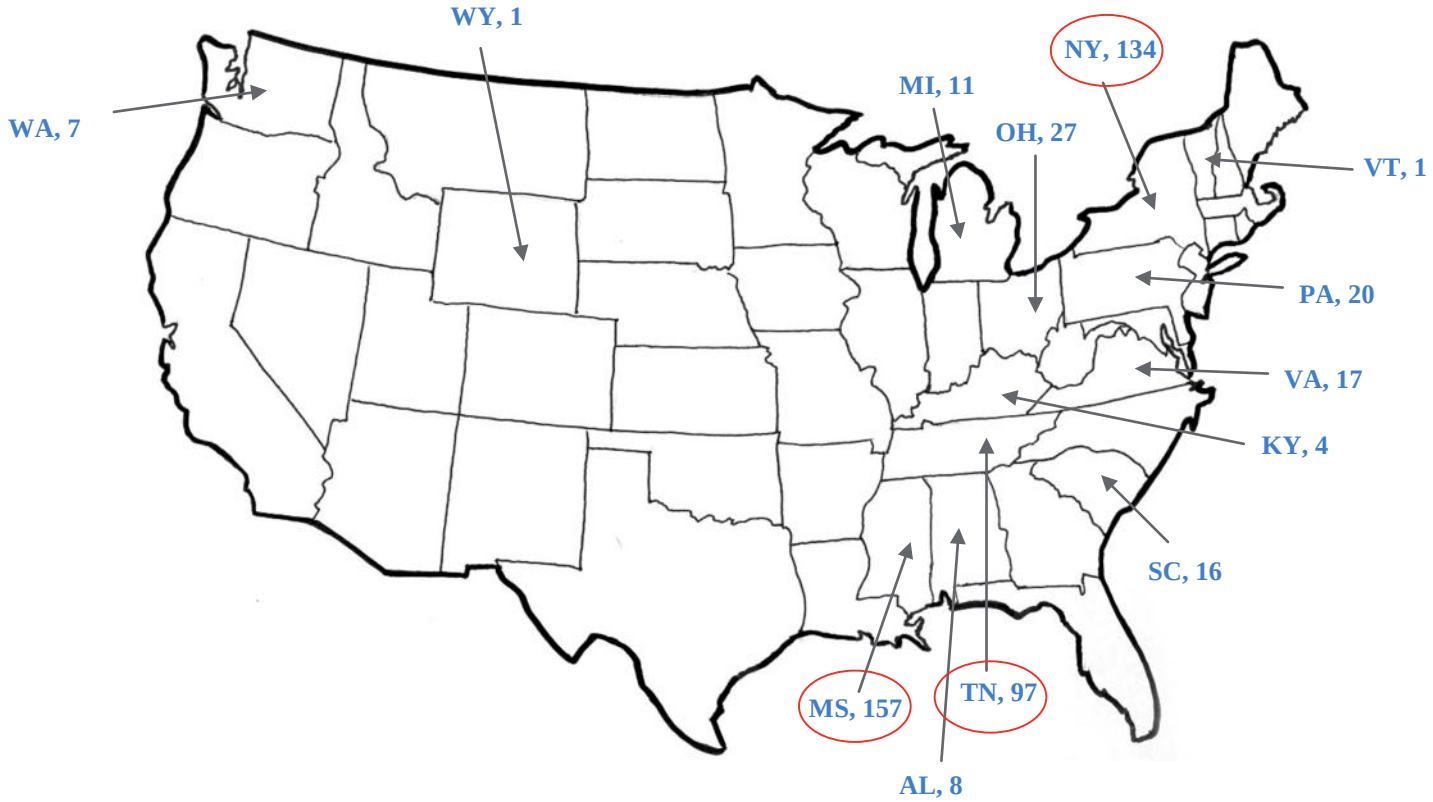
Lung Cancer Screening: Is it right for me?





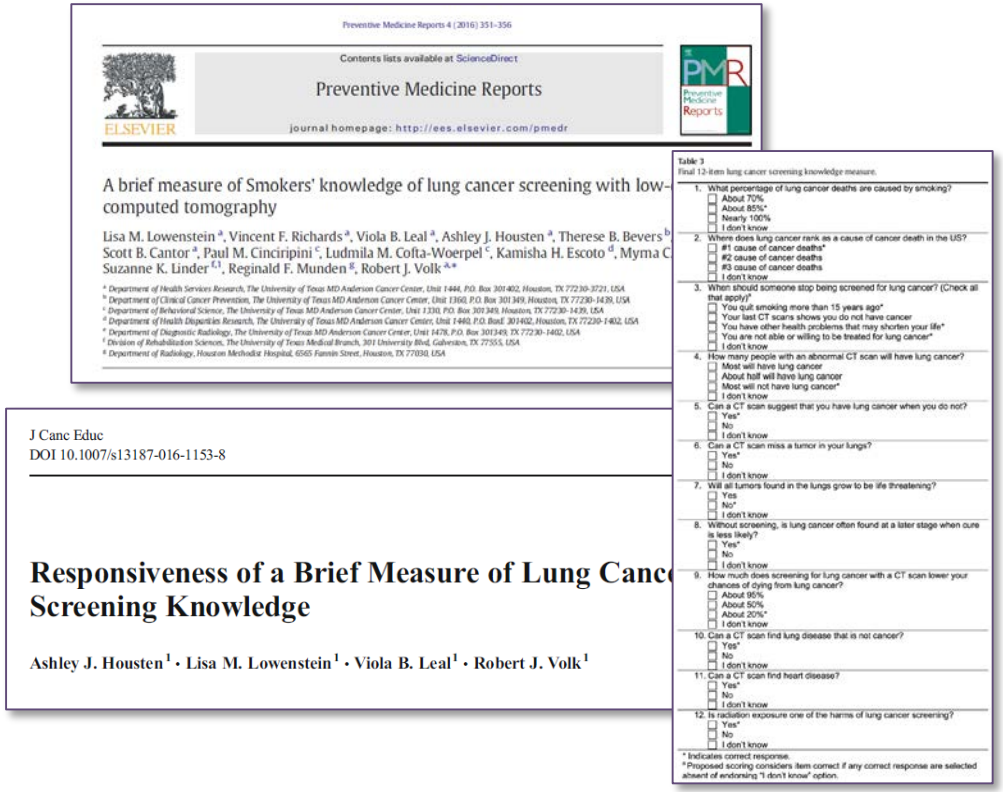


Enrollment by state (n = 500 quitline patients)



Lung Cancer Screening Knowledge: LCS-12

- Brief, self-report measure of lung cancer screening knowledge.
- Items reflect risk factors, LCS eligibility, harms and benefits of screening.
- Good known-groups validity.
- Excellent test-retest reliability (ICC=0.84).
- High responsiveness to decision aid (effect size 1.59).



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journal homepage: http://ees.elsevier.com/pmedr

A brief measure of Smokers' knowledge of lung cancer screening with low-dose computed tomography

Lisa M. Lowenstein [a], Vincent F. Richards [a], Viola B. Leal [a], Ashley J. Housten [a], Therese B. Bevers [b], Scott B. Cantor [a], Paul M. Cinciripini [c], Ludmila M. Cofta-Woerpel [c], Kamisha H. Escoto [d], Myrna C. Suzanne K. Linder [e,1], Reginald F. Munden [g], Robert J. Volk [a,*]

J Canc Educ
DOI 10.1007/s13187-016-1153-8

Responsiveness of a Brief Measure of Lung Cancer Screening Knowledge

Ashley J. Housten [1] · Lisa M. Lowenstein [1] · Viola B. Leal [1] · Robert J. Volk [1]

Table 3
Final 12-item lung cancer screening knowledge measure.

1. What percentage of lung cancer deaths are caused by smoking?
   - ☐ About 70%
   - ☐ About 85%*
   - ☐ Nearly 100%
   - ☐ I don't know
2. Where does lung cancer rank as a cause of cancer death in the US?
   - ☐ #1 cause of cancer deaths*
   - ☐ #2 cause of cancer deaths
   - ☐ #3 cause of cancer deaths
   - ☐ I don't know
3. When should someone stop being screened for lung cancer? (Check all that apply)*
   - ☐ You quit smoking more than 15 years ago*
   - ☐ Your last CT scans shows you do not have cancer
   - ☐ You have other health problems that may shorten your life*
   - ☐ You are not able or willing to be treated for lung cancer*
   - ☐ I don't know
4. How many people with an abnormal CT scan will have lung cancer?
   - ☐ Most will have lung cancer
   - ☐ About half will have lung cancer
   - ☐ Most will not have lung cancer*
   - ☐ I don't know
5. Can a CT scan suggest that you have lung cancer when you do not?
   - ☐ Yes*
   - ☐ No
   - ☐ I don't know
6. Can a CT scan miss a tumor in your lungs?
   - ☐ Yes*
   - ☐ No
   - ☐ I don't know
7. Will all tumors found in the lungs grow to be life threatening?
   - ☐ Yes
   - ☐ No*
   - ☐ I don't know
8. Without screening, is lung cancer often found at a later stage when cure is less likely?
   - ☐ Yes*
   - ☐ No
   - ☐ I don't know
9. How much does screening for lung cancer with a CT scan lower your chances of dying from lung cancer?
   - ☐ About 95%
   - ☐ About 50%
   - ☐ About 20%*
   - ☐ I don't know
10. Can a CT scan find lung disease that is not cancer?
    - ☐ Yes*
    - ☐ No
    - ☐ I don't know
11. Can a CT scan find heart disease?
    - ☐ Yes*
    - ☐ No
    - ☐ I don't know
12. Is radiation exposure one of the harms of lung cancer screening?
    - ☐ Yes*
    - ☐ No
    - ☐ I don't know

* Indicates correct response.
* Proposed scoring considers item correct if any correct response are selected absent of endorsing "I don't know" option.

Lowenstein, *Prev Med Reports* 2016; Housten, *J Canc Educ* 2016.

Characteristics of the Participants (n=516)

Age:

- Under 65: 71.7%
- 65+: 28.3%

Gender

- Female: 62.0%

Race/ethnicity

- Black or African American: 26.7%
- white: 70.2%

No health coverage: 9.1%

Education:

- High school graduate or less: 43.8%

Pack-year smoking history:

- Median: 47.5 pack years

High variability in patients' values related benefits and harms of LCS

30 current/former smokers viewed patient decision aid "Lung cancer Screening: is it right for me?"

Rated benefits/harms of LCS (0-10 scales).

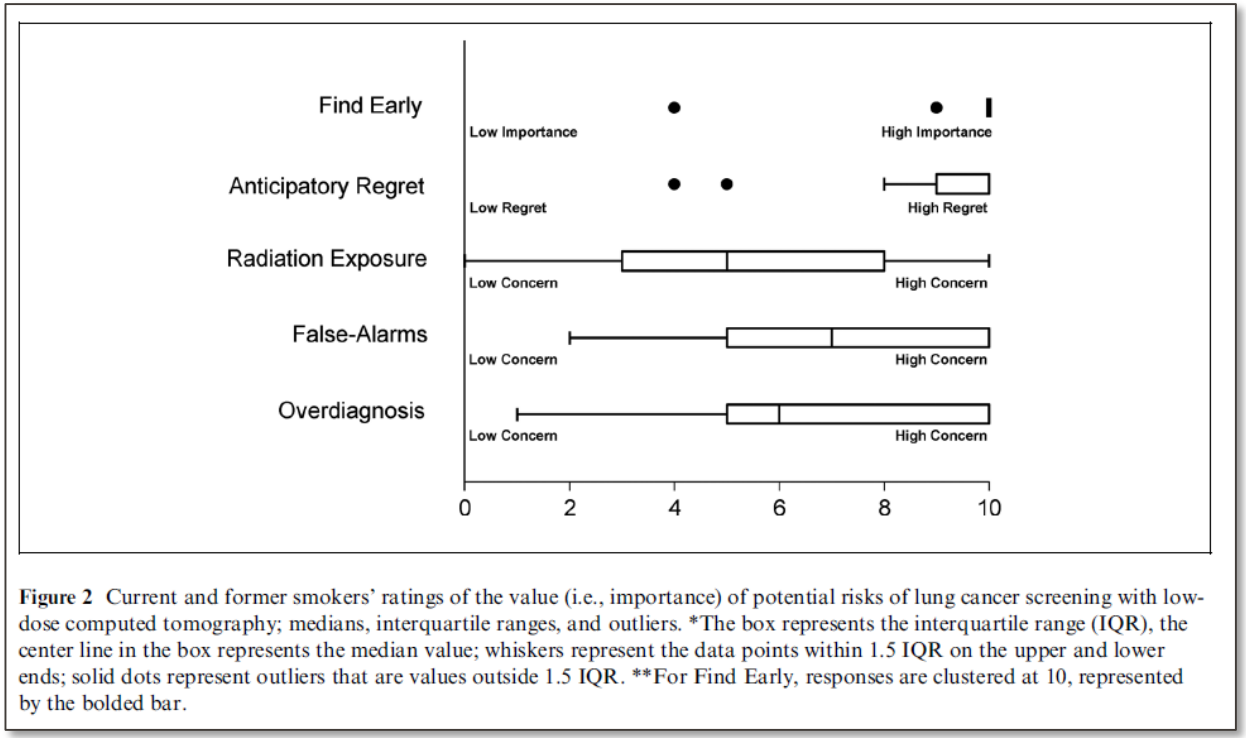
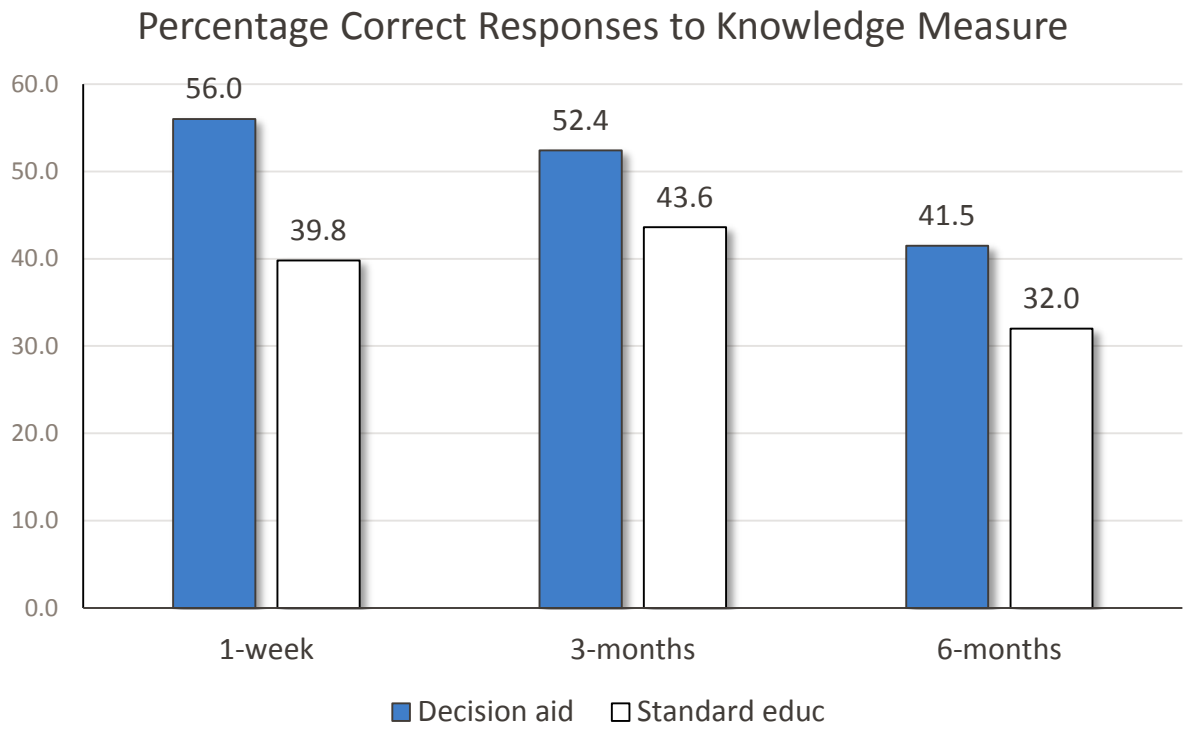


Figure 2 Current and former smokers' ratings of the value (i.e., importance) of potential risks of lung cancer screening with low-dose computed tomography; medians, interquartile ranges, and outliers. *The box represents the interquartile range (IQR), the center line in the box represents the median value; whiskers represent the data points within 1.5 IQR on the upper and lower ends; solid dots represent outliers that are values outside 1.5 IQR. **For Find Early, responses are clustered at 10, represented by the bolded bar.

Hoffman, MDM P&P in press.

Project INFORM: Changes in Knowledge between Groups



Group comparisons significantly different, P<.001

Knowledge of LCS Harms

Percentage correct at 1-week follow-up.

	Decision Aid n=235	Standard Educ n=233	*P*-value
How many people with an abnormal CT scan will have lung cancer? (most will not)	38.0	9.0	<0.001
Can a CT scan suggest you have cancer when you do not? (yes)	72.7	46.5	<0.001
Will all tumors found in the lung grow to be life threatening? (no)	83.7	67.8	<0.001
Is radiation exposure one of the harms of LCS? (yes)	67.7	63.9	0.397

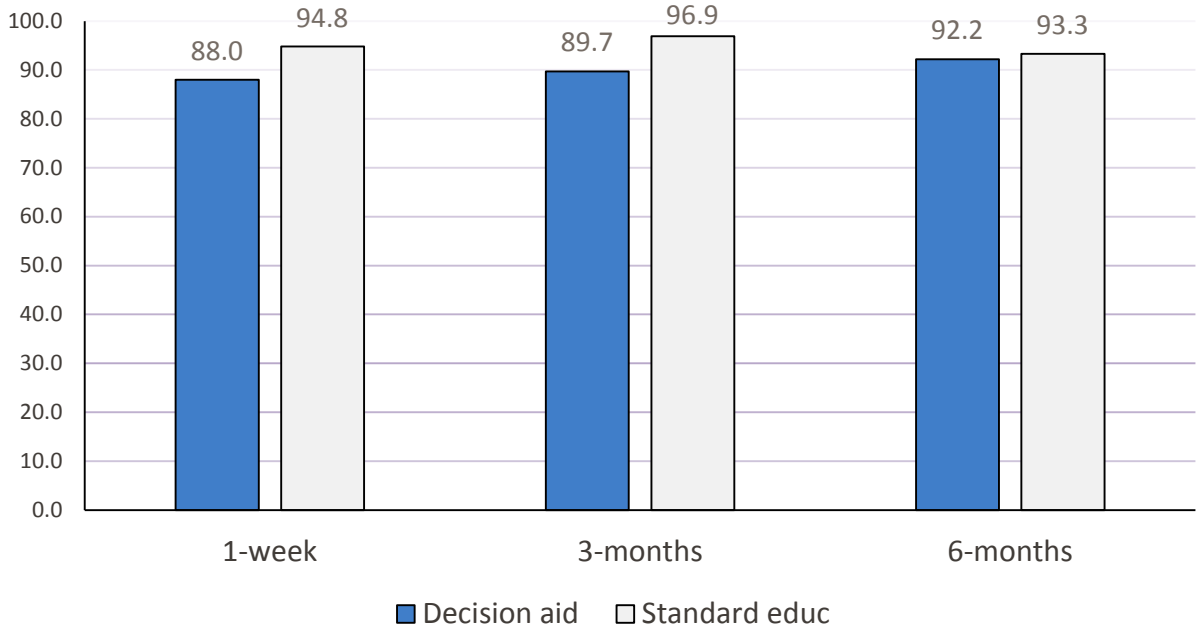
Knowledge of LCS Benefits

Percentage correct at 1-week follow-up.

	Decision Aid n=235	Standard Educ n=233	*P*-value
Without screening, is lung cancer often found at a later stage when cure is less likely? (yes)	86.4	75.2	0.014
Can a CT scan find heart disease? (yes)	65.1	33.9	<0.001

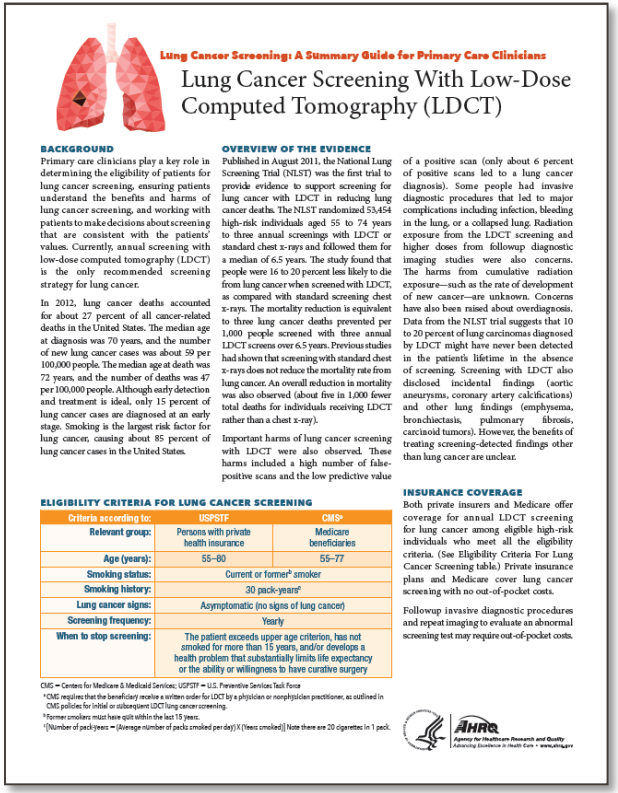
Problems with enthusiasm about lung cancer screening

Should all current and former smokers be screened for lung cancer (% yes)



Implementing SDM for LCS

A Summary Guide for Primary Care Clinicians



Lung Cancer Screening: A Summary Guide for Primary Care Clinicians

Lung Cancer Screening With Low-Dose Computed Tomography (LDCT)

BACKGROUND

Primary care clinicians play a key role in determining the eligibility of patients for lung cancer screening, ensuring patients understand the benefits and harms of lung cancer screening, and working with patients to make decisions about screening that are consistent with the patients' values. Currently, annual screening with low-dose computed tomography (LDCT) is the only recommended screening strategy for lung cancer.

In 2012, lung cancer deaths accounted for about 27 percent of all cancer-related deaths in the United States. The median age at diagnosis was 70 years, and the number of new lung cancer cases was about 59 per 100,000 people. The median age at death was 72 years, and the number of deaths was 47 per 100,000 people. Although early detection and treatment is ideal, only 15 percent of lung cancer cases are diagnosed at an early stage. Smoking is the largest risk factor for lung cancer, causing about 85 percent of lung cancer cases in the United States.

OVERVIEW OF THE EVIDENCE

Published in August 2011, the National Lung Screening Trial (NLST) was the first trial to provide evidence to support screening for lung cancer with LDCT in reducing lung cancer deaths. The NLST randomized 53,454 high-risk individuals aged 55 to 74 years to three annual screenings with LDCT or standard chest x-rays and followed them for a median of 6.5 years. The study found that people were 16 to 20 percent less likely to die from lung cancer when screened with LDCT, as compared with standard screening chest x-rays. The mortality reduction is equivalent to three lung cancer deaths prevented per 1,000 people screened with three annual LDCT screens over 6.5 years. Previous studies had shown that screening with standard chest x-rays does not reduce the mortality rate from lung cancer. An overall reduction in mortality was also observed (about five in 1,000 fewer total deaths for individuals receiving LDCT rather than a chest x-ray).

Important harms of lung cancer screening with LDCT were also observed. These harms included a high number of false-positive scans and the low predictive value of a positive scan (only about 6 percent of positive scans led to a lung cancer diagnosis). Some people had invasive diagnostic procedures that led to major complications including infection, bleeding in the lung, or a collapsed lung. Radiation exposure from the LDCT screening and higher doses from followup diagnostic imaging studies were also concerns. The harms from cumulative radiation exposure—such as the rate of development of new cancer—are unknown. Concerns have also been raised about overdiagnosis. Data from the NLST trial suggests that 10 to 20 percent of lung carcinomas diagnosed by LDCT might have never been detected in the patient's lifetime in the absence of screening. Screening with LDCT also disclosed incidental findings (aortic aneurysms, coronary artery calcifications) and other lung findings (emphysema, bronchiectasis, pulmonary fibrosis, carcinoid tumors). However, the benefits of treating screening-detected findings other than lung cancer are unclear.

ELIGIBILITY CRITERIA FOR LUNG CANCER SCREENING

Criteria according to:	USPSTF	CMS[a]
Relevant group:	Persons with private health insurance	Medicare beneficiaries
Age (years):	55–80	55–77
Smoking status:	Current or former[b] smoker	
Smoking history:	30 pack-years[c]	
Lung cancer signs:	Asymptomatic (no signs of lung cancer)	
Screening frequency:	Yearly	
When to stop screening:	The patient exceeds upper age criterion, has not smoked for more than 15 years, and/or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative surgery	

CMS = Centers for Medicare & Medicaid Services; USPSTF = U.S. Preventive Services Task Force

[a] CMS requires that the beneficiary receive a written order for LDCT by a physician or nonphysician practitioner, as outlined in CMS policies for initial or subsequent LDCT lung cancer screening.

[b] Former smokers must have quit within the last 15 years.

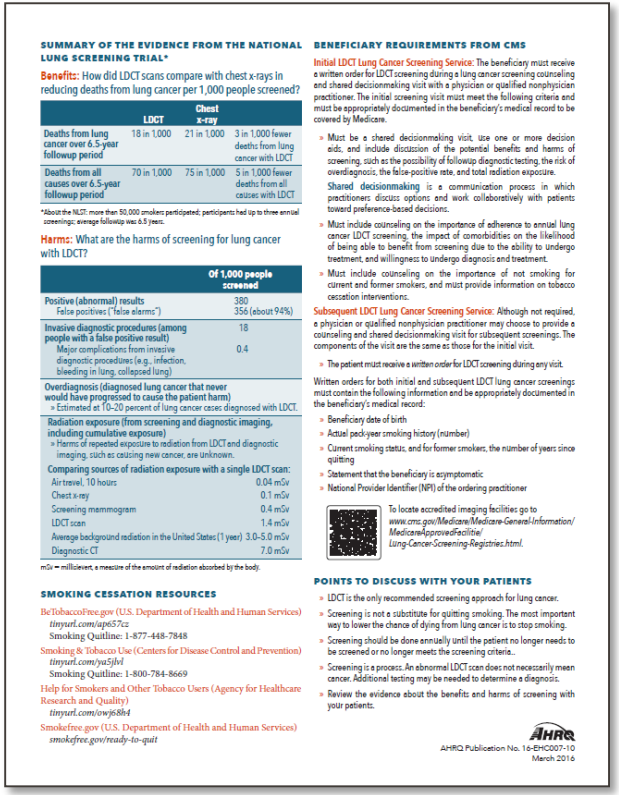
[c] (Number of pack-years = [Average number of packs smoked per day] X [Years smoked]) Note there are 20 cigarettes in 1 pack.

INSURANCE COVERAGE

Both private insurers and Medicare offer coverage for annual LDCT screening for lung cancer among eligible high-risk individuals who meet all the eligibility criteria. (See Eligibility Criteria For Lung Cancer Screening table.) Private insurance plans and Medicare cover lung cancer screening with no out-of-pocket costs.

Followup invasive diagnostic procedures and repeat imaging to evaluate an abnormal screening test may require out-of-pocket costs.

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov



SUMMARY OF THE EVIDENCE FROM THE NATIONAL LUNG SCREENING TRIAL*

Benefits: How did LDCT scans compare with chest x-rays in reducing deaths from lung cancer per 1,000 people screened?

	LDCT	Chest x-ray	
Deaths from lung cancer over 6.5-year followup period	18 in 1,000	21 in 1,000	3 in 1,000 fewer deaths from lung cancer with LDCT
Deaths from all causes over 6.5-year followup period	70 in 1,000	75 in 1,000	5 in 1,000 fewer deaths from all causes with LDCT

*About the NLST: more than 50,000 smokers participated; participants had up to three annual screenings; average followup was 6.5 years.

Harms: What are the harms of screening for lung cancer with LDCT?

	Of 1,000 people screened
Positive (abnormal) results False positives ("false alarms")	380 356 (about 94%)
Invasive diagnostic procedures (among people with a false positive result) Major complications from invasive diagnostic procedures (e.g., infection, bleeding in lung, collapsed lung)	18 0.4
Overdiagnosis (diagnosed lung cancer that never would have progressed to cause the patient harm) » Estimated at 10–20 percent of lung cancer cases diagnosed with LDCT.	
Radiation exposure (from screening and diagnostic imaging, including cumulative exposure) » Harms of repeated exposure to radiation from LDCT and diagnostic imaging, such as causing new cancer, are unknown.	
Comparing sources of radiation exposure with a single LDCT scan:	
Air travel, 10 hours	0.04 mSv
Chest x-ray	0.1 mSv
Screening mammogram	0.4 mSv
LDCT scan	1.4 mSv
Average background radiation in the United States (1 year)	3.0–5.0 mSv
Diagnostic CT	7.0 mSv

mSv = millisievert, a measure of the amount of radiation absorbed by the body.

SMOKING CESSATION RESOURCES

BeTobaccoFree.gov (U.S. Department of Health and Human Services)
tinyurl.com/apt57cz
Smoking Quitline: 1-877-448-7848

Smoking & Tobacco Use (Centers for Disease Control and Prevention)
tinyurl.com/ya5jlvl
Smoking Quitline: 1-800-784-8669

Help for Smokers and Other Tobacco Users (Agency for Healthcare Research and Quality)
tinyurl.com/owj68h4

Smokefree.gov (U.S. Department of Health and Human Services)
smokefree.gov/ready-to-quit

BENEFICIARY REQUIREMENTS FROM CMS

Initial LDCT Lung Cancer Screening Service: The beneficiary must receive a written order for LDCT screening during a lung cancer screening counseling and shared decisionmaking visit with a physician or qualified nonphysician practitioner. The initial screening visit must meet the following criteria and must be appropriately documented in the beneficiary's medical record to be covered by Medicare.

- Must be a shared decisionmaking visit, use one or more decision aids, and include discussion of the potential benefits and harms of screening, such as the possibility of followup diagnostic testing, the risk of overdiagnosis, the false-positive rate, and total radiation exposure.

  Shared decisionmaking is a communication process in which practitioners discuss options and work collaboratively with patients toward preference-based decisions.
- Must include counseling on the importance of adherence to annual lung cancer LDCT screening, the impact of comorbidities on the likelihood of being able to benefit from screening due to the ability to undergo treatment, and willingness to undergo diagnostic and treatment.
- Must include counseling on the importance of not smoking for current and former smokers, and must provide information on tobacco cessation interventions.

Subsequent LDCT Lung Cancer Screening Service: Although not required, a physician or qualified nonphysician practitioner may choose to provide a counseling and shared decisionmaking visit for subsequent screenings. The components of the visit are the same as those for the initial visit.

- The patient must receive a written order for LDCT screening during any visit.

Written orders for both initial and subsequent LDCT lung cancer screenings must contain the following information and be appropriately documented in the beneficiary's medical record:

- Beneficiary date of birth
- Actual pack-year smoking history (number)
- Current smoking status, and for former smokers, the number of years since quitting
- Statement that the beneficiary is asymptomatic
- National Provider Identifier (NPI) of the ordering practitioner

To locate accredited imaging facilities go to *www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Cancer-Screening-Registries.html*.

POINTS TO DISCUSS WITH YOUR PATIENTS

- LDCT is the only recommended screening approach for lung cancer.
- Screening is not a substitute for quitting smoking. The most important way to lower the chance of dying from lung cancer is to stop smoking.
- Screening should be done annually until the patient no longer needs to be screened or no longer meets the screening criteria.
- Screening is a process. An abnormal LDCT scan does not necessarily mean cancer. Additional testing may be needed to determine a diagnosis.
- Review the evidence about the benefits and harms of screening with your patients.

AHRQ

AHRQ Publication No. 16-EHC007-10
March 2016

https://www.effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/lung-cancer-screening/

Implementing SDM for LCS

ELIGIBILITY CRITERIA FOR LUNG CANCER SCREENING

Criteria according to:	USPSTF	CMS[a]
Relevant group:	Persons with private health insurance	Medicare beneficiaries
Age (years):	55–80	55–77
Smoking status:	Current or former[b] smoker	
Smoking history:	30 pack-years[c]	
Lung cancer signs:	Asymptomatic (no signs of lung cancer)	
Screening frequency:	Yearly	
When to stop screening:	The patient exceeds upper age criterion, has not smoked for more than 15 years, and/or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative surgery	

CMS = Centers for Medicare & Medicaid Services; USPSTF = U.S. Preventive Services Task Force

[a] CMS requires that the beneficiary receive a written order for LDCT by a physician or nonphysician practitioner, as outlined CMS policies for initial or subsequent LDCT lung cancer screening.

[b] Former smokers must have quit within the last 15 years.

[c] [Number of pack-years = (Average number of packs smoked per day) X (Years smoked)] Note there are 20 cigarettes in 1

To locate accredited imaging facilities go to *www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Cancer-Screening-Registries.html.*

SUMMARY OF THE EVIDENCE FROM THE NATIONAL LUNG SCREENING TRIAL*

Benefits: How did LDCT scans compare with chest x-rays in reducing deaths from lung cancer per 1,000 people screened?

	LDCT	Chest x-ray	
Deaths from lung cancer over 6.5-year followup period	18 in 1,000	21 in 1,000	3 in 1,000 fewer deaths from lung cancer with LDCT
Deaths from all causes over 6.5-year followup period	70 in 1,000	75 in 1,000	5 in 1,000 fewer deaths from all causes with LDCT

*About the NLST: more than 50,000 smokers participated; participants had up to three annual screenings; average followup was 6.5 years.

Harms: What are the harms of screening for lung cancer with LDCT?

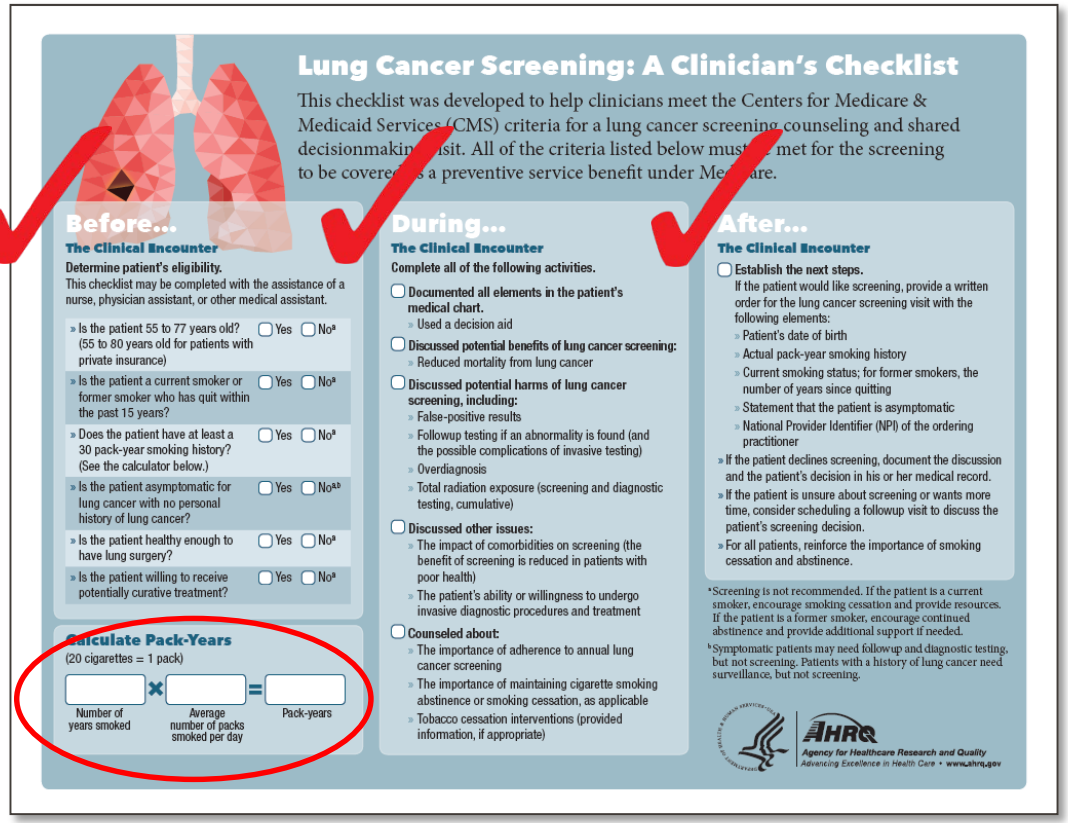
	Of 1,000 people screened
Positive (abnormal) results	380
False positives ("false alarms")	356 (about 94%)
Invasive diagnostic procedures (among people with a false positive result)	18
Major complications from invasive diagnostic procedures (e.g., infection, bleeding in lung, collapsed lung)	0.4
Overdiagnosis (diagnosed lung cancer that never would have progressed to cause the patient harm)	
» Estimated at 10–20 percent of lung cancer cases diagnosed with LDCT.	
Radiation exposure (from screening and diagnostic imaging, including cumulative exposure)	
» Harms of repeated exposure to radiation from LDCT and diagnostic imaging, such as causing new cancer, are unknown.	
Comparing sources of radiation exposure with a single LDCT scan:	
Air travel, 10 hours	0.04 mSv
Chest x-ray	0.1 mSv
Screening mammogram	0.4 mSv
LDCT scan	1.4 mSv
Average background radiation in the United States (1 year)	3.0–5.0 mSv
Diagnostic CT	7.0 mSv

mSv = millisievert, a measure of the amount of radiation absorbed by the body.

https://www.effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/lung-cancer-screening/

Implementing SDM for LCS

A Clinician's Checklist



Lung Cancer Screening: A Clinician's Checklist

This checklist was developed to help clinicians meet the Centers for Medicare & Medicaid Services (CMS) criteria for a lung cancer screening counseling and shared decisionmaking visit. All of the criteria listed below must be met for the screening to be covered as a preventive service benefit under Medicare.

Before...

The Clinical Encounter

Determine patient's eligibility.
This checklist may be completed with the assistance of a nurse, physician assistant, or other medical assistant.

- Is the patient 55 to 77 years old? (55 to 80 years old for patients with private insurance) ☐ Yes ☐ No[a]
- Is the patient a current smoker or former smoker who has quit within the past 15 years? ☐ Yes ☐ No[a]
- Does the patient have at least a 30 pack-year smoking history? (See the calculator below.) ☐ Yes ☐ No[a]
- Is the patient asymptomatic for lung cancer with no personal history of lung cancer? ☐ Yes ☐ No[a,b]
- Is the patient healthy enough to have lung surgery? ☐ Yes ☐ No[a]
- Is the patient willing to receive potentially curative treatment? ☐ Yes ☐ No[a]

Calculate Pack-Years
(20 cigarettes = 1 pack)

Number of years smoked × Average number of packs smoked per day = Pack-years

During...

The Clinical Encounter

Complete all of the following activities.

- ☐ **Documented all elements in the patient's medical chart.**
  - Used a decision aid
- ☐ **Discussed potential benefits of lung cancer screening:**
  - Reduced mortality from lung cancer
- ☐ **Discussed potential harms of lung cancer screening, including:**
  - False-positive results
  - Followup testing if an abnormality is found (and the possible complications of invasive testing)
  - Overdiagnosis
  - Total radiation exposure (screening and diagnostic testing, cumulative)
- ☐ **Discussed other issues:**
  - The impact of comorbidities on screening (the benefit of screening is reduced in patients with poor health)
  - The patient's ability or willingness to undergo invasive diagnostic procedures and treatment
- ☐ **Counseled about:**
  - The importance of adherence to annual lung cancer screening
  - The importance of maintaining cigarette smoking abstinence or smoking cessation, as applicable
  - Tobacco cessation interventions (provided information, if appropriate)

After...

The Clinical Encounter

- ☐ **Establish the next steps.**
  If the patient would like screening, provide a written order for the lung cancer screening visit with the following elements:
  - Patient's date of birth
  - Actual pack-year smoking history
  - Current smoking status; for former smokers, the number of years since quitting
  - Statement that the patient is asymptomatic
  - National Provider Identifier (NPI) of the ordering practitioner
- If the patient declines screening, document the discussion and the patient's decision in his or her medical record.
- If the patient is unsure about screening or wants more time, consider scheduling a followup visit to discuss the patient's screening decision.
- For all patients, reinforce the importance of smoking cessation and abstinence.

[a] Screening is not recommended. If the patient is a current smoker, encourage smoking cessation and provide resources. If the patient is a former smoker, encourage continued abstinence and provide additional support if needed.

[b] Symptomatic patients may need followup and diagnostic testing, but not screening. Patients with a history of lung cancer need surveillance, but not screening.

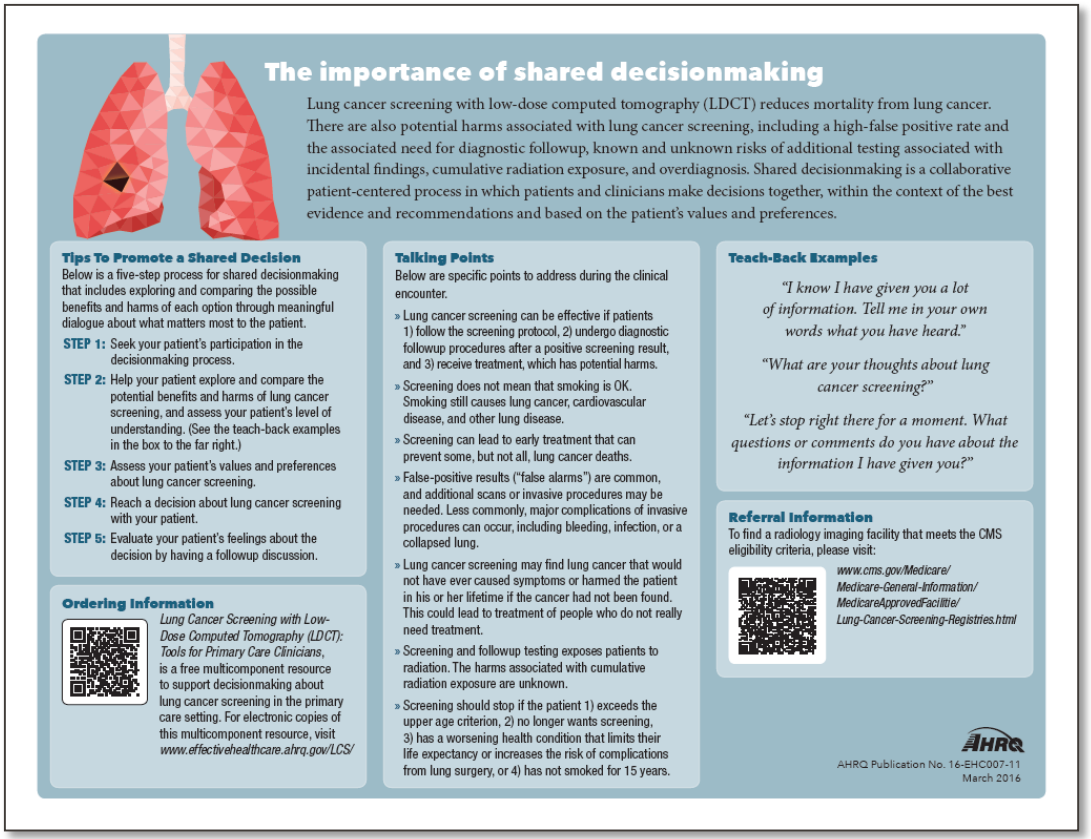
AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Follows CMS eligibility criteria

https://www.effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/lung-cancer-screening/

Implementing SDM for LCS

- Tips to promote SDM
- Talking points
- Teach-back examples



The importance of shared decisionmaking

Lung cancer screening with low-dose computed tomography (LDCT) reduces mortality from lung cancer. There are also potential harms associated with lung cancer screening, including a high-false positive rate and the associated need for diagnostic followup, known and unknown risks of additional testing associated with incidental findings, cumulative radiation exposure, and overdiagnosis. Shared decisionmaking is a collaborative patient-centered process in which patients and clinicians make decisions together, within the context of the best evidence and recommendations and based on the patient's values and preferences.

Tips To Promote a Shared Decision

Below is a five-step process for shared decisionmaking that includes exploring and comparing the possible benefits and harms of each option through meaningful dialogue about what matters most to the patient.

STEP 1: Seek your patient's participation in the decisionmaking process.

STEP 2: Help your patient explore and compare the potential benefits and harms of lung cancer screening, and assess your patient's level of understanding. (See the teach-back examples in the box to the far right.)

STEP 3: Assess your patient's values and preferences about lung cancer screening.

STEP 4: Reach a decision about lung cancer screening with your patient.

STEP 5: Evaluate your patient's feelings about the decision by having a followup discussion.

Ordering Information

Lung Cancer Screening with Low-Dose Computed Tomography (LDCT): Tools for Primary Care Clinicians, is a free multicomponent resource to support decisionmaking about lung cancer screening in the primary care setting. For electronic copies of this multicomponent resource, visit *www.effectivehealthcare.ahrq.gov/LCS/*

Talking Points

Below are specific points to address during the clinical encounter.

- Lung cancer screening can be effective if patients 1) follow the screening protocol, 2) undergo diagnostic followup procedures after a positive screening result, and 3) receive treatment, which has potential harms.
- Screening does not mean that smoking is OK. Smoking still causes lung cancer, cardiovascular disease, and other lung disease.
- Screening can lead to early treatment that can prevent some, but not all, lung cancer deaths.
- False-positive results ("false alarms") are common, and additional scans or invasive procedures may be needed. Less commonly, major complications of invasive procedures can occur, including bleeding, infection, or a collapsed lung.
- Lung cancer screening may find lung cancer that would not have ever caused symptoms or harmed the patient in his or her lifetime if the cancer had not been found. This could lead to treatment of people who do not really need treatment.
- Screening and followup testing exposes patients to radiation. The harms associated with cumulative radiation exposure are unknown.
- Screening should stop if the patient 1) exceeds the upper age criterion, 2) no longer wants screening, 3) has a worsening health condition that limits their life expectancy or increases the risk of complications from lung surgery, or 4) has not smoked for 15 years.

Teach-Back Examples

"I know I have given you a lot of information. Tell me in your own words what you have heard."

"What are your thoughts about lung cancer screening?"

"Let's stop right there for a moment. What questions or comments do you have about the information I have given you?"

Referral Information

To find a radiology imaging facility that meets the CMS eligibility criteria, please visit:

www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Cancer-Screening-Registries.html

AHRQ

AHRQ Publication No. 16-EHC007-11
March 2016

https://www.effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/lung-cancer-screening/

SDM Implementation Do's and Don'ts

Don'ts	Do's
Assume SDM will get done because "it is the right thing to do"	Carefully plan SDM intervention to benefit clinical process – add value.
Go create a decision aid on your own	Engage clinicians (end-users) in needs assessments, decisions about design requirements, content, etc.
"Make the aid available"	Consider how the aid will complement clinical encounters; consider flow; who will provide support.
Rely on physicians to identify patients (and perform SDM)	Involve clinical staff in identification (and SDM).
Assume its easy to identify patients for SDM	Automate the process, make it routine (default).
Passively distribute aids	Find ways to deliver support at point-of-care.

Where are we going?

Policy is ahead of practice!

Priorities going forward:

1. New SDM delivery models
2. Clinician training
3. Tools for priority patient groups
4. Risk tailoring
5. Measuring quality

LUNG-RADS™ & the ACR Lung Cancer Screening Registry

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- No financial disclosures
- Chair, American Cancer Society National Lung Cancer Roundtable
- Chair, American College of Radiology Lung Cancer Screening Committee
- Chair, ACR Lung Cancer Screening Registry
- Vice-Chair NCCN Lung Cancer Screening Panel
- Chair, ACR LungRADS committee

Lung Cancer Screening: Tools & Structure

- ACR Practice Parameter for Lung Cancer CT Screening
- AAPM protocols across > 30 CT makes & models
- ACR Designated Centers under CT accreditation
- ACR LungRADS Structured Reporting/Management
- ACR Lung Cancer Screening Registry

ACR LungRADS™ 1.0 - Released April 2014

- Modeled after 20+ year experience with BIRADS
- Now part of a suite of ACR Radiology Reporting & Data Systems
- Structured reporting and management tool for lung cancer screening CT interpretation
- Categories 0-4 with increasing risk of lung cancer
- Modifier S for other significant findings
- Variables to evaluate quality assurance & improvement

http://www.acr.org/Quality-Safety/Resources/LungRADS

ACR® American College of Radiology

ACR RADS

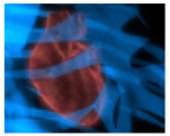
newly formed RADS steering committee

Breast Imaging Reporting and Data System (BI-RADS®) Atlas

The BI-RADS Atlas provides standardized breast imaging findings terminology, report organization, assessment structure and a classification system for mammography, ultrasound and MRI of the breast.

CT Colonography Reporting and Data System (C-RADS)

C-RADS is a standardized reporting, risk assessment and management tool for colorectal and extra-colonic findings which allows monitoring of quality metrics and patient outcomes.



Coronary Artery Disease Reporting and Data System (CAD-RADS™)

CAD-RADS™ is a standardized system to classify and report patient data for CT angiography (CTA).

Head Injury Imaging Reporting and Data System (HI-RADS)

HI-RADS is being developed to standardize the reporting and data collection of imaging in patients with traumatic brain injury.

Liver Imaging Reporting and Data System (LI-RADS)

LI-RADS was created to standardize the reporting and data collection of CT and MR imaging for hepatocellular carcinoma (HCC) to classify observations as either definite HCC or definitely benign.

Lung CT Screening Reporting and Data System (Lung-RADS™)

Lung-RADS is a quality assurance tool designed to standardize lung cancer screening CT reporting and management recommendations, reduce confusion in lung cancer screening CT interpretations, and facilitate outcome monitoring.

Neck Imaging Reporting and Data Systems (NI-RADS)

The goal of NI-RADS is to provide practitioners with a widely applicable, understandable, and validated template for the management of neck masses on the basis of CT, PET, and MRI features.

Prostate Imaging Reporting and Data System (PI-RADS)

The goal of PI-RADS is to expedite the transfer of high-quality MRI from laboratories to patients to address the major need in prostate cancer care — reducing unnecessary biopsies and treatment.

Thyroid Imaging Reporting and Data System (TI-RADS)

The goal of TI-RADS is to provide practitioners with evidence-based recommendations for the management of thyroid nodules on the basis a set of well-defined sonographic features or terms that can be applied to every lesion.

ACR LungRADS™ - Why?

- To provides a common lexicon & definitions
- To standardizes practice among radiologists for communicating with ordering providers
- To define a positive screen
- To address uncertainty in positive screen management
- To facilitate quality assurance & improvement
- *To be updated as knowledge evolves*

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ACR LungRADS®

- **0-4 Categories**
- **2 Modifiers:**
  S - Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)
  C - Prior diagnosis of lung cancer who return to screening
- **Facilitates practice audit**
  - Total # of screens
  - Distribution of screens across categories
  - Positive screen rate, cancer diagnosis rate
  - PPVs

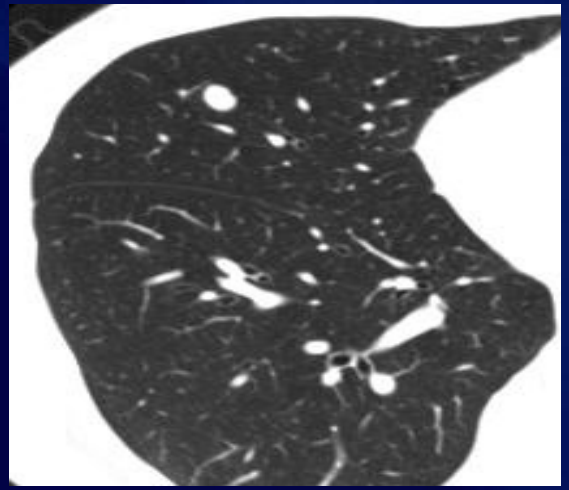
ACR LungRADS®

Category Descriptor	Category Descriptor	Primary Category	Management
Incomplete	-	0	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed
Negative	No nodules & definitely benign nodules	1	Continue annual screening with LDCT in 12 months
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	6 month LDCT
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component
		4B	chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component.

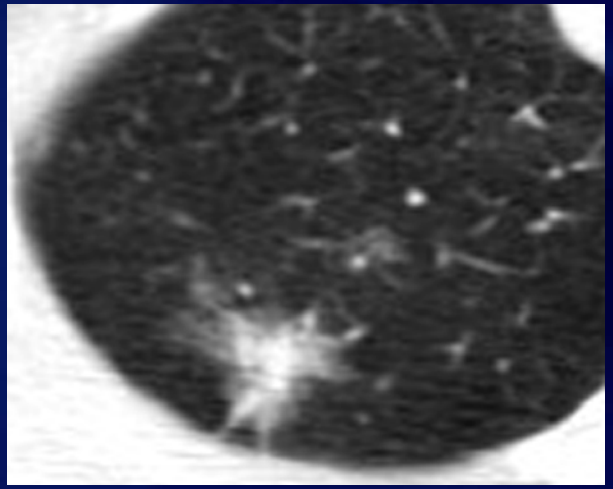
ACR LungRADS®

- **Nodule size**
  - baseline, growth v stability
- **Nodule consistency**
  - solid, part solid, non solid (aka ground glass nodule)
  - calcification, fat
- **Benign & benign behavior vs. clinically active cancer (*what is cancer*?)**
- **Reduces false positives from > 1 in 4, to 1 in 10**

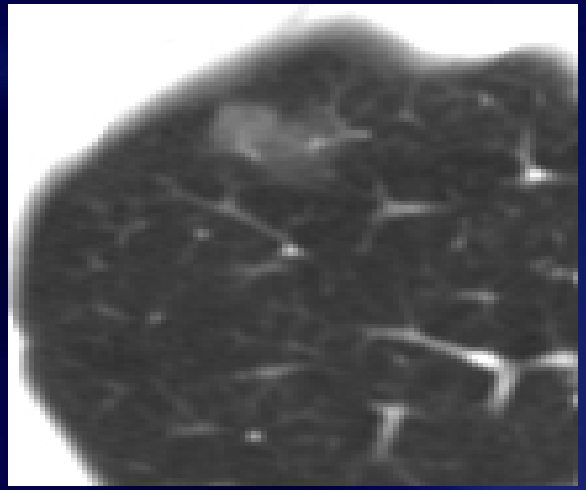
Classifying Screen-Detected Lung Nodules



solid



part solid



non solid

aka GGO or GGN

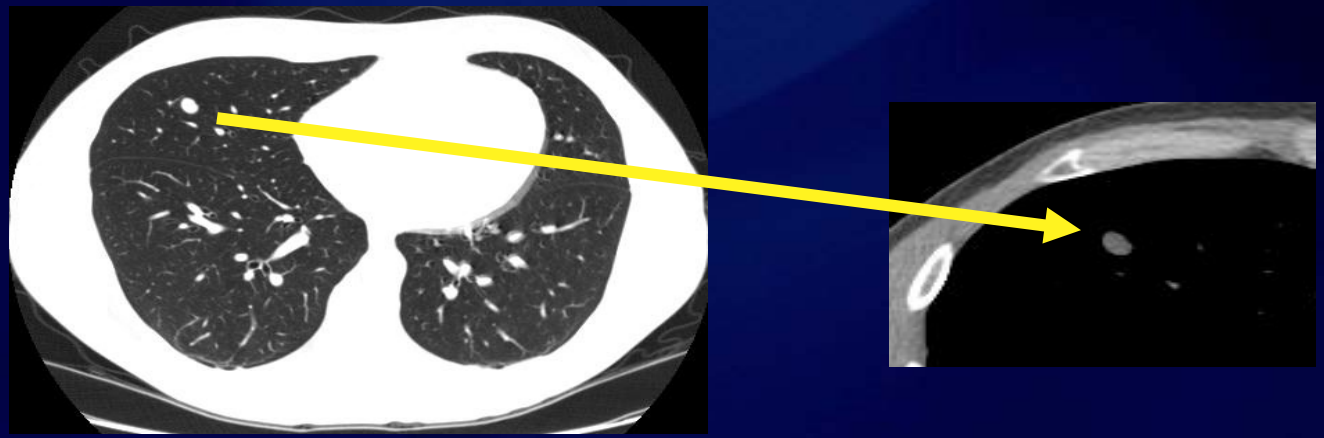
ACR LungRADS®

Fundamental question:

What is a positive screen?

Lung Cancer CT Screening & False Positives

- 40% of NLST subjects had at least one FP over 3 years
- Uncertainty about best management protocol for FPs
- Among patients with a positive screen who underwent a diagnostic procedure, 1.4% experienced a complication



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NLST: Positive CT Screen Definition

- Nodule ≥ 4 mm
- Independent of nodule consistency
- Positive screen rates:
  - 27.3% baseline
  - 27.9% T1 screen
  - 16.8% T2 screen

NLST: Diagnostic Follow-up of *Positive* Screens

Category	LDCT				CXR			
	T0 (%)	T1 (%)	T2 (%)	Total (%)	T0 (%)	T1 (%)	T2 (%)	Total (%)
Total positives	7191 (100%)	6901 (100%)	4054 (100%)	18,146 (100%)	2387 (100%)	1482 (100%)	1174 (100%)	5043 (100%)
Confirmed lung cancer	270 (3.8%)	168 (2.4%)	211 (5.2%)	649 (3.6%)	136 (5.7%)	65 (4.4%)	78 (6.6%)	279 (5.5%)

Non-invasive Procedures	T0 (%)	T1 (%)	T2 (%)	Total (%)	T0 (%)	T1 (%)	T2 (%)	Total (%)
Imaging Exam	81.1%	37.4%	51.3%	57.9%	85.6%	66.5%	78.9%	78.4%
CXR	18.2%	9.1%	16.6%	14.4%	36.9%	26.2%	31.8%	32.6%
Chest CT	73.1%	30.4%	41.1%	49.8%	65.8%	51.2%	62.0%	60.6%
PET or PET-CT	10.3%	5.2%	10.0%	8.3%	7.6%	7.2%	9.8%	8.0%

Invasive Procedures	T0 (%)	T1 (%)	T2 (%)	Total (%)	T0 (%)	T1 (%)	T2 (%)	Total (%)
Percutaneous FNA/Core	2.2%	1.1%	2.4%	1.8%	3.5%	2.5%	4.5%	3.5%
Bronchoscopy	4.6%	2.6%	4.8%	3.8%	4.6%	3.8%	5.4%	4.5%
Surgical procedure(s)	4.2%	2.9%	5.6%	4.0%	5.2%	3.5%	5.8%	4.8%
Mediastinoscopy	0.9%	0.5%	0.6%	0.7%	0.9%	0.8%	1.7%	1.1%
VATS	1.2%	0.8%	2.5%	1.3%	0.9%	0.8%	1.7%	1.1%
Thoracotomy	2.8%	2.2%	4.2%	2.9%	4.1%	3.0%	3.8%	3.7%

NLST Investigators; NEJM 2011;365:396-409

National Lung Cancer Screening Trial

ORIGINAL ARTICLE

The NEW ENGLAND JOURNAL of MEDICINE

Cost-Effectiveness of CT Screening in the National Lung Screening Trial

William C. Black, M.D., Ilana F. Gareen, Ph.D., Samir S. Soneji, Ph.D., JoRean D. Sicks, M.S., Emmett B. Keeler, Ph.D., Denise R. Aberle, M.D., Arash Naeim, M.D., Timothy R. Church, Ph.D., Gerard A. Silvestri, M.D., Jeremy Gorelick, Ph.D., and Constantine Gatsonis, Ph.D. for the National Lung Screening Trial Research Team

N Engl J Med 2014; 371:1793-1802 | November 6, 2014 | DOI: 10.1056/NEJMoa1312547

$81,000 / QALY

…but we also determined that modest changes in our assumptions would greatly alter this figure. The determination of whether screening outside the trial will be cost-effective will depend on how screening is implemented.

Size Threshold for a Positive Lung Cancer Screening CT

ORIGINAL RESEARCH | Annals of Internal Medicine

Definition of a Positive Test Result in Computed Tomography Screening for Lung Cancer

A Cohort Study

Claudia I. Henschke, PhD, MD; Rowena Yip, MPH; David F. Yankelevitz, MD; and James P. Smith, MD, for the International Early Lung Cancer Action Program Investigators*

Ann Intern Med. 2013;158:246-252.

effect of alternative thresholds for defining a positive result on the rates of positive results and cancer diagnoses

Size Threshold for a Positive Lung Cancer Screening CT

- 21,136 individuals with baseline CT performed between 2006 and 2010

Size	(+) Screen Rate	Work Up Reduction
≥ 5 mm	16.0%	
≥ 6 mm	10.2%	36%
≥ 7 mm	7.1%	56%
≥ 8 mm	5.1%	68%
≥ 9 mm	4.0%	75%

9 month delay in cancer dx 0%, 5%, 5.9%, 6.7%

Non Solid Nodules & ACR LungRADS®

2011 IASLC/ATS/ERS
International Multidisciplinary Classification of Lung Adenocarcinoma

- Preinvasive Lesions:
  - Atypical adenomatous hyperplasia (AAH)
    - localized small proliferation of atypical Type II pneumocytes and/or Clara cells lining the alveolar walls and respiratory bronchioles
  - Adenocarcinoma in situ (AIS)
    - ≤ 3 cm solitary adenocarcinoma with pure lepidic growth
    - complete resection achieves 100% disease-specific survival

Non Solid Nodules & ACR LungRADS®:

2011 IASLC/ATS/ERS
International Multidisciplinary Classification of Lung Adenocarcinoma

- Minimally invasive adenocarcinoma (MIA)
  - ≤ 3 cm with predominantly lepidic pattern and ≤5 mm invasion at the largest dimension
  - does not invade lymphatics, blood vessels, or pleura
  - contains no necrosis
  - complete resection achieves nearly 100% disease-specific survival
- Invasive adenocarcinoma

NEGATIVE SCREEN: ACR LungRADS™

Category	Category Descriptor	Category	Findings	Management
Negative	No nodules and definitely benign nodules	1	no lung nodules	Continue annual screening with LDCT in 12 months
			nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules	
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a *clinically active cancer* due to size or lack of growth	2	solid nodule(s):	
			< 6 mm	
			new < 4 mm	
			part solid nodule(s):	
			< 6 mm total diameter on baseline screening	
			non solid nodule(s) (GGN):	
			< 20 mm OR	
			≥ 20 mm and unchanged or slowly growing	
			category 3 or 4 nodules unchanged for ≥ 3 months	

POSITIVE SCREEN ACR LungRADS™ 3

Category	Category Descriptor	Category	Findings	Management
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	solid nodule(s):	6 month LDCT
			≥ 6 to < 8 mm at baseline OR	
			new 4 mm to < 6 mm	
			part solid nodule(s)	
			≥ 6 mm total diameter with solid component < 6 mm OR	
			new < 6 mm total diameter	
			non solid nodule(s) (GGN) ≥ 20 mm on baseline CT or new	

POSITIVE SCREEN ACR LungRADS™ 4

Category	Category Descriptor	Category	Findings	Management
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	solid nodule(s): ≥ 8 to < 15 mm at baseline OR growing < 8 mm OR new 6 to < 8 mm part solid nodule(s: ≥ 6 mm with solid component ≥ 6 mm to < 8 mm OR with a new or growing < 4 mm solid component endobronchial nodule	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component
		4B	solid nodule(s) ≥ 15 mm OR new or growing, and ≥ 8 mm part solid nodule(s) with: a solid component ≥ 8 mm OR a new or growing ≥ 4 mm solid component	chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component
		4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy	

ACR LungRADS™

J Am Coll Radiol 2014;

Performance of ACR Lung-RADS in a Clinical CT Lung Screening Program

Brady J. McKee, MD[a], Shawn M. Regis, PhD[b], Andrea B. McKee, MD[b], Sebastian Flacke, MD, PhD[a], Christoph Wald, MD, PhD[a]

- 2180 consecutive high-risk patients undergoing clinical CT screening between 1/2012-05/2014 reclassified using LungRADS
- Lung-RADS:
  - Reduced positive screen rate from 27.6% to 10.6%
  - No false negatives in the 152 patients with >12-month follow-up reclassified as benign
  - Increased PPV for malignancy from 6.9% to 17.3%

http://www.jacr.org/article/S1546-1440(14)00473-6/abstract

Data In Submission

ACR LungRADS™

Performance in the NLST: A Retrospective Assessment

- Reclassified NLST CT screening exams using LungRADS
- 26,722 LDCT arm subjects (26,309 baseline; 48,671 post-baseline

	BASELINE		POST BASELINE	
	LungRADS	*(NLST)*	*LungRADS*	*(NLST)*
FPR (1-Specificity)	12.9%	(26.6%)	5.3%	(27.4%)
Sensitivity	86.1%	(93.8%)	78.6%	(94.4%)
PPV	6.9%	(3.8%)	10.9%	(2.4%)

ACR LungRADS™

Performance in the NLST: A Retrospective Assessment

- False negative LungRADS screens were nodules with no growth and/or pure nonsolid nodules (5 year survival 64% TPs vs. 73% FNs)
- Compared to the original NLST criteria
  - FPRs with LungRADS were ½ at baseline and ¼ post-baseline
  - Sensitivity was 8% and 15% lower at baseline and post-baseline
  - PPV was 2-3 fold higher for LungRADS

ACR LungRADS™ 4X : Subsolid Nodules

Category Descriptor	Category Descriptor	Primary Category	Expected Distribution	Probability of Malignancy
Suspicious	Radiologist discretion to upcode categories based on additional findings and nodule features	4X		?
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4B	2%	> 15%

Malignancy Rates for Lesions Upgraded to Category 4X

Observer	Total Upgraded to Category 4X	Upgraded from Lung-RADS 3	Upgraded from Lung-RADS 4A	Upgraded from Lung-RADS 4B
1	30/58 (52)	8/18 (44)	2/3 (67)	20/37 (54)
2	42/74 (57)	14/28 (50)	8/12 (67)	20/34 (59)
3	35/64 (55)	10/19 (53)	6/10 (60)	19/35 (54)
4	29/55 (53)	9/19 (47)	4/8 (50)	16/28 (57)
5	42/91 (46)	11/30 (37)	8/12 (67)	23/49 (47)
6	35/66 (53)	8/19 (42)	7/9 (78)	20/38 (53)
Average (%)*	53 (49, 56)	46 (40, 52)	65 (55, 74)	54 (50, 58)

Feature
Effect on surrounding tissue
Internal nodule structure
Border characteristics

4X malignancy rate was 46-57% per observer & substantially higher than malignancy rates of categories 3, 4A& 4B SSNs

Radiology 2016 Chung et al

ACR LungRADS™ - Update

Lung-RADS: Pushing the Limits[1]

Maria D. Martin, MD
Jeffrey P. Kanne, MD
Lynn S. Broderick, MD
Ella A. Kazerooni, MD, MS
Cristopher A. Meyer, MD

Abbreviations: ACR = American College of Radiology, BI-RADS = Breast Imaging Reporting and Data System, LCS = lung cancer screening, Lung-RADS = Lung CT Screening Reporting and Data System

RadioGraphics 2017; 37:1975–1993

https://doi.org/10.1148/rg.2017170051

Content Codes: CH CT HP OI

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In response to the recommendation of the U.S. Preventive Services Task Force and the coverage decision by the Centers for Medicare and Medicaid Services for lung cancer screening (LCS) computed tomography (CT), the American College of Radiology introduced the Lung CT Screening Reporting and Data System (Lung-RADS) in 2014 to standardize the reporting and management of screening-detected lung nodules. As with many first-edition guidelines, questions arise when such reporting systems are used in daily practice. In this article, a collection of 15 LCS-related scenarios are presented that address situations in which the Lung-RADS guidelines are unclear or situations that are not currently addressed in the Lung-RADS guidelines. For these 15 scenarios, the authors of this article provide the reader with recommendations that are based on their collective experiences, with the hope that future versions of Lung-RADS will provide additional guidance, particularly as more data from widespread LCS are collected and analyzed.

ACR LungRADS™ - Update

Lung-RADS: Pushing the Limits[1]

Scenario 1: New LungRADS category 3 solid lung nodule in a patient who is aging out of the screening program.
Scenario 2: Lung mass in a patient with vague symptoms.
Scenario 3: Solid suspicious (Lung-RADS category 4B) nodule with very slow growth rate.
Scenario 4: Ground-glass nodule that increases in density but remains stable in size.
Scenario 5: Ground-glass nodule with slow growth rate.
Scenario 6: How to measure and classify a part-solid nodule.
Scenario 7: Nodule that decreases in size but increases in attenuation.
Scenario 8: Nodule with characteristic features of an intrapulmonary lymph node.
Scenario 9: Airway (endotracheal or endobronchial) nodule.
Scenario 10: Incidental potentially important finding other than lung cancer detected at low-dose LCS CT.
Scenario 11: Reenrolling patients in the LCS CT program after a stable abnormality.
Scenario 12: Low-dose LCS CT of a patient with a recent respiratory infection.
Scenario 13: Categorization of a cavitary lung nodule or nodules.
Scenario 14: Low-dose LCS CT of a patient with a history of a treated lung malignancy.
Scenario 15: Low-dose LCS CT of a patient with a treated low-risk non lung malignancy.

ACR LungRADS™ - Update

The American College of Radiology Lung Imaging Reporting and Data System

Potential Drawbacks and Need for Revision

Hiren J. Mehta, MD; Tan-Lucien Mohammed, MD; and Michael A. Jantz, MD

Lung cancer screening using low-dose CT scanning reduces lung-cancer-specific and overall mortality in high-risk patients. A significant limitation of lung cancer screening is the false-positive rate. The American College of Radiology Lung Imaging Reporting and Data System (Lung-RADS) was designed to standardize reporting of low-dose lung cancer screening results and to decrease the false-positive rate without significantly compromising sensitivity. Implementing Lung-RADS can also improve cost-effectiveness. However, Lung-RADS has never been studied in a prospective fashion. It also does not have a specific reporting category for patients with isolated hilar and mediastinal adenopathy or pleural effusion in the absence of lung nodules. We report four such cases from our lung cancer screening program. We believe that this is a significant limitation of Lung-RADS and should be revised in its new version.

CHEST 2017; 151(3):539-543

does not have a specific reporting category for patients with isolated hilar and mediastinal adenopathy or pleural effusion in the absence of lung nodules

LungRADS Update #1 – ’18 – Perifissural Nodules

- Define perifissural nodules
- Current:
  - Nodules with features of an intrapulmonary lymph node should be managed by mean diameter and the 0-4 numerical category classification
- *Future:*
  - *Solid nodules with smooth margins, an oval, lentiform or triangular shape, and maximum diameter less than 10 mm (perifissural nodules) should be classified as category 2*

LungRADS Update #2 – ’18 – Non Solid Nodules

- Raise the size threshold for pure non solid nodules from 20 mm to 30 mm
- Current: Category 2
  - non solid nodule(s) (GGN):
    - < 20 mm OR
    - ≥ 20 mm and unchanged or slowly growing
- *Future: Category 2*
  - *non solid nodule(s) (GGN):*
    - *< 30 mm OR*
    - *≥ 30 mm and unchanged or slowly growing*

LungRADS Update #3 – ’18 – 4B Management

- Address management for new large nodules
- Current: Category 4B Management
  - Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component. For new large nodules that develop on an annual repeat screening CT
- *Future: Category 4B Management*
  - Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component. *For new large nodules that develop on an annual repeat screening CT, a 1 month LDCT may be considered*

LungRADS Update #4 – ’18 – Nodule Measurement

- Change in how nodule diameter is measured & recorded
- Current:
  - Report average diameter (of long and short axis diameters) rounded to the nearest whole number
- *Future:*
  - To calculate nodule mean diameter, measure both the long and short axis to one decimal point, and report mean nodule diameter to one decimal point

LungRADS Update - Future

Size & growth defined in mm to volume

- Current: Mean diameter
- Future: Volumetric; new QIBA small nodule profile and growth profile to aid in measuring system performance and the variance around size measurements
- Obstacles:
  - Availability of accurate, robust software tools
  - Fully integrated into radiologist workflow
  - Reimbursement for lung nodule CAD/CAD-like tools which require facility investment & radiologist time to translate

So how are we doing?

ACR Lung Cancer Screening Registry™

- Approved by CMS as a qualified registry March 5, 2015
- Only CMS approved registry
- ACR National Radiology Database Registries (NRDR) aid facilities with quality improvement programs & efforts to improve patient care by comparing facility data to others regionally and nationally and are approved by CMS as a Qualified Clinical Data Registry (QCDR)
- NRDR registries include:
  - Dose Index Registry (DIR)
  - CT Colonography Registry (CTC)
  - National Mammography Database (NMD)
  - National Oncologic PET Registry (NOPR)
  - General Radiology Improvement Database (GRID)

ACR Lung Cancer Screening Registry™

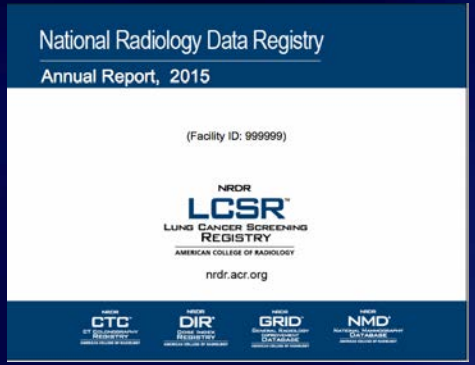
- Major data categories:
  - Patient, Facility & Radiologist
  - Appropriateness of screening
  - Smoking cessation
  - Screening test itself
    - CT radiation exposure
    - LungRADS structured reporting category
  - Outcomes at 12 months from screening CT
  - Additional risk factors *optional, recommended in patients who do not meet USPSTF screening criteria*

http://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Lung-Cancer-Screening-Registry

ACR Lung Cancer Screening Registry™

- Benchmark Reports:
  - Facility level in aggregate
  - Individual radiologists within the imaging facility
  - Performance comparisons on core metrics
    - Appropriateness
    - Radiation exposure
    - LungRADS™ category distribution
    - Diagnostic testing and tissue sampling rates
    - Lung cancer diagnosis rates

NRDR
LCSR™
LUNG CANCER SCREENING REGISTRY
AMERICAN COLLEGE OF RADIOLOGY



ACR Lung Cancer Screening Registry

	2015*	2016	2017~	Total
# of facilities	908	905 new since 2015	307 new since 2016	2120
# of screening exams	42,126	167,663	171,075	380,864

* 2015 facility enrollment began in September 2015
~ 2017 data through 8/30/2017 (8 months)

NRDR LCSR™ Lung Cancer Screening Registry
American College of Radiology

ACR Lung Cancer Screening Registry

Appropriateness (USPSTF criteria)

	2015	2016	2017
% appropriate	82.9%	87.9%	90.5%
# appropriate	34,343	146,134	146,134
total screens	41,407	166,158	167,228

* 2015 facility enrollment began in September 2015
~ 2017 data through 8/30/2017 (8 months)

NRDR LCSR™ Lung Cancer Screening Registry
American College of Radiology

ACR Lung Cancer Screening Registry™

Smoking & Smoking Cessation

	2015	2016	2017
% current smokers	56%	58%	59%
smoking cessation offered to current smokers	79%	84%	85%

* 2015 facility enrollment began in September 2015
~ 2017 data through 8/30/2017 (8 months)

NRDR LCSR™ Lung Cancer Screening Registry
American College of Radiology

ACR Lung Cancer Screening Registry™

Radiation Exposure (mean CTDIvol)

	2015	2016	2017
underweight (BMI <18.5)	2.48	2.64	2.77
normal (BMI of 18.5 - 24.9)	2.79	2.66	2.666
overweight (BMI of 25 - 29.9)	3.22	2.98	3.19
obese (BMI 30 or greater)	4.06	3.88	3.91

* 2015 facility enrollment began in September 2015
~ 2017 data through 8/30/2017 (8 months)

NRDR LCSR Lung Cancer Screening Registry American College of Radiology

ACR Lung Cancer Screening Registry™

Positive Screen Rate (LungRADS 3, 4A/B/X)

	2015	2016	2017
baseline screens	21.2 %	19.6%	18.3%
subsequent screens	14.2%	12.7%	11.2%
overall	20.7%	18.6%	16.8%
# of screens	41,407	166,158	167,228

* 2015 facility enrollment began in September 2015
~ 2017 data through 8/30/2017 (8 months)

NRDR LCSR Lung Cancer Screening Registry American College of Radiology

ACR Lung Cancer Screening Registry™

Cancer Detection Rates

	2015	2016	2017
prevalence (baseline)	6.5% N = 245	5.1% N = 707	2.9% N = 365
incidence (subsequent screens)	1.5% N = 5	2.2% N = 56	1.3% N = 51

* 2015 facility enrollment began in September 2015
~ 2017 data through 8/30/2017 (8 months)

NRDR LCSR Lung Cancer Screening Registry American College of Radiology

ACR Lung Cancer Screening Registry™

Positive Predictive Values (LungRads 3,4A/B/X)

	2015	2016	2017
PPV 1 lung cancers detected on percutaneous biopsies	0.48	0.57	0.53
PPV 1 lung cancers detected on bronchoscopies	0.46	0.44	0.51
PPV 1 surgically detected lung cancers	0.63	0.69	0.72

* 2015 facility enrollment began in September 2015
~ 2017 data through 8/30/2017 (8 months)

NRDR LCSR Lung Cancer Screening Registry American College of Radiology

ACR Lung Cancer Screening Registry™

Positive Predictive Values at 1 year

	2015	2016	2017
PPV 2a for LungRADS 3 with 6 month recommended CT	0.01	0.01	0.00
PPV 2b for LungRADS 4A with 3 month recommended CT	0.14	0.12	0.08
PPV 3 LungRADS 3, 4A/B/X all biopsy types with tissue diagnosis of cancer	0.62	0.62	0.62

* 2015 facility enrollment began in September 2015
~ 2017 data through 8/30/2017 (8 months)

NRDR LCSR Lung Cancer Screening Registry American College of Radiology

ACR Lung Cancer Screening Registry™

Where Screening is Being Done

Top 10 by exam count

State	# of Facilities	# of Screens
MA	45	12644
PA	107	11612
MI	78	10520
NY	102	10032
FL	117	8391
OH	108	8081
KY	66	8061
NC	78	7992
IL	54	6294
TX	113	6121

Lowest 10 by exam count

State	# of Facilities	# of Screens
AR	8	600
HI	8	543
NE	22	541
NV	7	417
DE	4	403
GU	1	341
AK	6	232
DC	3	199
WY	2	42
UT	2	7

LUNG-RADS™ & the ACR Lung Cancer Screening Registry

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Implementation of a Lung Cancer Screening Program

Peter Mazzone

Cleveland Clinic

April 10th, 2018

Overview

- Balance of Benefit and Harm
- Implementation Considerations

Balance of Benefit and Harms

BENEFIT:

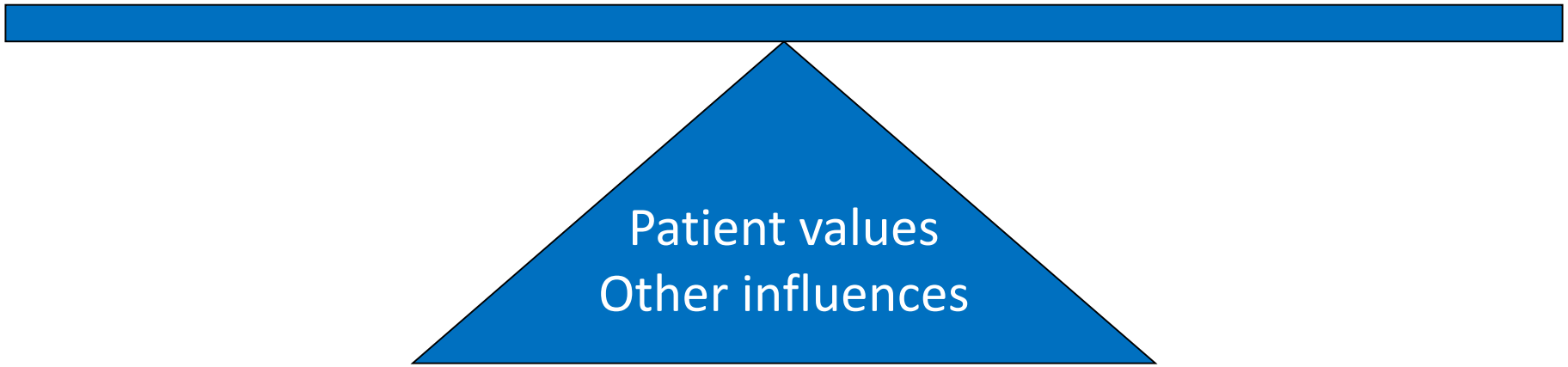
Mortality reduction

HARMS:

Pseudodisease

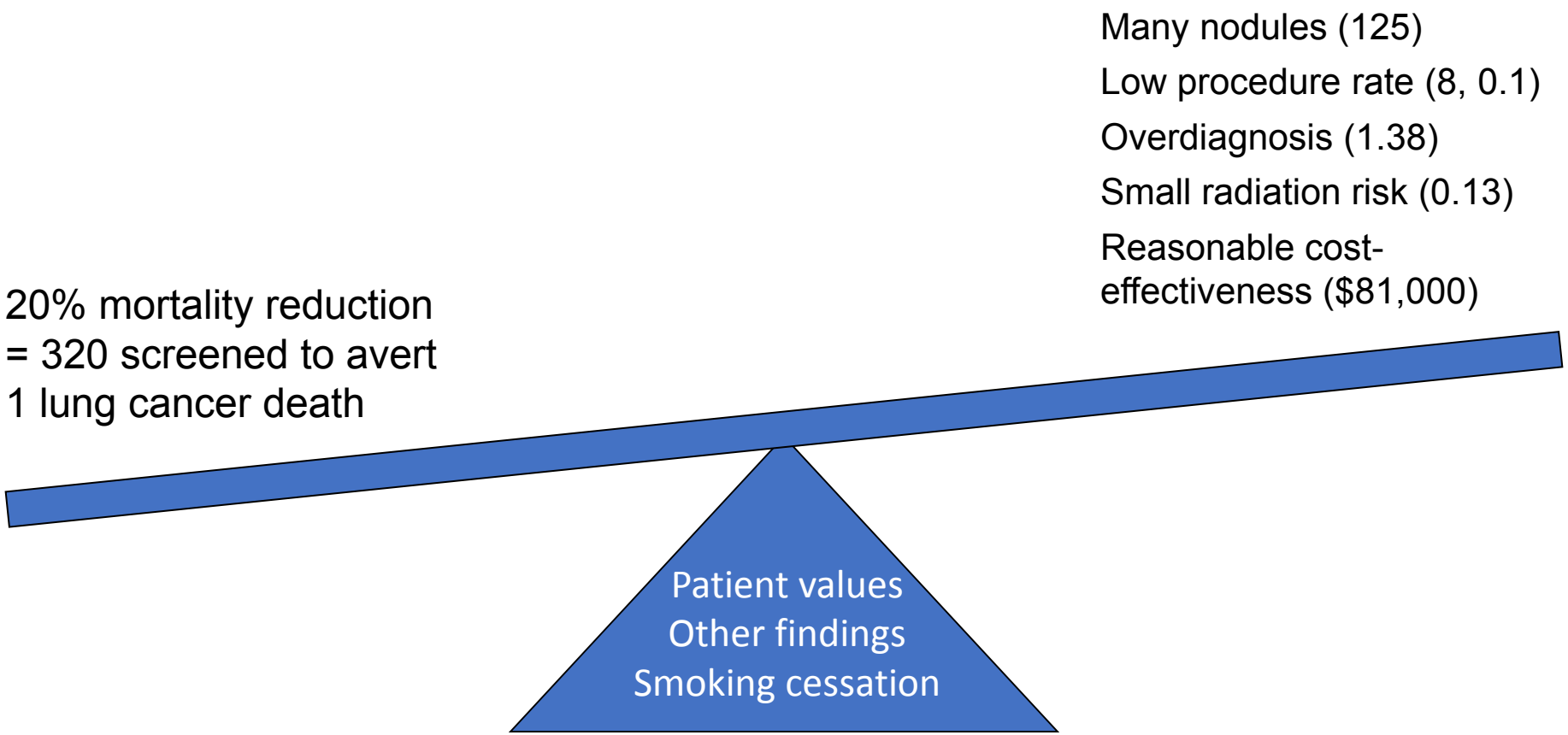
Morbidity

Cost

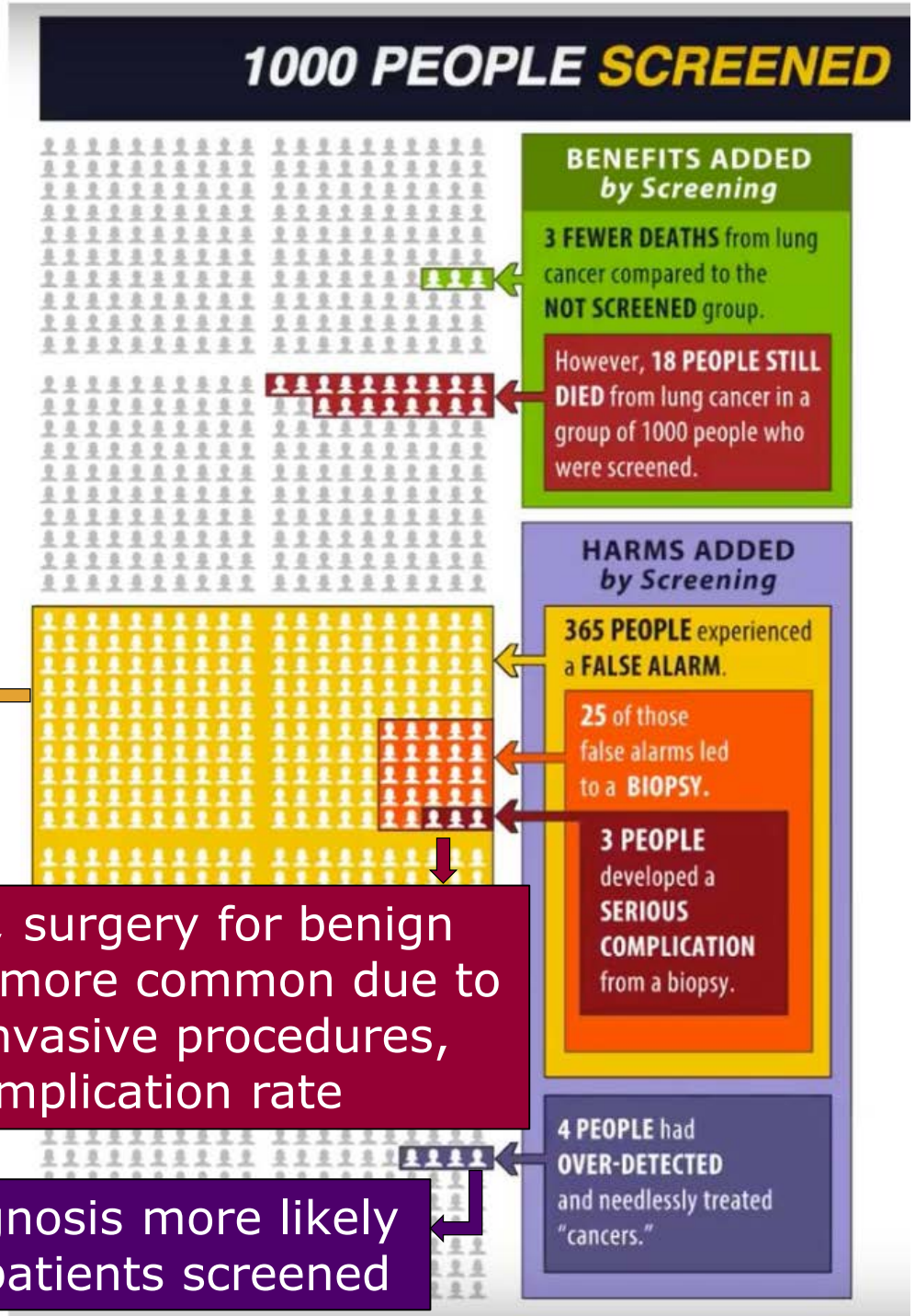


Balance of Benefit and Harms

- **3 annual low-dose CT** of people **age 55-74**, with **30+ pack-year** smoking, who have **smoked within the past 15 years** performed in **capable settings**.



Balance of Benefit and Harms



Nodule detection rate may be substantially higher (59% in VA site)

Distress related to nodule detection may be worse if less attention to patient counseling, communication

Complications, surgery for benign disease may be more common due to wider use of invasive procedures, higher complication rate

Type 2 Overdiagnosis more likely if older, sicker patients screened

Questions to Address

- Who to offer lung cancer screening
- How to identify eligible patients
- How to schedule appropriate patients
- How to conduct the SDM visit
- How to perform the LDCT
- How to communicate the results
- How to manage abnormal findings
- How to insure compliance with annual screening
- How to incorporate smoking cessation
- How to collect, analyze, and report data

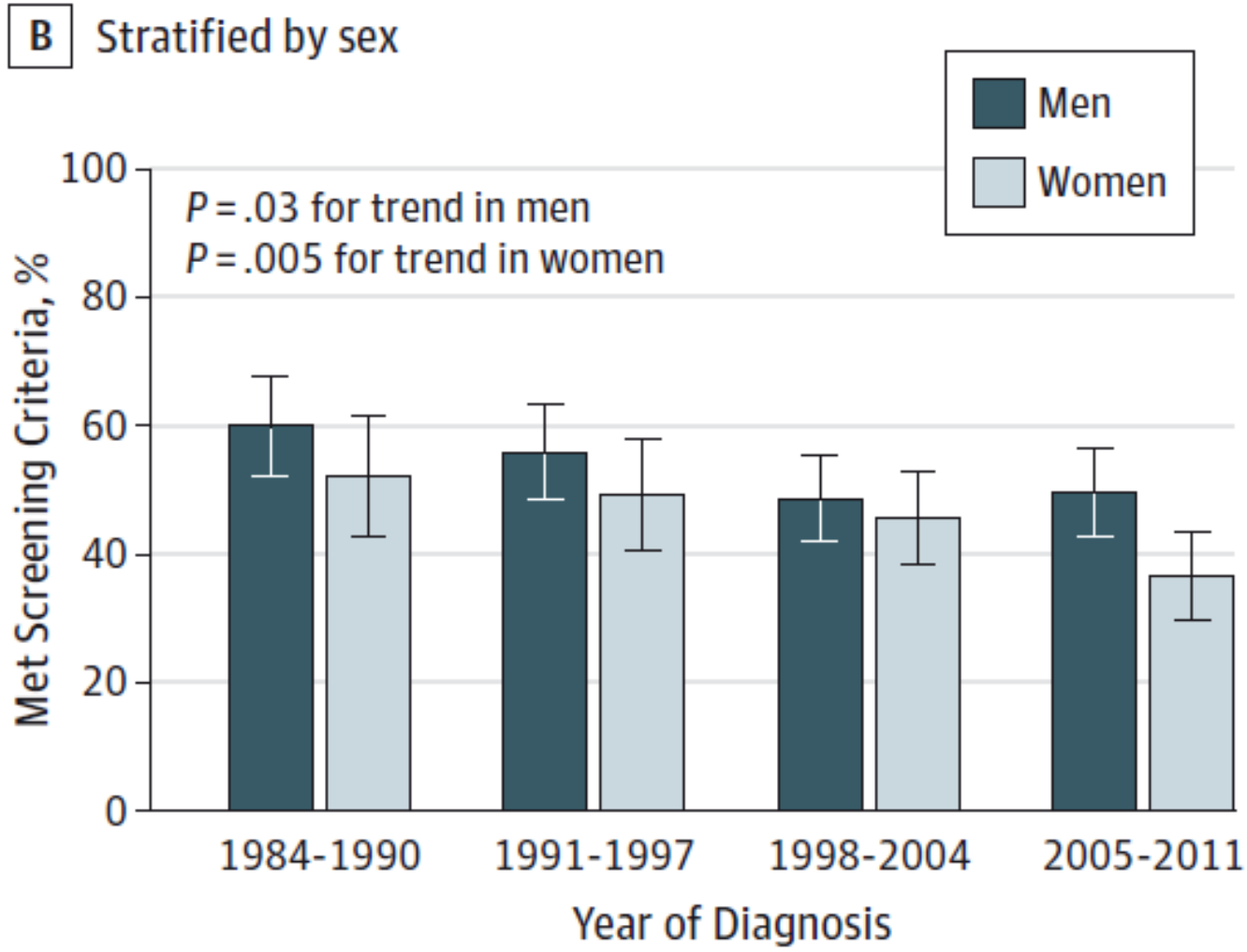
Who to Offer Lung Cancer Screening

To Consider	Our Approach
Who to screen	• Follow **CMS guidelines** for Medicare patients and **USPSTF guidelines** for those with private insurance. • Attempt to develop a **research arm** for high risk patients who do not meet current screening criteria.
Local providers coverage policies	• Develop a list of local providers coverage policies.
Symptomatic patient	• Program redirects to **diagnostic testing.**
Patients with severe comorbidities	• Discussions with pulmonary and cardiology stakeholders.

Who is offered lung cancer screening

- **Starting point**: The NLST population, age 55-74 years, 30+ pack-years of smoking, smoked within past 15 years, healthy enough to tolerate curative intent treatment
- **Questions**:
  - Should we screen a lower risk group?
  - Should we screen the entire NLST population or select the highest risk groups within the NLST population to screen?
  - Can we extend screening to other high risk patients who do not meet the NLST definition of risk?

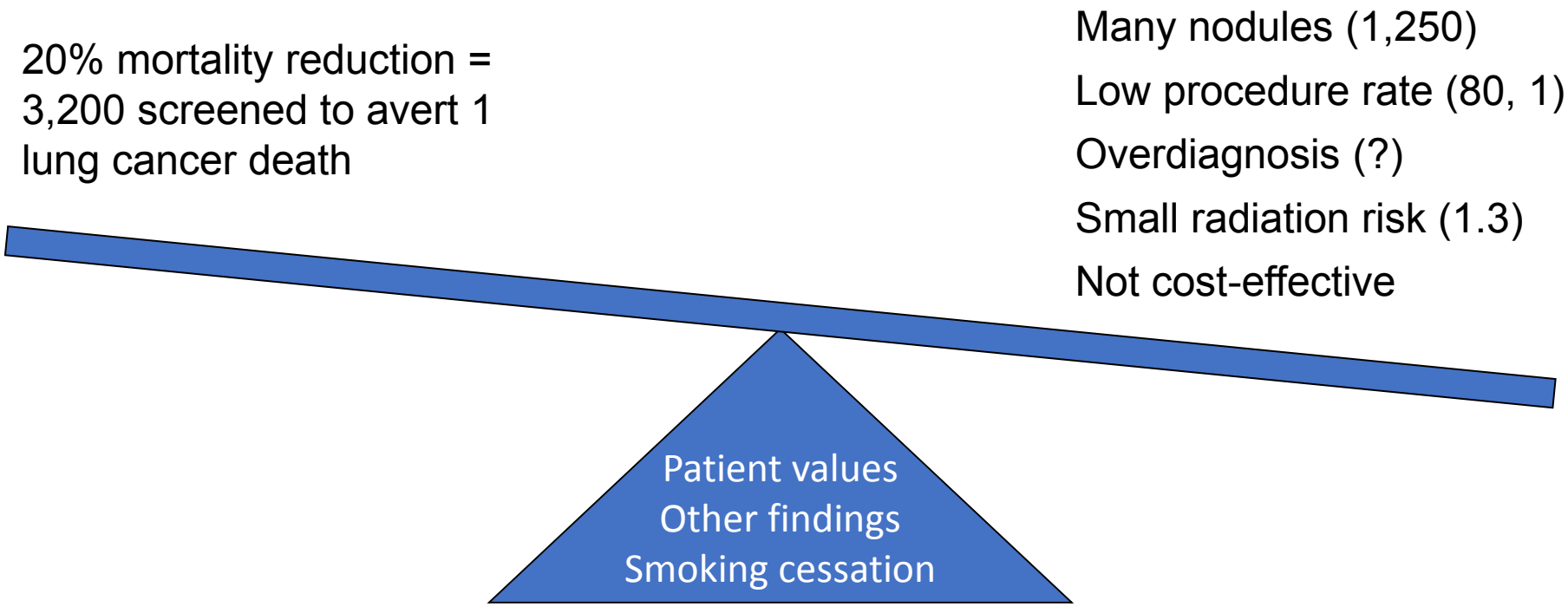
Who is offered lung cancer screening



Wang, JAMA 15.

Who is offered lung cancer screening

- **3 annual low-dose CT** of people **age 50-54**, with **20 pack-years** smoking, who have **smoked within the past 5 years** performed in **capable settings**.

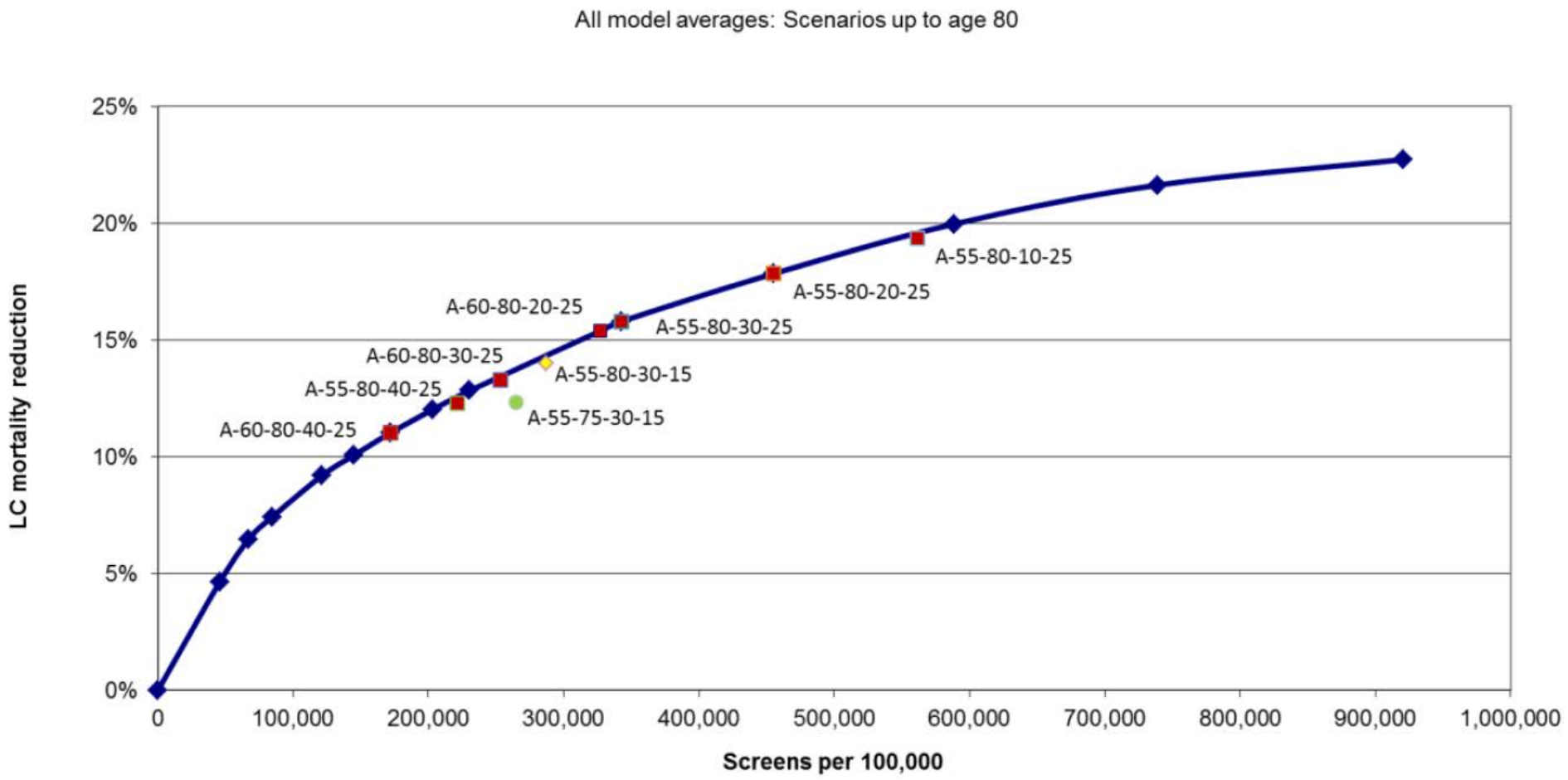


Who is offered lung cancer screening

5-Year Risk of Lung Cancer Death (%)	FP per Prevented Lung Cancer Death	Number Needed to Screen
All	108	302
0.15-0.55	1648	5276
0.56-0.84	181	531
0.85-1.23	147	415
1.24-2.00	64	171
>2.00	65	161

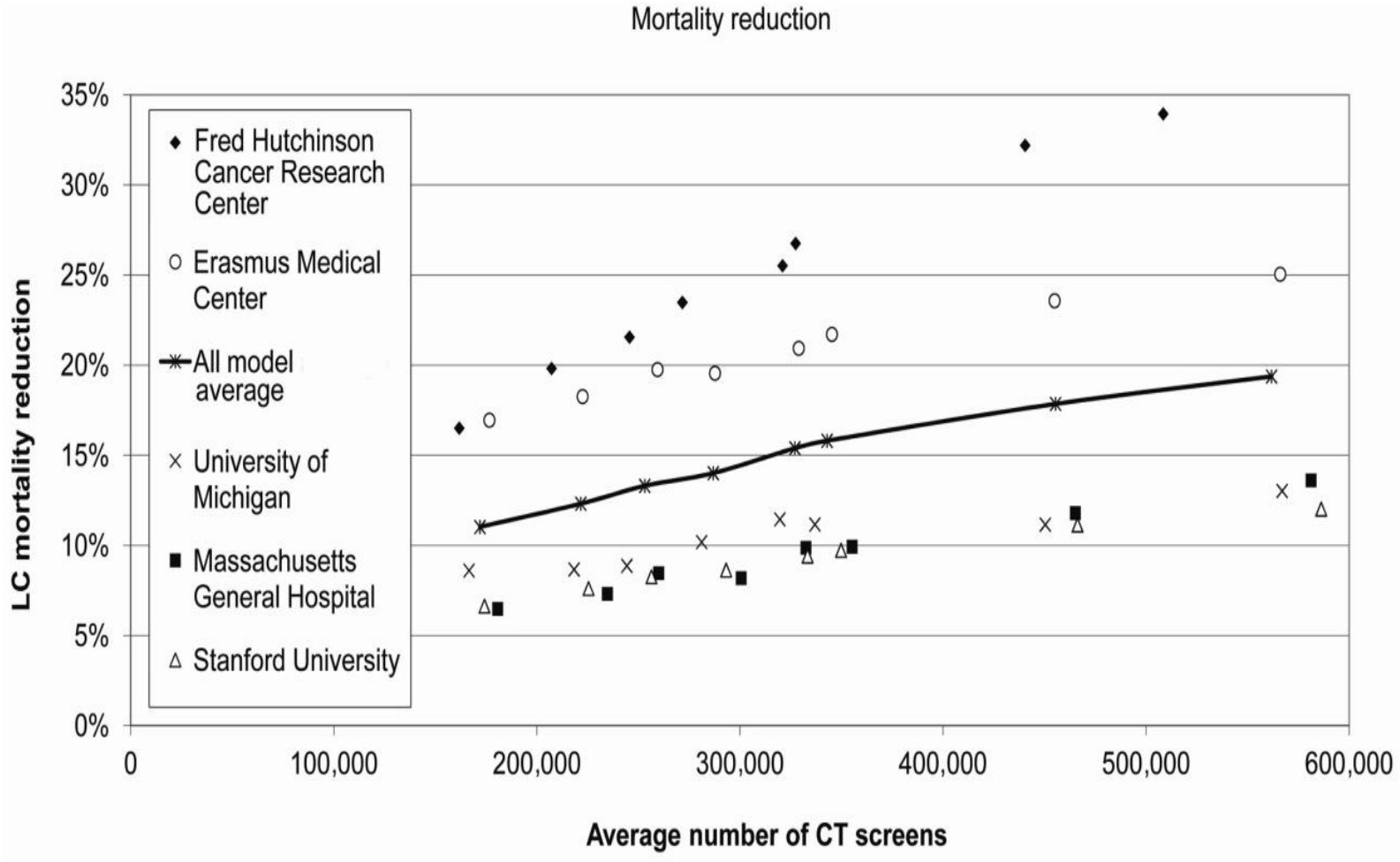
Kovalchik, N Engl J Med 13.

Who is offered lung cancer screening



de Koning, AHRQ Publication No. 13-05196-EF-2

Who is offered lung cancer screening



de Koning, AHRQ Publication No. 13-05196-EF-2

Who is offered lung cancer screening

Author	Bach	Spitz	Cassidy	Tammemegi	Hogart	Katki
Source	Caret	MDA (Case-Control)	LLP (Case-Control)	PLCO	EPIC	PLCO
Subjects	18,172 10-60 cpd 25-55 yrs	3,852 never and ever smokers	1,736 never and ever smokers	80,375 ever smokers	169,035 ever smokers	105,556 ever smokers
Ages	50-75	20-80	20-80	55-74	35-65	55-74
Variables	**Age** Asbestos Sex **Smoking**	**Age** Dust Emphysema Family hx Sex **Smoking**	**Age** Asbestos Family hx Pneumonia Prior cancer Sex **Smoking**	**Age** BMI COPD Education Family hx Prior cancer **Smoking**	**Age** **Smoking**	**Age** BMI Education Emphysema Family hx Race Sex **Smoking**

Who is offered lung cancer screening

PLCOm2012 Risk	USPSTF Negative	USPSTF Positive	Total
Negative	20,712 101	3,695 33	24,407 135
Positive	2,445 93	10,475 449	**12,920** **542**
Total	23,157 195	**14,170** **482**	37,327 677

Tammemagi, PLoS One 2014.

Who is offered lung cancer screening

	Men	Women
Histology	**Mortality RR (CI)**	**Mortality RR (CI)**
Adenocarcinoma	0.77 (0.6-1.02)	0.73 (0.51-1.05)
Squamous cell	1.31 (0.9-1.8)	1.04 (0.6-1.8)
Small cell	1.10 (0.8-1.6)	0.67 (0.4-1.03)
Non-squamous NSCLC	0.71 (0.6-0.9)	0.70 (0.5-0.9)
All	0.92 (0.8-1.08)	0.73 (0.6-0.9)

Pinsky, Cancer 2013.

Who is offered lung cancer screening

	With COPD (%)	Without COPD (%)
Squamous	50.0	17.4
Adenocarcinoma	27.3	69.1
Large cell	3.0	3.9
Other NSCLC	8.1	5.3
Small cell	11.6	4.3

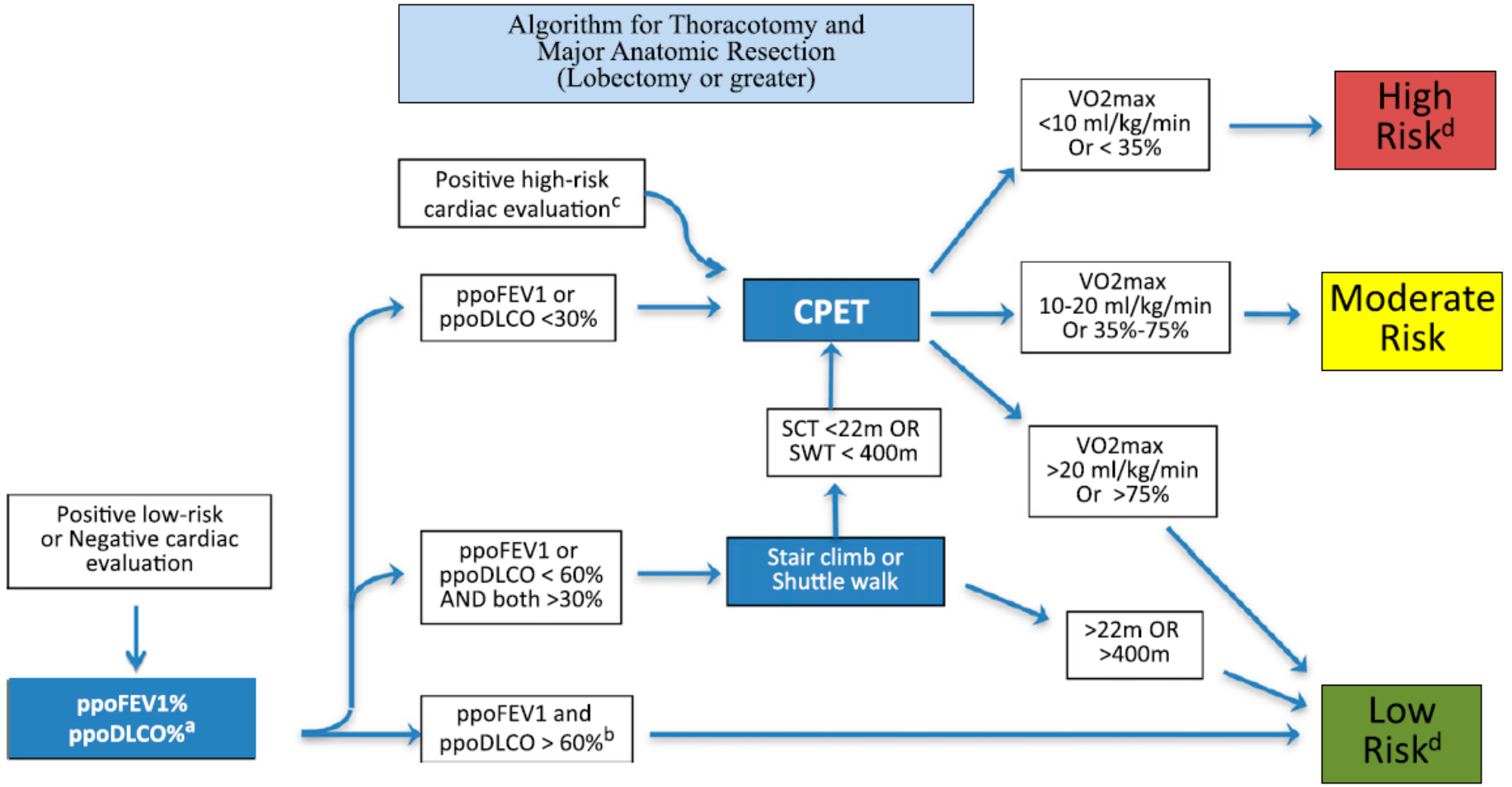
Lim AJR 2015.

Who is offered lung cancer screening

	Hemorrhage	PTX	PTX with tube
Age 60-69	Ref	Ref	Ref
Female	1.42	NS	NS
Tobacco use	NS	1.37	1.50
COPD	**1.61**	**1.88**	**2.52**
Scheduled	1.64	1.60	1.86

Wiener, Ann Int Med 2011.

Who is offered lung cancer screening



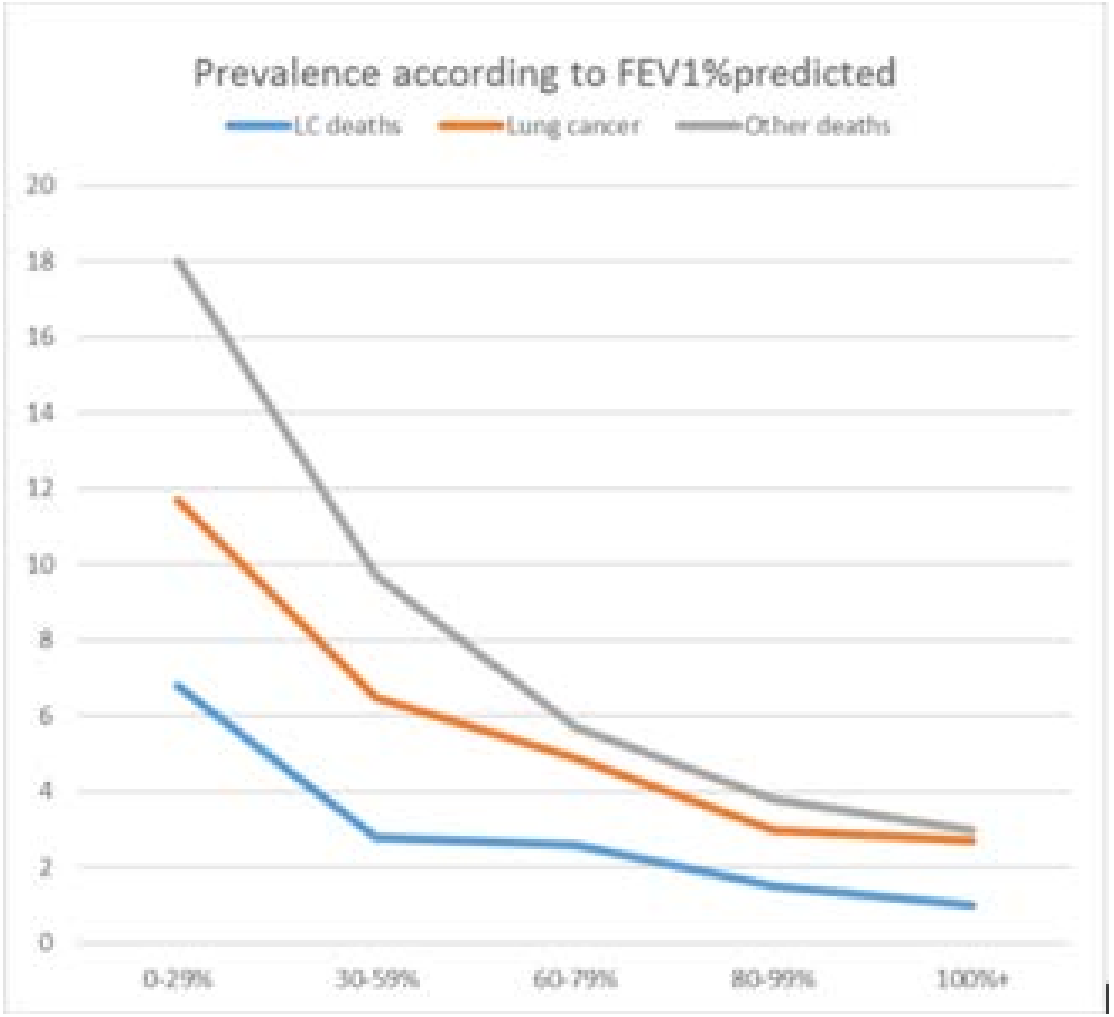
Brunelli, Chest 2013.

Who is offered lung cancer screening

	Perioperative Mortality	5-Year Survival (95% CI)
FEV_1		
>80% predicted	1.8% (5/277)	70.1% (63.9–76.9)
61%–80% predicted	1.8% (5/269)	59.3% (52.6–66.9)
41%–60% predicted	4.4% (8/181)	52.5% (44.8–61.6)
40% predicted	2.1% (1/47)	53.4% (39.7–71.7)
DLCO		
>80% predicted	1.5% (4/272)	70.2% (63.9–77.0)
61%–80% predicted	0.8% (2/253)	63.4% (56.6–70.9)
41%–60% predicted	6.5% (10/153)	44.2% (35.7–54.8)
40% predicted	0% (0/21)	33.1% (16.3–67.1)

Berry, Ann Thorac Surg 2015.

Who is offered lung cancer screening



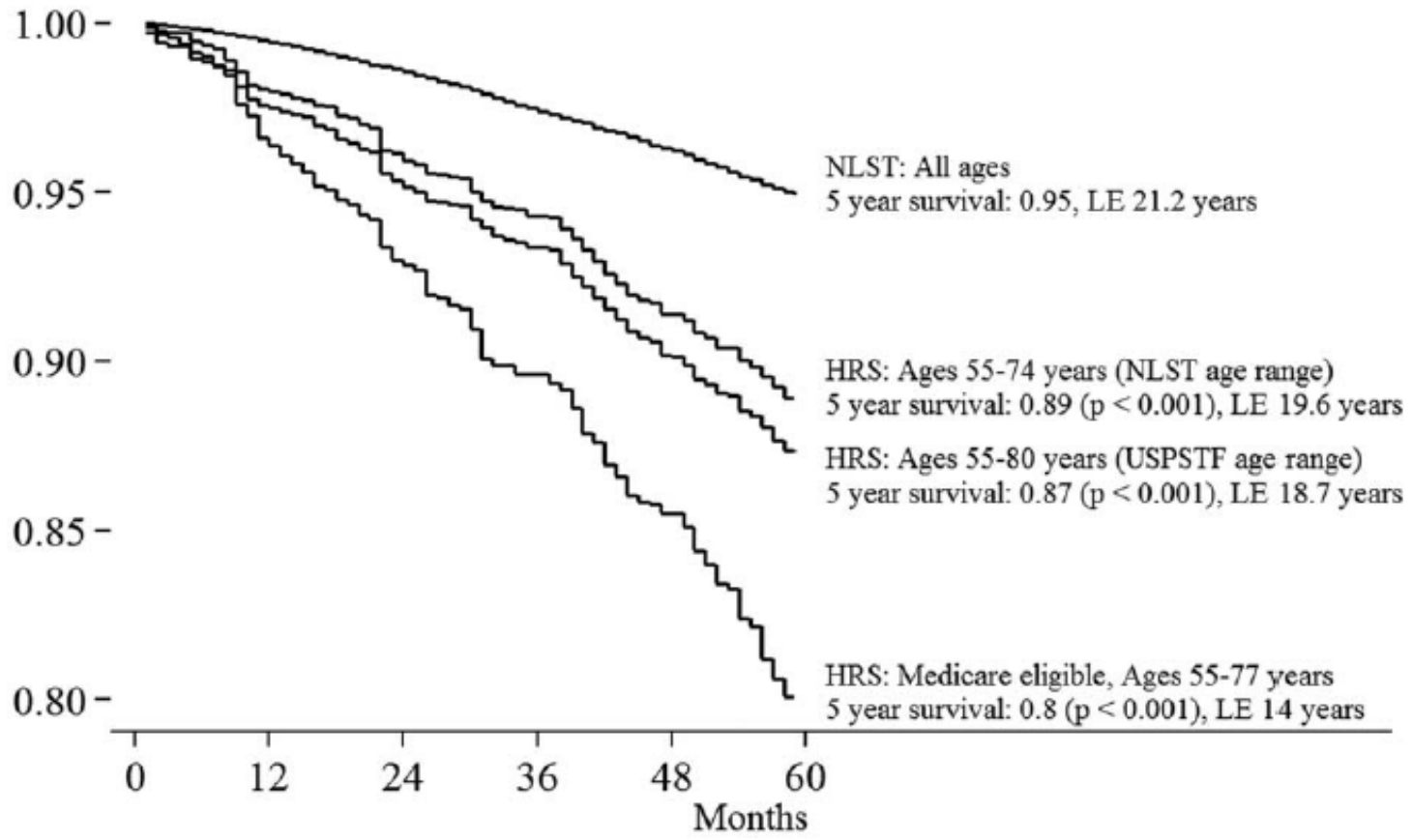
Hopkins, ATS 2017.

Who is offered lung cancer screening

	NLST	US Census Survey
Male/Female	59/41	58.5/41.5
Age 55-59	**42.8**	**35.2**
Age 60-64	30.6	29.3
Age 65-69	17.8	20.8
Age 70-74	**8.8**	**14.7**
% Black	4.4	5.5
% Hispanic	1.7	2.4
Current smoker	**48.2**	**57.1**
College education	**31.5**	**14.4**

Aberle, N Engl J Med 2010.

Who is offered lung cancer screening



HRS: Health and Retirement Study; NLST: National Lung Cancer Screening Trial.
USPSTF: United States Preventive Services Task Force; LE: Life expectancy.

Howard, Cancer 2015.

Who is offered lung cancer screening

- More likely to have nodule.
- More risk from invasive procedures for nodule evaluation.
- More complications from resection for early-stage cancer.
- Poorer survival after treatment of early-stage cancer.
- Competing mortality that may increase out of proportion to increased lung cancer risk.

Mazzone, Chest 2018.

Who is offered lung cancer screening

	Overall	Brock	Clinical
% reduction in Lung Cancer death	17	T1 – 25	T1 – 34
		T2 – 34	T2 – 36
		T3 – 8	**T3 – 2**
Lung Cancer deaths averted per 1000 screened	3.4	T1 – 1.8	T1 – 3.8
		T2 – 5.4	T2 – 6.5
		T3 – 3.0	**T3 – 0**
NNS	296	T1 – 599	T1 – 232
		T2 – 187	T2 – 163
		T3 – 336	**T3 – 0**

Young, ATS 2017.

Recommendation 1

For asymptomatic smokers and former smokers age 55 to 77 who have smoked 30 pack years or more and either continue to smoke or have quit within the past 15 years, we suggest that annual screening with low-dose CT should be offered. (Weak recommendation, moderate-quality evidence)

- ***Remark***: Age 77 represents the oldest age of participants in the NLST at the end of the screening period. Age 77 also matches the oldest age of CMS coverage for low-dose CT screening. Age 80 has been recommended by the USPSTF based on modeling studies. Recommendation #2 can be applied to individuals age 78 to 80.
- ***Remark***: Asymptomatic refers to the absence of symptoms suggesting the presence of lung cancer.

Mazzone, Chest 2018.

Recommendation 2

For asymptomatic smokers and former smokers who do not meet the smoking and age criteria in Recommendation #1 but are deemed to be at high risk of having/developing lung cancer based on clinical risk prediction calculators, we suggest that low-dose CT screening should not be routinely performed. (Weak recommendation, low-quality evidence)

Mazzone, Chest 2018.

Recommendation 2

- ***Remark***: It is recognized that clinical risk prediction calculators may be **slightly more efficient** at identifying individuals who have or will develop lung cancer than the eligibility criteria listed in Recommendation #1. It is also recognized that the variables included in the clinical risk prediction calculators are **risk factors for morbidity** from the evaluation and treatment of screen detected findings, **and death** from any cause. Thus a cohort at high risk for lung cancer based on a clinical risk prediction calculator may be less likely to benefit and more likely to be harmed by lung cancer screening than the cohort identified by the eligibility criteria listed in Recommendation #1. Thus, we **do not believe the evidence supports a policy to screen this group**.

Mazzone, Chest 2018.

Recommendation 2

- ***Remark***: It is also recognized that there will be **individuals** within the cohort deemed to be at high risk for lung cancer from a clinical risk prediction calculator who are **healthy enough to benefit** from lung cancer screening, and that **low-dose CT screening could be considered** in these individuals.
- ***Remark***: A risk threshold of 1.51% over 6 years on the PLCOm2012 calculator is an example of high risk.
- ***Remark***: Insurance coverage of low-dose CT screening may not be provided for those who do not meet the eligibility criteria listed in Recommendation #1.
- ***Remark***: Additional lung cancer screening trials that include patients who do not meet the eligibility criteria listed in Recommendation #1 but have a high risk of having/developing lung cancer based on clinical risk prediction calculators are needed.

Mazzone, Chest 2018.

Recommendations

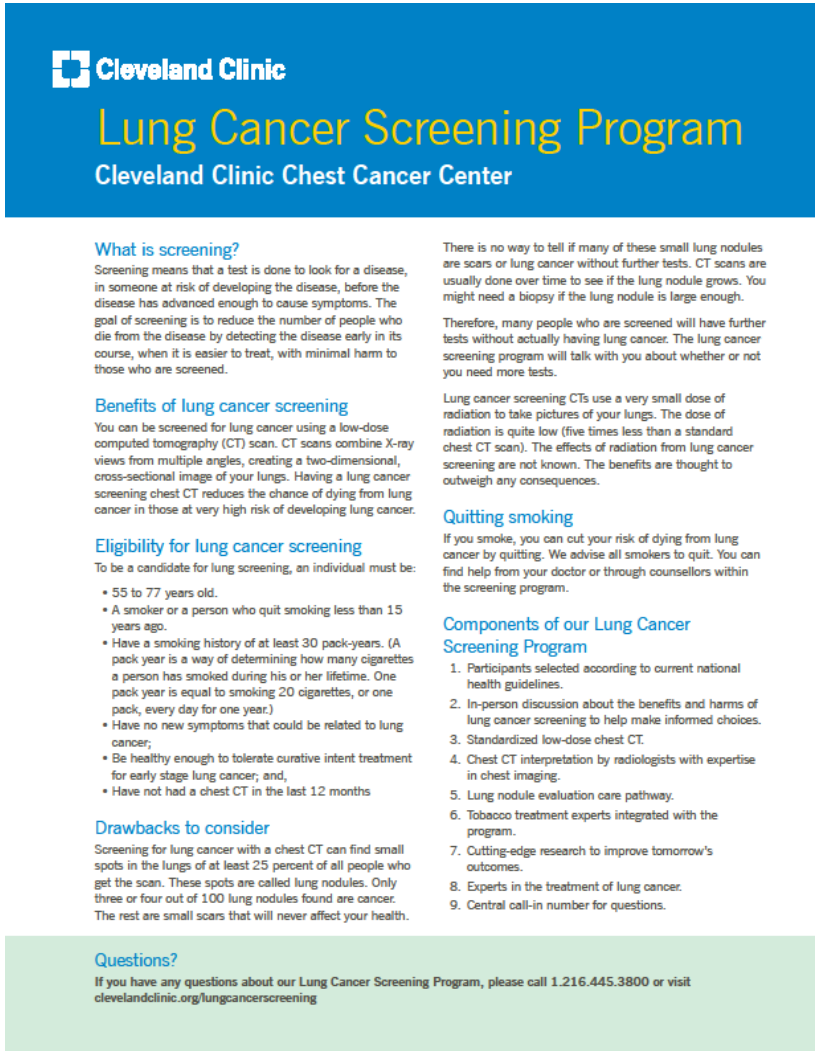
- **Recommendation 3**: For individuals who have accumulated fewer than 30 pack years of smoking or are younger than age 55 or older than 77, or have quit smoking more than 15 years ago, and **do not have a high risk** of having/developing lung cancer based on clinical risk prediction calculators, we recommend that low-dose CT screening **should not be performed**. (Strong recommendation, moderate-quality evidence)
- **Recommendation 4**: For individuals with **comorbidities** that adversely influence their ability to tolerate the evaluation of screen detected findings, or tolerate treatment of an early stage screen detected lung cancer, or that substantially limit their life expectancy, we recommend that low-dose CT screening should not be performed. (Strong recommendation, low-quality evidence)
- **Recommendation 5**: We suggest that low-dose CT screening programs develop strategies to determine whether patients have symptoms that suggest the presence of lung cancer, so that **symptomatic patients** do not enter screening programs but instead receive appropriate diagnostic testing, regardless of whether the symptomatic patient meets screening eligibility criteria. (Ungraded Consensus-Based Statement)

Mazzone, Chest 2018.

How to Identify the Proper Risk Group

To Consider	Our Approach
How to educate referring providers	• Grand rounds presentations, office visits, newsletters, web-based overviews and decision aids, on-hold messages, health fairs, journal articles • **Multi-faceted, repeated**
Develop EHR tool	• **Reminder system** • Mining of patient data
How to educate patients	• Pamphlets, call-line, on-hold messages, internet, letters

How to Identify the Proper Risk Group



Cleveland Clinic

Lung Cancer Screening Program

Cleveland Clinic Chest Cancer Center

What is screening?

Screening means that a test is done to look for a disease, in someone at risk of developing the disease, before the disease has advanced enough to cause symptoms. The goal of screening is to reduce the number of people who die from the disease by detecting the disease early in its course, when it is easier to treat, with minimal harm to those who are screened.

Benefits of lung cancer screening

You can be screened for lung cancer using a low-dose computed tomography (CT) scan. CT scans combine X-ray views from multiple angles, creating a two-dimensional, cross-sectional image of your lungs. Having a lung cancer screening chest CT reduces the chance of dying from lung cancer in those at very high risk of developing lung cancer.

Eligibility for lung cancer screening

To be a candidate for lung screening, an individual must be:

- 55 to 77 years old.
- A smoker or a person who quit smoking less than 15 years ago.
- Have a smoking history of at least 30 pack-years. (A pack year is a way of determining how many cigarettes a person has smoked during his or her lifetime. One pack year is equal to smoking 20 cigarettes, or one pack, every day for one year.)
- Have no new symptoms that could be related to lung cancer;
- Be healthy enough to tolerate curative intent treatment for early stage lung cancer; and,
- Have not had a chest CT in the last 12 months

Drawbacks to consider

Screening for lung cancer with a chest CT can find small spots in the lungs of at least 25 percent of all people who get the scan. These spots are called lung nodules. Only three or four out of 100 lung nodules found are cancer. The rest are small scars that will never affect your health.

There is no way to tell if many of these small lung nodules are scars or lung cancer without further tests. CT scans are usually done over time to see if the lung nodule grows. You might need a biopsy if the lung nodule is large enough.

Therefore, many people who are screened will have further tests without actually having lung cancer. The lung cancer screening program will talk with you about whether or not you need more tests.

Lung cancer screening CTs use a very small dose of radiation to take pictures of your lungs. The dose of radiation is quite low (five times less than a standard chest CT scan). The effects of radiation from lung cancer screening are not known. The benefits are thought to outweigh any consequences.

Quitting smoking

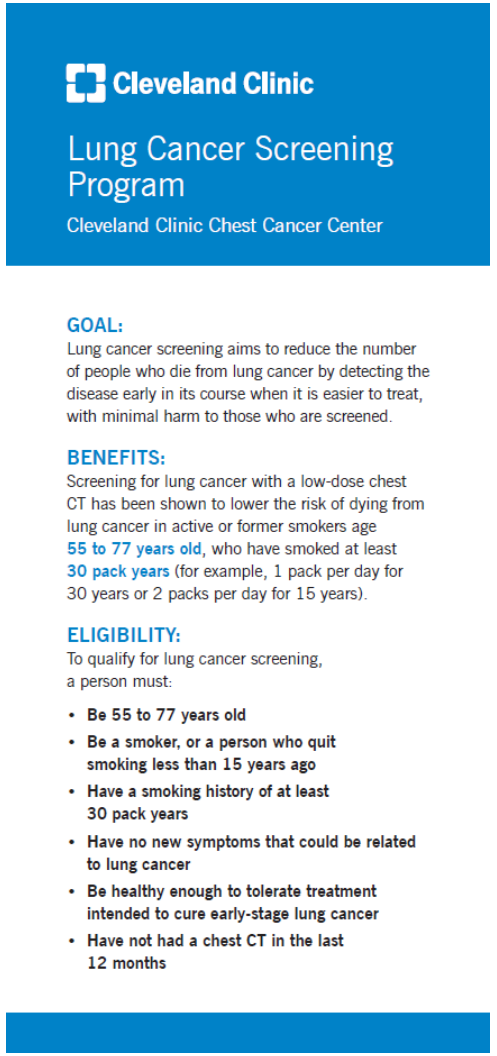
If you smoke, you can cut your risk of dying from lung cancer by quitting. We advise all smokers to quit. You can find help from your doctor or through counsellors within the screening program.

Components of our Lung Cancer Screening Program

1. Participants selected according to current national health guidelines.
2. In-person discussion about the benefits and harms of lung cancer screening to help make informed choices.
3. Standardized low-dose chest CT.
4. Chest CT interpretation by radiologists with expertise in chest imaging.
5. Lung nodule evaluation care pathway.
6. Tobacco treatment experts integrated with the program.
7. Cutting-edge research to improve tomorrow's outcomes.
8. Experts in the treatment of lung cancer.
9. Central call-in number for questions.

Questions?

If you have any questions about our Lung Cancer Screening Program, please call 1.216.445.3800 or visit clevelandclinic.org/lungcancerscreening



Cleveland Clinic

Lung Cancer Screening Program

Cleveland Clinic Chest Cancer Center

GOAL:

Lung cancer screening aims to reduce the number of people who die from lung cancer by detecting the disease early in its course when it is easier to treat, with minimal harm to those who are screened.

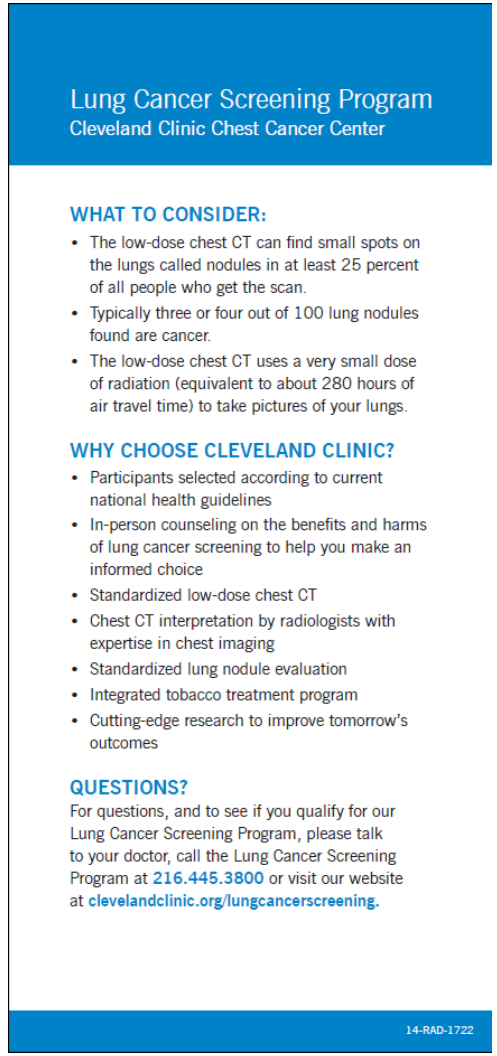
BENEFITS:

Screening for lung cancer with a low-dose chest CT has been shown to lower the risk of dying from lung cancer in active or former smokers age **55 to 77 years old**, who have smoked at least **30 pack years** (for example, 1 pack per day for 30 years or 2 packs per day for 15 years).

ELIGIBILITY:

To qualify for lung cancer screening, a person must:

- **Be 55 to 77 years old**
- **Be a smoker, or a person who quit smoking less than 15 years ago**
- **Have a smoking history of at least 30 pack years**
- **Have no new symptoms that could be related to lung cancer**
- **Be healthy enough to tolerate treatment intended to cure early-stage lung cancer**
- **Have not had a chest CT in the last 12 months**



Lung Cancer Screening Program

Cleveland Clinic Chest Cancer Center

WHAT TO CONSIDER:

- The low-dose chest CT can find small spots on the lungs called nodules in at least 25 percent of all people who get the scan.
- Typically three or four out of 100 lung nodules found are cancer.
- The low-dose chest CT uses a very small dose of radiation (equivalent to about 280 hours of air travel time) to take pictures of your lungs.

WHY CHOOSE CLEVELAND CLINIC?

- Participants selected according to current national health guidelines
- In-person counseling on the benefits and harms of lung cancer screening to help you make an informed choice
- Standardized low-dose chest CT
- Chest CT interpretation by radiologists with expertise in chest imaging
- Standardized lung nodule evaluation
- Integrated tobacco treatment program
- Cutting-edge research to improve tomorrow's outcomes

QUESTIONS?

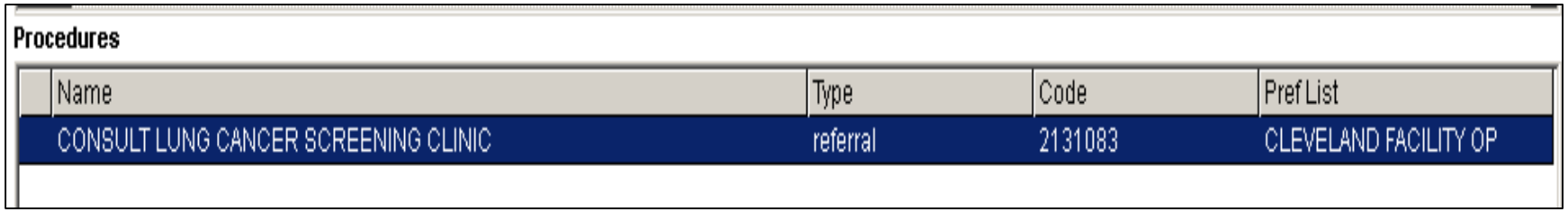
For questions, and to see if you qualify for our Lung Cancer Screening Program, please talk to your doctor, call the Lung Cancer Screening Program at **216.445.3800** or visit our website at **clevelandclinic.org/lungcancerscreening.**

14-RAD-1722

How to Schedule Appropriate Patients

To Consider	Our Approach
How to order test	• Develop specific **order and order set** • **Limit access** to CT order • Incorporate education tool
How to coordinate with SDM visit	• **Order for consult** to program only • Pre-review of patient for eligibility • Small group of schedulers • Collaboration with radiology
How to provide access for outside patient	• Program access line • On-line referral form

How to Schedule Appropriate Patients



Procedures

Name	Type	Code	Pref List
CONSULT LUNG CANCER SCREENING CLINIC	referral	2131083	CLEVELAND FACILITY OP

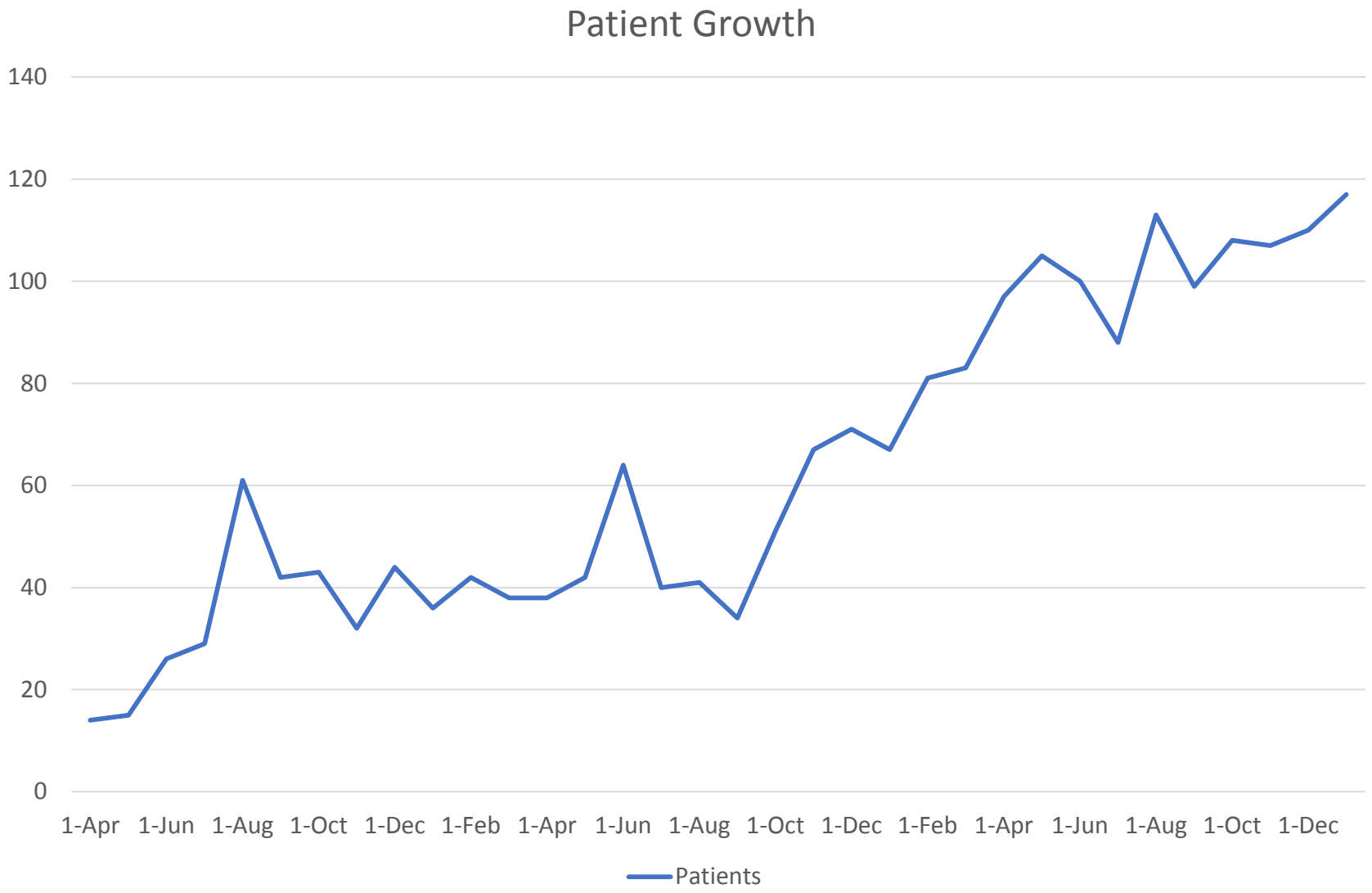
How to Identify Eligible Patients

- Hard stop – diagnostic CT scans performed
- Research arm not yet funded
- MyFamily Tool
  - Reported smoking history correlated poorly with the smoking history documented in a 4 month test:
    - 342 (30.5%) were current/former smokers and went through the risk calculator (average calculated risk 0.48%)
    - 23 (6.4% of smokers, 1.9% of all) met NLST criteria
    - 6 of 23 no variance in reported and documented smoking hx, mean variance 14 pyrs, (range -55 to 40)
- COPD group
  - Exclude ventilatory failure (pCO_2 > 55 mmHg) and BODE > 7

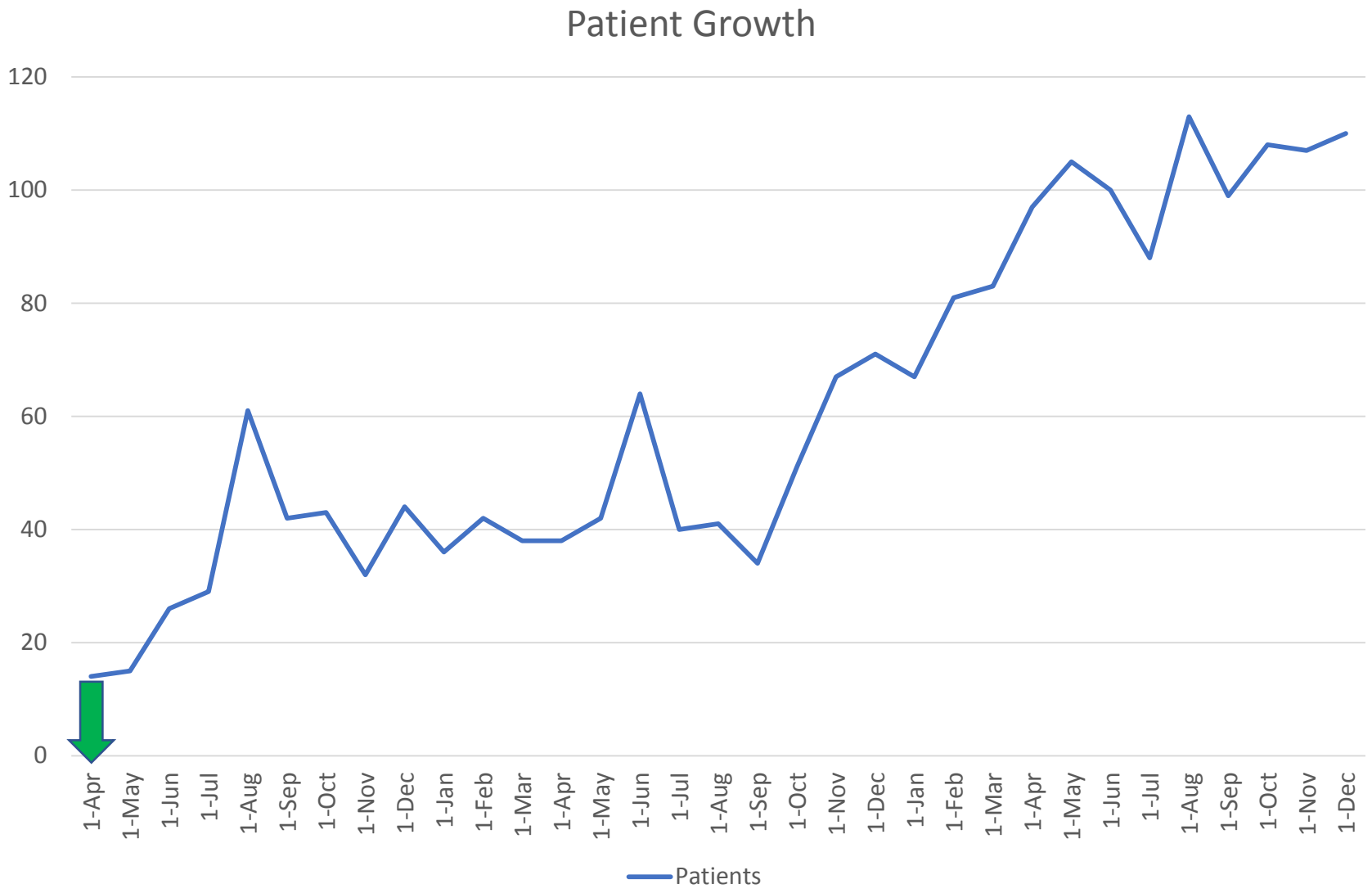
How to Schedule Appropriate Patients

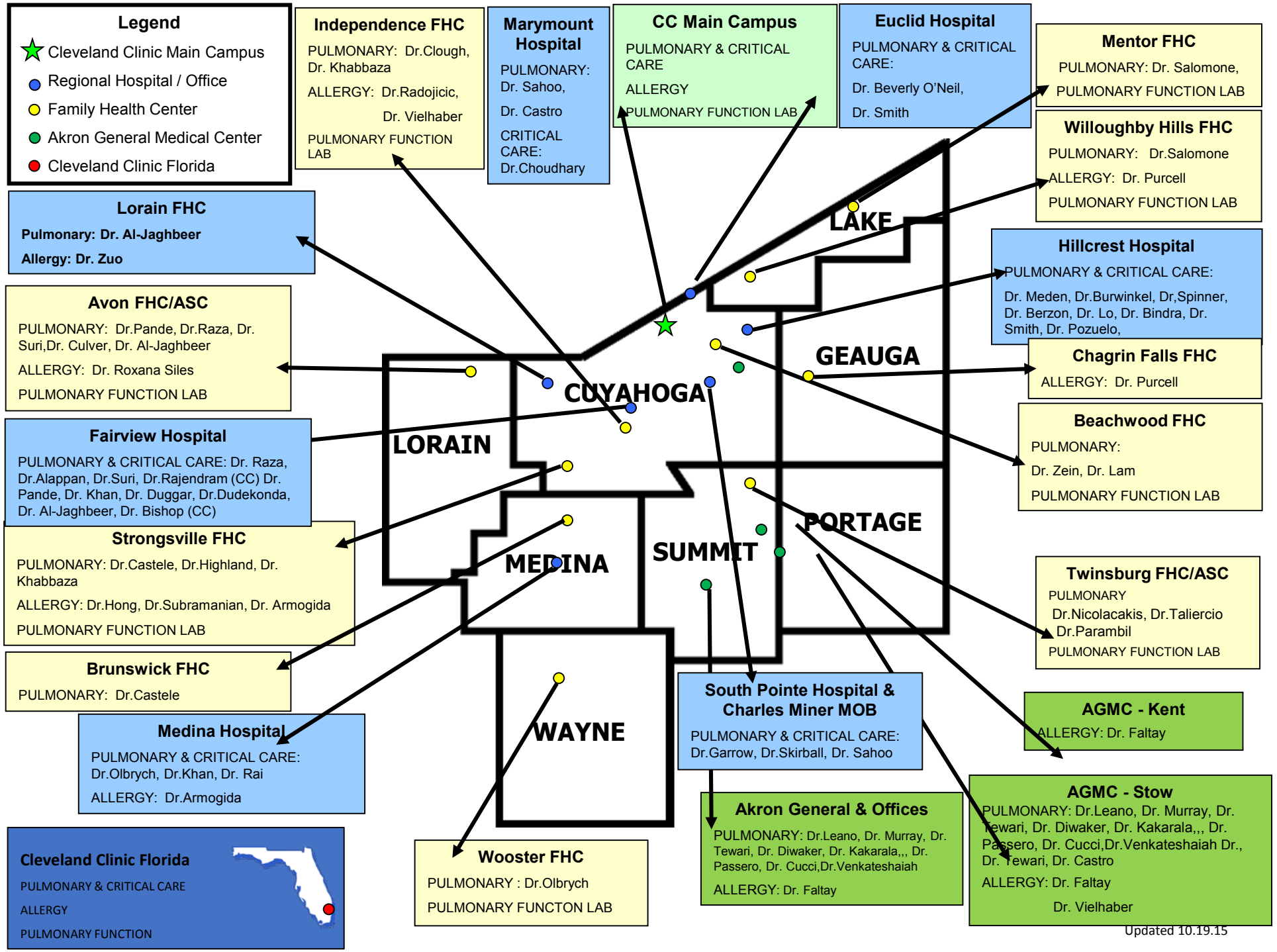
- 819 patients, 542 screening participants and 277 non-participants.
  - Male gender, higher pack-years, former smoking status, history of COPD/emphysema and CAD were **independent predictors for participation**, while renal failure and a history of malignancy were independently associated with non-participation.
- A total of **100 non-participants completed telephone surveys**. The most common reasons cited for not participating were:
  - not being aware of the appointment (29%), concern about insurance coverage (27%), distance from the screening site (19%), and fear of the CT or its results (10% each).
- 69% of the non-participants were aware that screening helps detect lung cancer early.
- 69% of the non-participants were **unaware of any harm**.

How to Identify Eligible Patients



How to Identify Eligible Patients





Updated 10.19.15

Cleveland Clinic

Lung Cancer Screening Program

To refer a patient to the Lung Cancer Screening Program at Cleveland Clinic, please complete the following form and either email it to lungcancerscreening@ccf.org or fax it to 216.445.8794.

If you have any questions, please call the Lung Cancer Screening Program at 216.445.3800.

Patients must meet all the following criteria to be eligible for the screening.

- Have at least a 30 pack year history of smoking (cigarettes only)
- Ages 55-77
- Have smoked within the past 15 years
- Have no signs or symptoms of cancer
- Healthy enough and willing to undergo curative intent treatment

Patient name: _____

Patient date of birth: _____

Patient phone number: _____

Referring provider name: _____

Referring provider phone: _____

Referring provider fax: _____

How many years has the patient been a smoker? _____

On average, how many packs per day has the patient smoked? _____

Is the patient an active smoker? ☐ Yes ☐ No

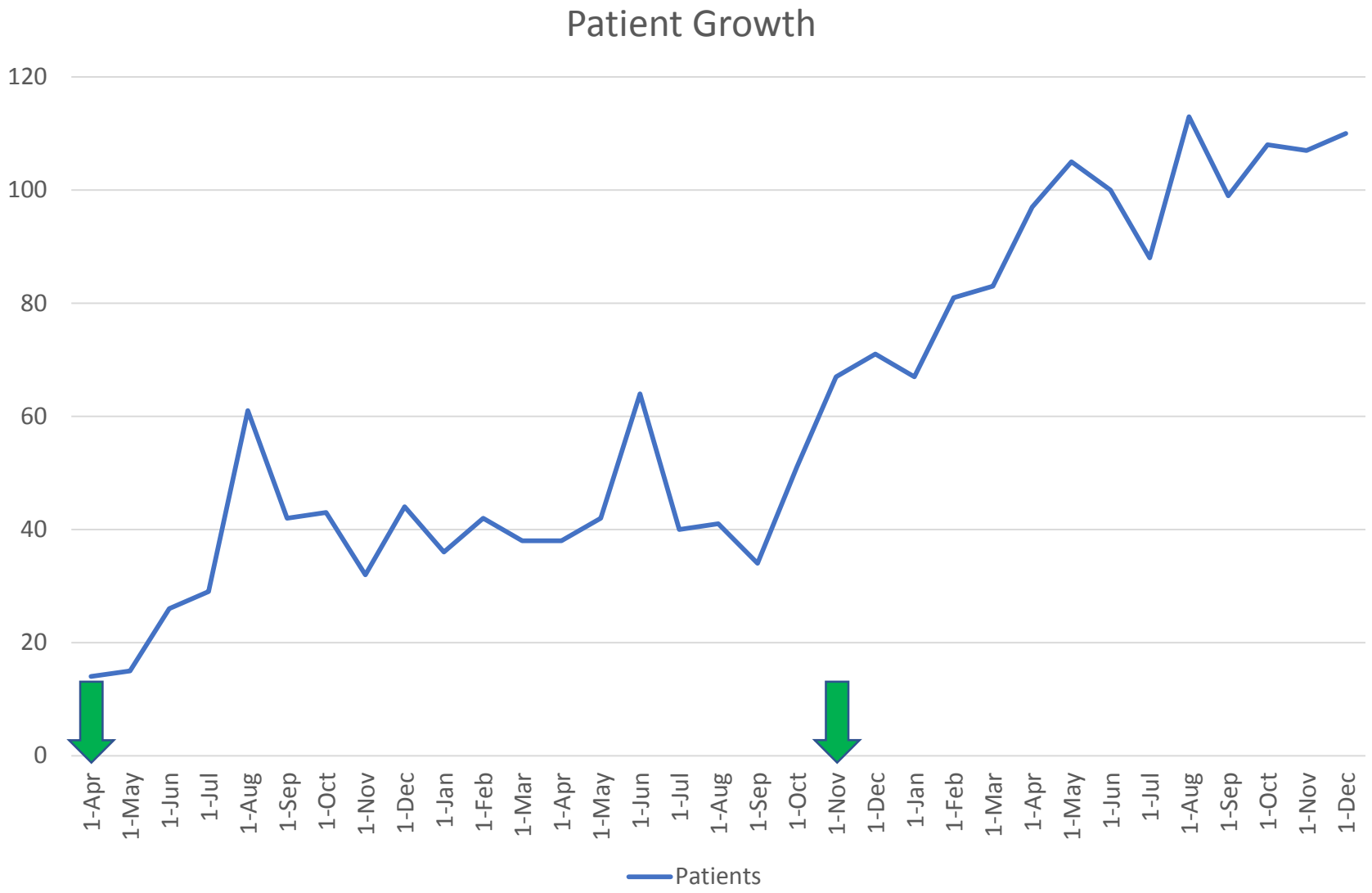
Has the patient has a chest CT scan within the last year? ☐ Yes ☐ No

Does the patient show any signs or symptoms of lung cancer? ☐ Yes ☐ No

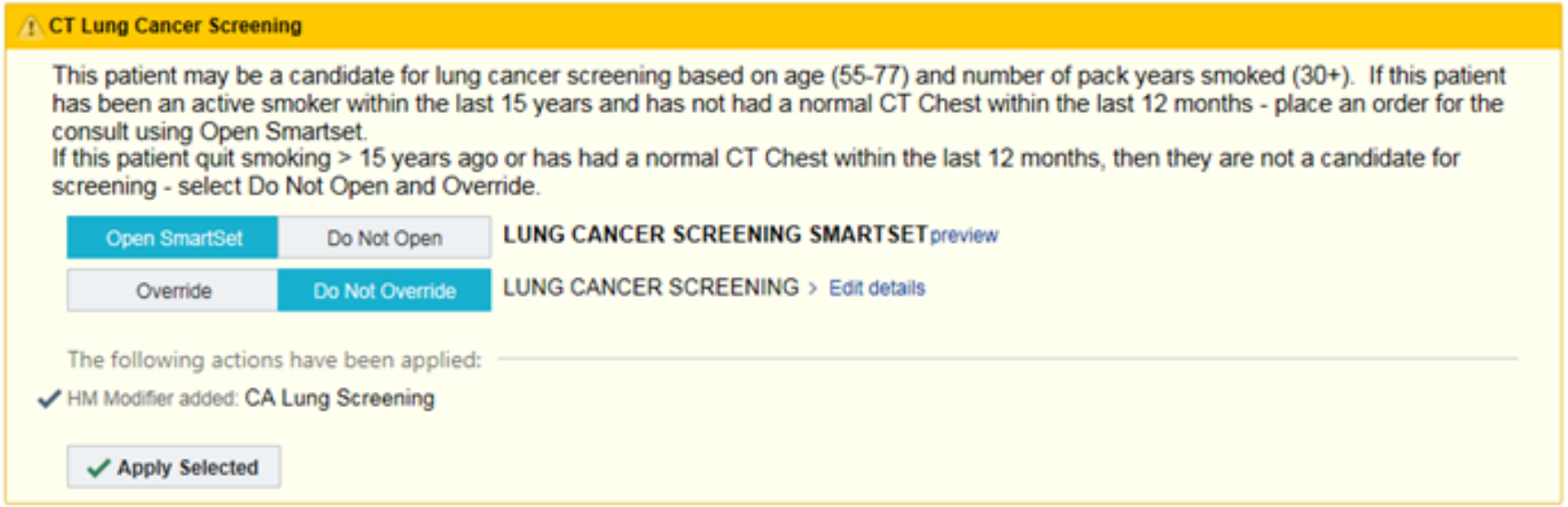
Please check the location you'd like your patient to have the screening:

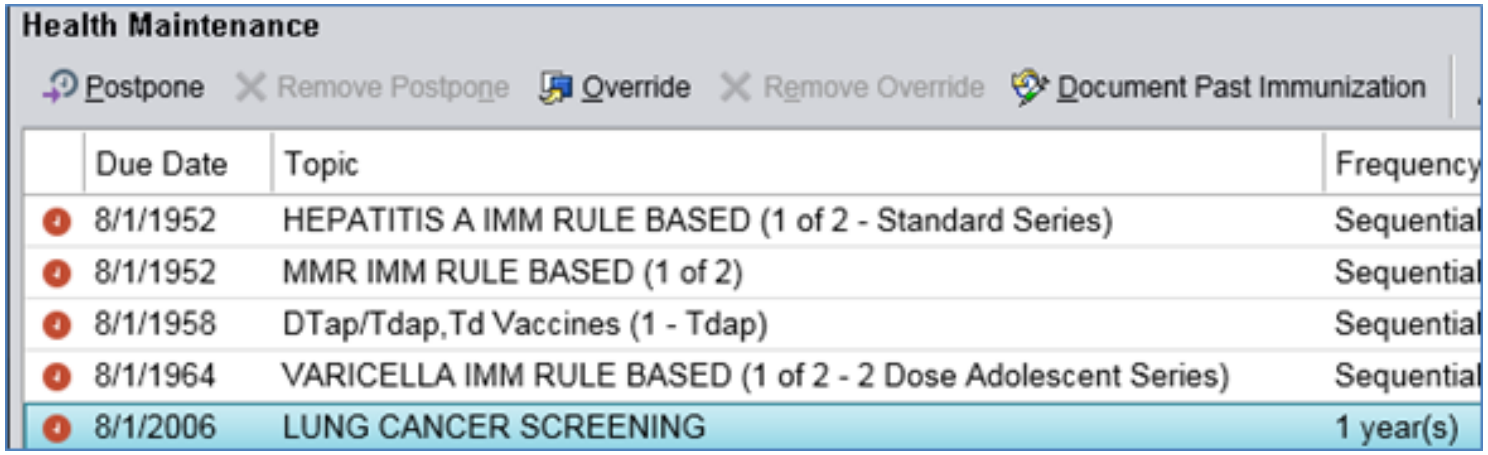
☐ Cleveland Clinic main campus
☐ Cleveland Clinic Akron General Medical Center
☐ Cleveland Clinic Richard E. Jacobs Health Center, Avon
☐ Cleveland Clinic Beachwood Family Health and Surgery Center
☐ Cleveland Clinic Strongsville Family Health and Surgery Center
☐ Cleveland Clinic Twinsburg Family Health and Surgery Center

How to Identify Eligible Patients

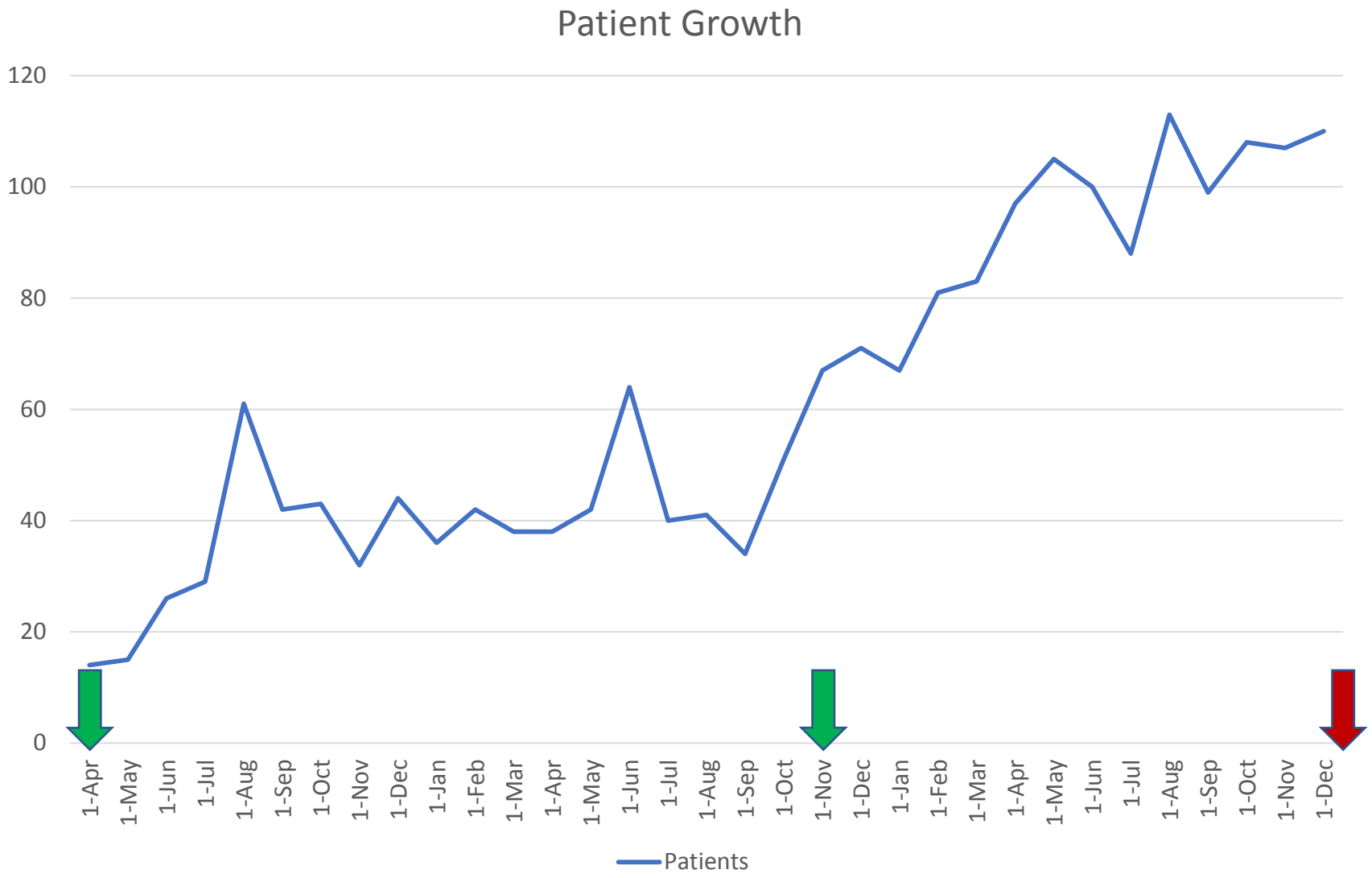


How to Identify the Proper Risk Group





How to Identify Eligible Patients



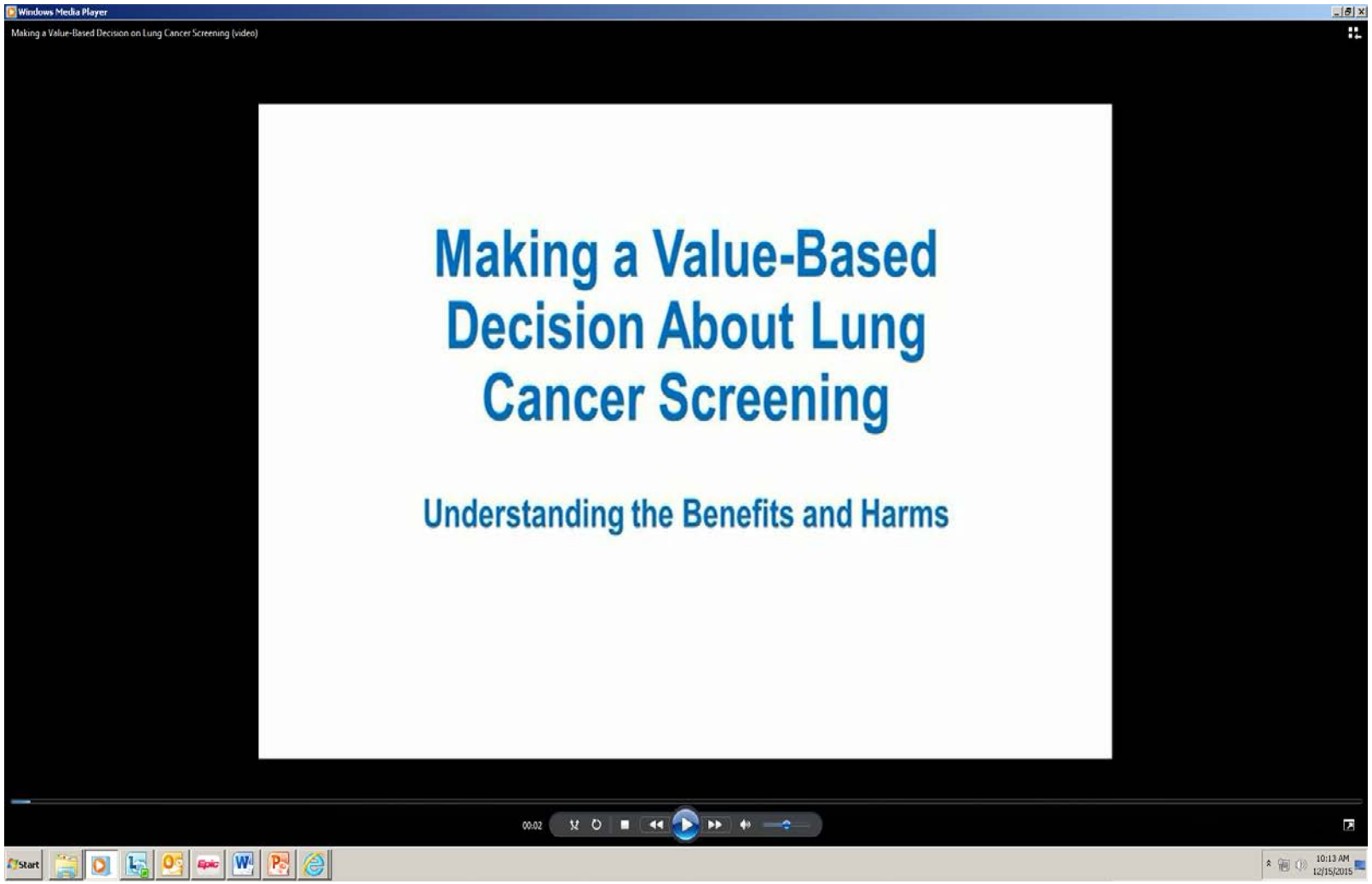
How to Identify Eligible Patients

- **Estimated volume – 6,320**
  - New patients – 18 to 47 per day, 29 per day average over second 2 weeks, 81% of whom were eligible = approximately 6,000 per year; 80% compliance = 4,800 per year
  - Former patients needing annual visit – approximately 800
  - Follow-up of category 3 and 4 patients – approximately 720 (15% of new patients)
  - Cancer registry 2017 – 100 patients who met eligibility criteria, rate of cancer in screening population 1% = 10,000

How to Conduct the SDM Visit

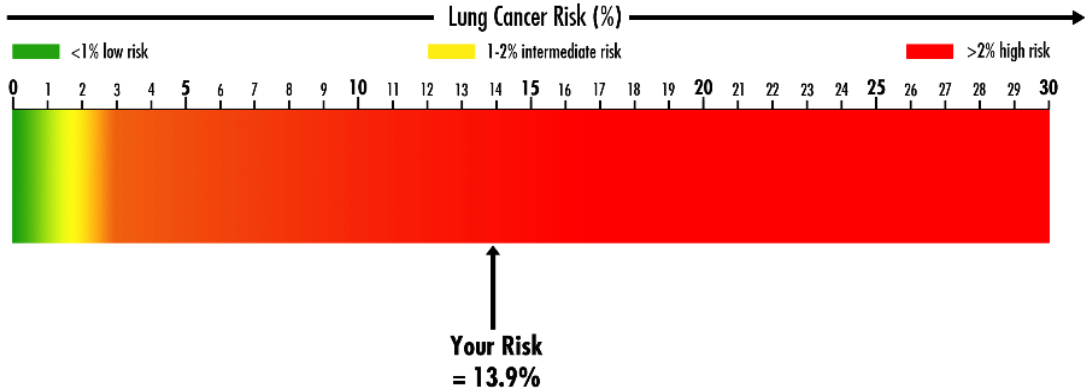
To Consider	Our Approach
Patient eligibility	• Age, smoking, symptoms, general health reviewed
Overview of benefit and harms	• Narrated slide show developed
Use of decision aid	• Shouldiscreen.com
Prepare patient for results	• Discuss likely findings • Stress annual screening • Decide how to communicate results
Incorporate smoking cessation counseling	• Connect to local resources • Train personnel
Documentation and reporting	• Templated note with extractable elements; knowledge project; population management

How to Conduct the SDM Visit

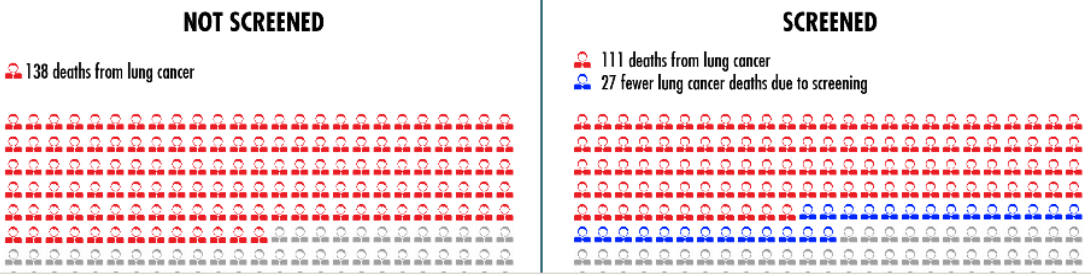


How to Conduct the SDM Visit

The chance of you developing lung cancer in the next 6 years is 13.9%. Talk to your doctor about the option to screen or not to screen as s/he will understand your situation best.

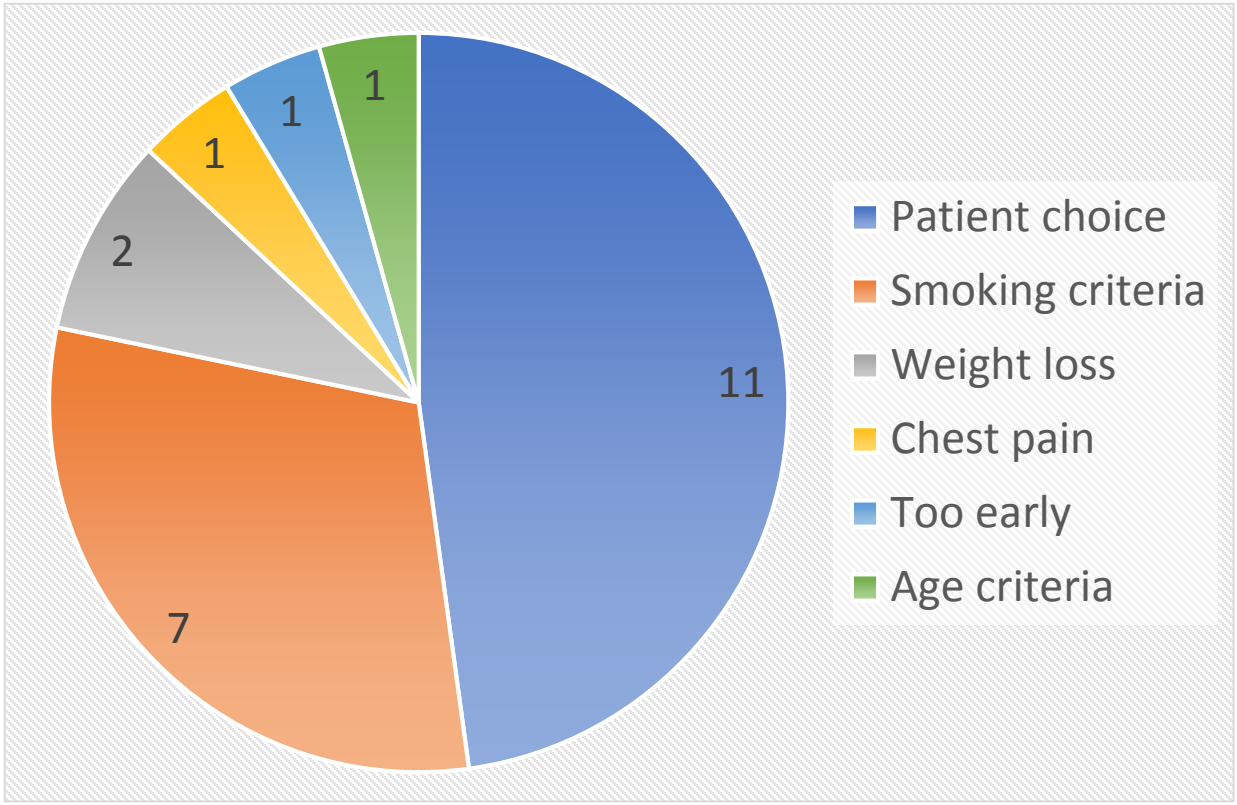


Compared to other people like you, there will be 27 fewer deaths out of 1000 in the next 6 years if you get screened.

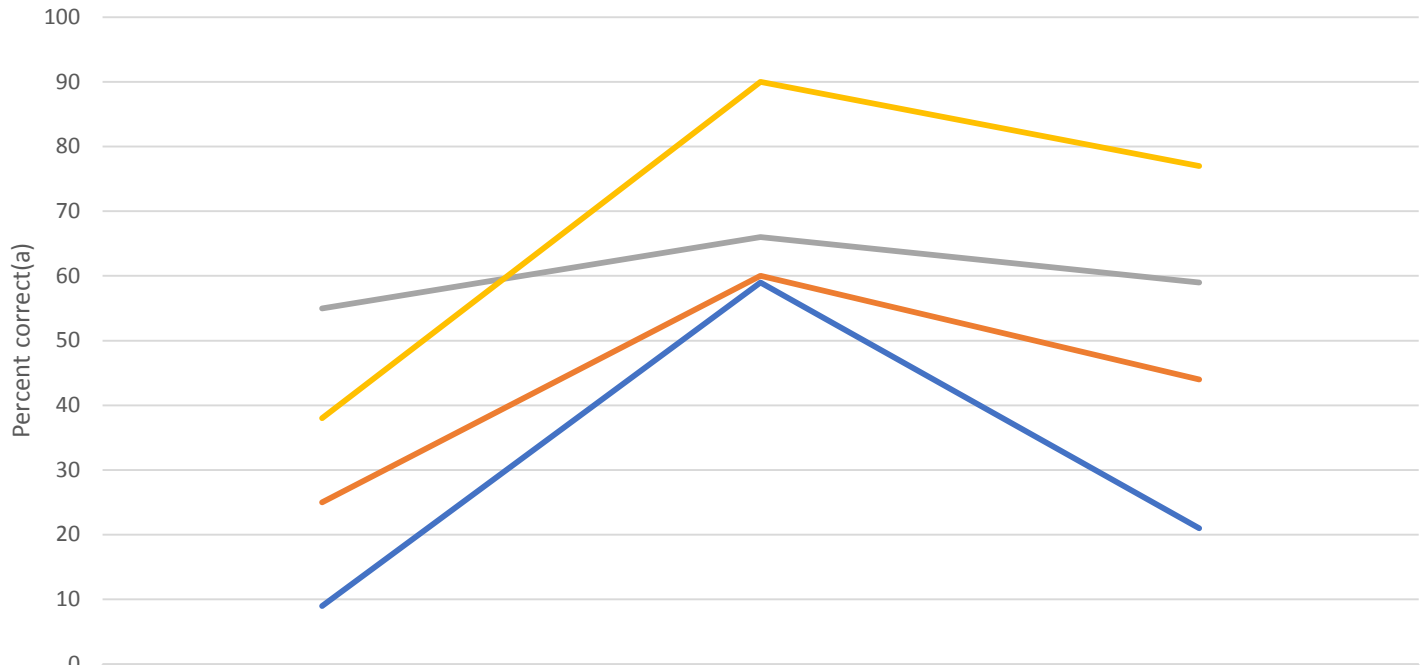


How to Conduct the SDM Visit

- 423 patients had a SDM visit 4/2015-4/2016
- 23 (5.4%) patients did not go on to have the LDCT



How to Conduct the SDM Visit



	Pretest (N = 125)	After visit (N = 123)	1-month follow-up (N = 113)
Age Criteria	9	59	21
Smoking Criteria (b)	25	60	44
Benefits	55	66	59
Harm (c)	38	90	77

Mazzone, Chest 2017.

How to Communicate the Results

To Consider	Our Approach
Structured radiology report	• Home grown evolved to **LungRADS** • Automate data abstraction
Report of other findings	• Separate section in structured report • **Standardizing reporting** of key other findings
How to communicate with patient	• **Options given** at time of SDM visit • Based on finding • Return, EHR, phone, letter
How to communicate with provider	• EHR, secure electronic, phone, letter

How to Communicate the Results

IMPRESSION:

LungRADS category: LungRADS:Incomplete (Category 0)/Negative (Category 1)/Benign appearance or behavior (Category 2)/Probably benign (Category 3)/Suspicious (4A)/Suspicious (4B)/Suspicious (4X)
LungRADS modifier: LungRADSModifier:None/Significant other (S)/Prior lung cancer (C)

Recommendations:

Recommendations:0: Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed./1: Continue annual screening with LDCT in 12 months./2: Continue annual screening with LDCT in 12 months./3: 6 month LDCT./4A: 3 month LDCT; PET/CT may be used when there is a = 8 mm solid component./4B: chest CT with or without contrast, PET/CT and/or tissue sampling depending on the probability of malignancy and comorbidities. PET/CT may be used when there is a = 8 mm solid component./4X: chest CT with or without contrast, PET/CT and/or tissue sampling depending on the probability of malignancy and comorbidities. PET/CT may be used when there is a = 8 mm solid component.

Other actionable findings:

OtherActionableFindings

CT Lung Screen Results

The CT scan that you will have done today will let us know if you have any nodules (small spots) in your lungs that are suspicious for cancer. Around ¾ of the patients who have this scan done will be found to have at least one nodule. Most nodules are benign (not cancer), and of no harm to you at all. A specialist will make a scientific evaluation about whether or not a nodule is worrisome based on its size and shape.

The radiologist who will read your scan will put it into one of four categories:

Category 1 – This means that you do not have any nodules of concern in your lungs at this time. It is advised that a CT lung screen should be repeated in one year.

Category 2 – This means that you have one or more extremely small nodules present in your lungs. These nodules are so small that there is a very low chance, less than 1% risk, that the nodule/s present are cancerous, so the recommendation is to follow with a CT lung screen in one year.

Category 3 – This means that there is a nodule/s present which are a little bit larger or have certain features that would warrant an additional CT scan in 6 months. Though we follow these nodules more closely than the first two categories, there is still only a 1-2% chance that they are cancerous.

Category 4 - This means that there is a larger nodule or other finding that requires special medical attention. These results will be discussed with you in detail with plans for further testing based on the specific findings.

We will communicate the results to you however you would like – MyChart, by phone, face to face visit. We will also send them in a letter to you. If you choose to receive the results through MyChart we will also call you with any Category 3 or 4 finding.

Lung Cancer Screening hotline: 216-445-3800

Specialist Provider (Amanda Tenenbaum, CNP; Rachel Malec, CNP; Kimberly Enochs, CNP; & Hilary Petersen, PA-C): 216-444-4222

How to Communicate the Results

Example of category 3 letter:

Cleveland Clinic
Peter Mazzone,M.D., M.P.H., F.C.C.P
Respiratory Institute
9500 Euclid Ave.
Cleveland, Ohio 44195
216-445-4812 (office)
216-636-6329 (fax)
mazzonp@ccf.org (email)

Dear Patient,

Thank you for choosing the Cleveland Clinic lung cancer screening program.

Results: Your recent lung cancer screening CT revealed at least one small lung nodule. These results suggest a low risk of having lung cancer at this time (1-2% chance).

Please review your full **CT Lung Screen Report** enclosed with this letter.

The nodule should be followed with a CT scan to be sure it does not grow.

It is recommended that you have a follow up visit and Chest CT in 6 months.

An order has been placed in your medical record for a Chest CT. You will be contacted to schedule this follow up appointment.

Thank you again for putting your trust in Cleveland Clinic. Please do not hesitate to call with any questions 216-445-3800

Sincerely,

Peter Mazzone, MD, MPH, FCCP
Director of the Lung Cancer Program of the Respiratory Institute

How to Manage Abnormal Findings

To Consider	Our Approach
Whether to centralize or de-centralize management	• Evolved to a **centralized** approach • Own all results
Surveillance of low risk nodules	• LungRADS
How to manage intermediate and high risk nodules	• **Care path** • Collaboration with relevant specialties • Present biopsy/surgery decisions at **tumor board**
How to manage "other findings"	• Review guidelines in these areas • **Collaboration** with relevant specialists
How to track patients	• **Registry** • Management tracking system

How to Manage Abnormal Findings

Threshold (mm)	Nodules (%)	Cancer (%)	Cancers (#)
4	26.7	3.8	267
7	12.6	7.4	249
11	4.6	17.3	214
21	1.1	33.9	103
30	0.4	41.3	45

NLST Research Team, NEJM 2013.

How to Manage Abnormal Findings

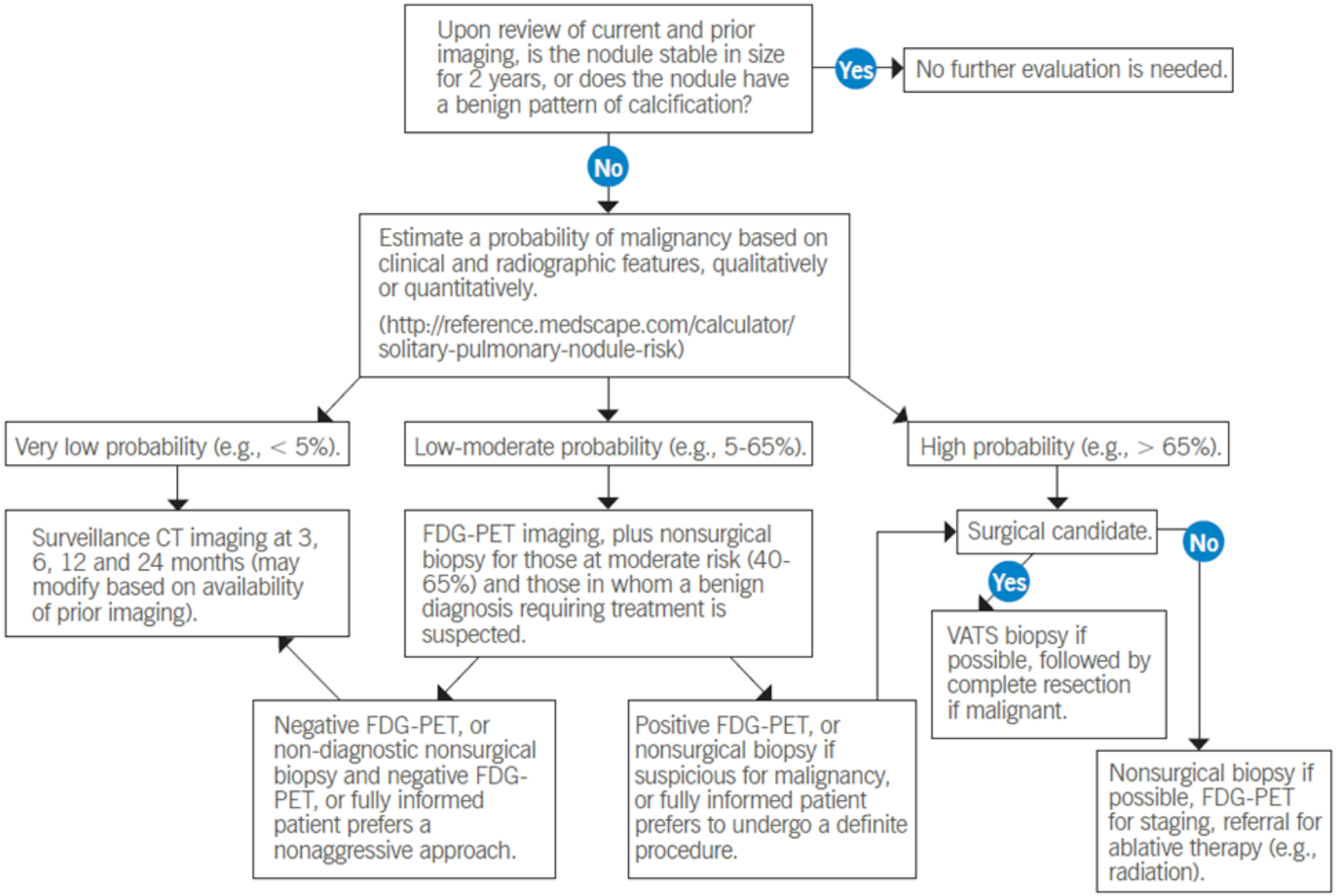
	Baseline	After Baseline
Sensitivity	84.9	78.6
False positive rate	12.8	5.3
PPV	6.9	11.0
NPV	99.81	99.81
NLST cancers delayed	**25 (9.2%)**	**61 (16.2%)**
NLST FP avoided	**3618 (52.1%)**	**7997 (76.1%)**
Procedures	60 (23.4)	57 (23.3)
Chest CT	3557 (50.5)	2150 (45.5)

Pinsky, Ann Intern Med 2015.

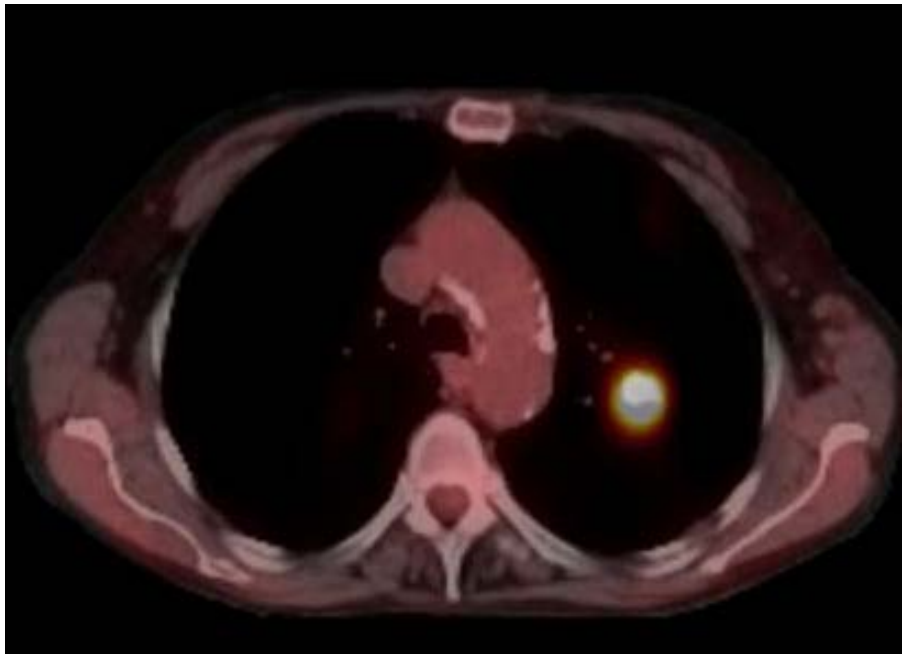
How to Manage Abnormal Findings

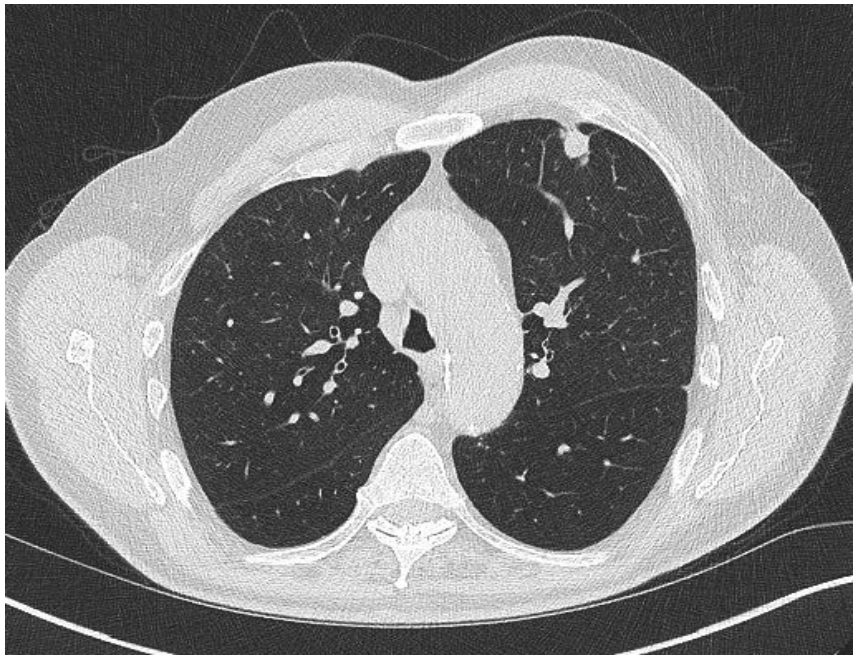
- The **NLST reported 95% compliance** over three years of annual screening.
- In the Early Lung Cancer Action Project (ELCAP) adherence was 88% in those who did not pay for their LDCT and 62% in those who had to pay for their scan.
- Patients enrolled in the NLST were better educated, > 90% were white, had a higher SES, and were more likely to be former smokers when compared to the population of Americans eligible for screening.
- In studies of other commonly screened for cancers the factors associated with poor adherence include being **unmarried, lower SES, black or Hispanic race, not having a primary care provider, and being a smoker.**
- A meta-analysis of adherence in cervical cancer screening showed a mean **adherence rate of 65%** (24% - 84%).
- A study of colorectal cancer screening found **fewer than 50%** were compliant with screening recommendations over the study period.

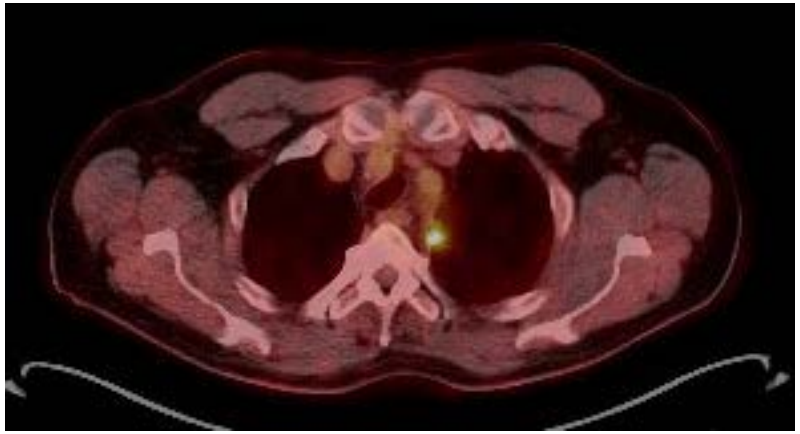
How to Manage Abnormal Findings



How to Manage Abnormal Findings



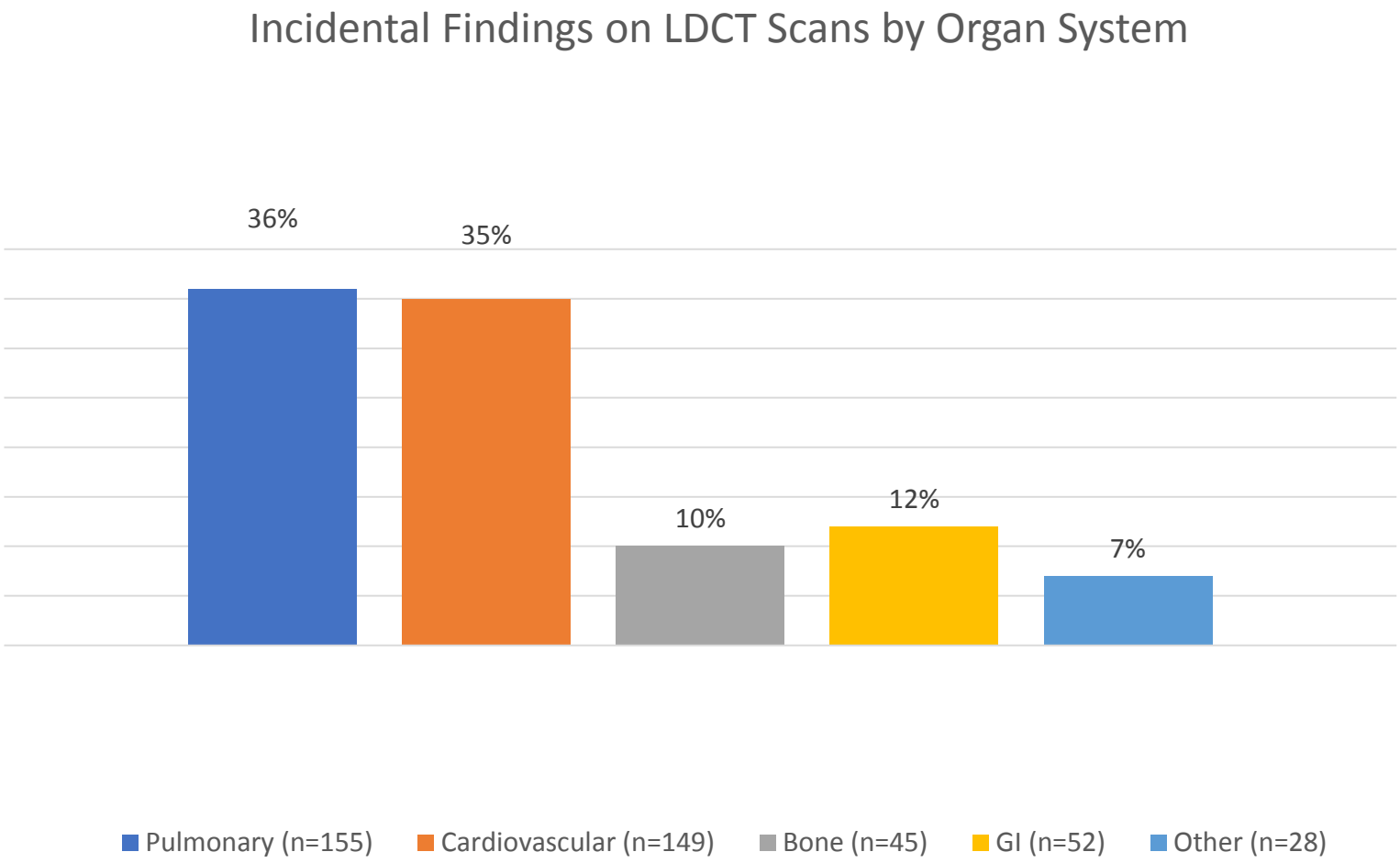




How to Manage Abnormal Findings

- Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association management guidelines for adult patients with **thyroid nodules** and differentiated thyroid cancer. Thyroid 2016;26(1):doi: 10.1089/thy.2015.0020
- https://www.aace.com/files/adrenal-guidelines.pdf.
- Chiles C, Duan F, Gladish GW, et al. Association of **coronary artery calcification** and mortality in the National Lung Screening Trial: A comparison of three scoring methods. Radiology 2015;276(1):82-90
- Htwe Y, Cham MD, Henschke CI, et al. **Coronary artery calcification** on low-dose computed tomography: comparison of Agatston and Ordinal scores. Clin Imaging 2015;39:799-802
- https://my.americanheart.org/idc/groups/ahaecc-internal/@wcm/@sop/documents/downloadable/ucm_423806.pdf

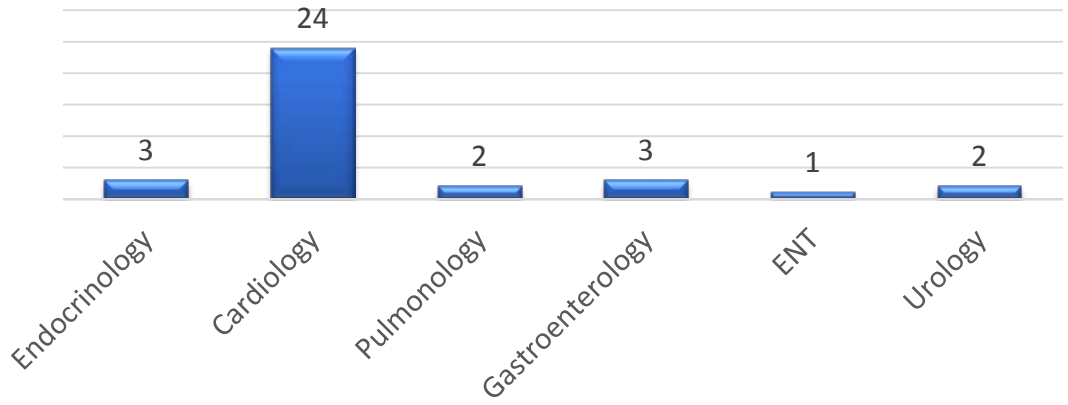
How to Manage Abnormal Findings



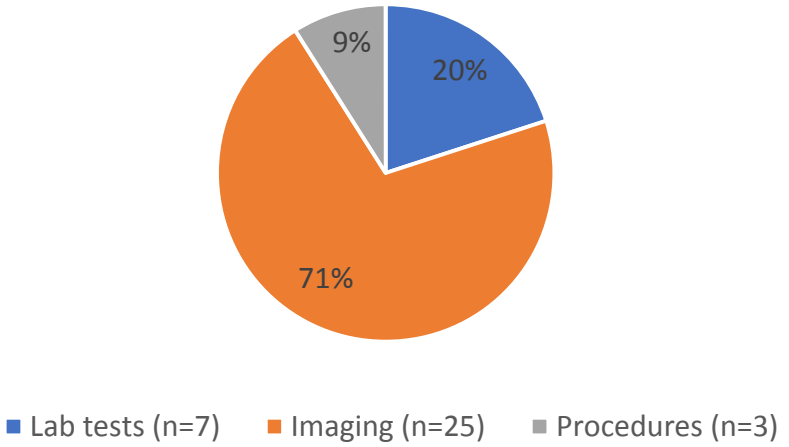
Morgan, Ann Am Thor Soc 2017.

How to Manage Abnormal Findings

Referral to Specialists was Required in 13.9% of Patients



Additional Testing was Required in 11.8% of Patients



- $817 per patient screened based on Medicare reimbursement rates; 46% related to management of other findings.

Morgan, Ann Am Thor Soc 2017.

Compliance with Annual Screening

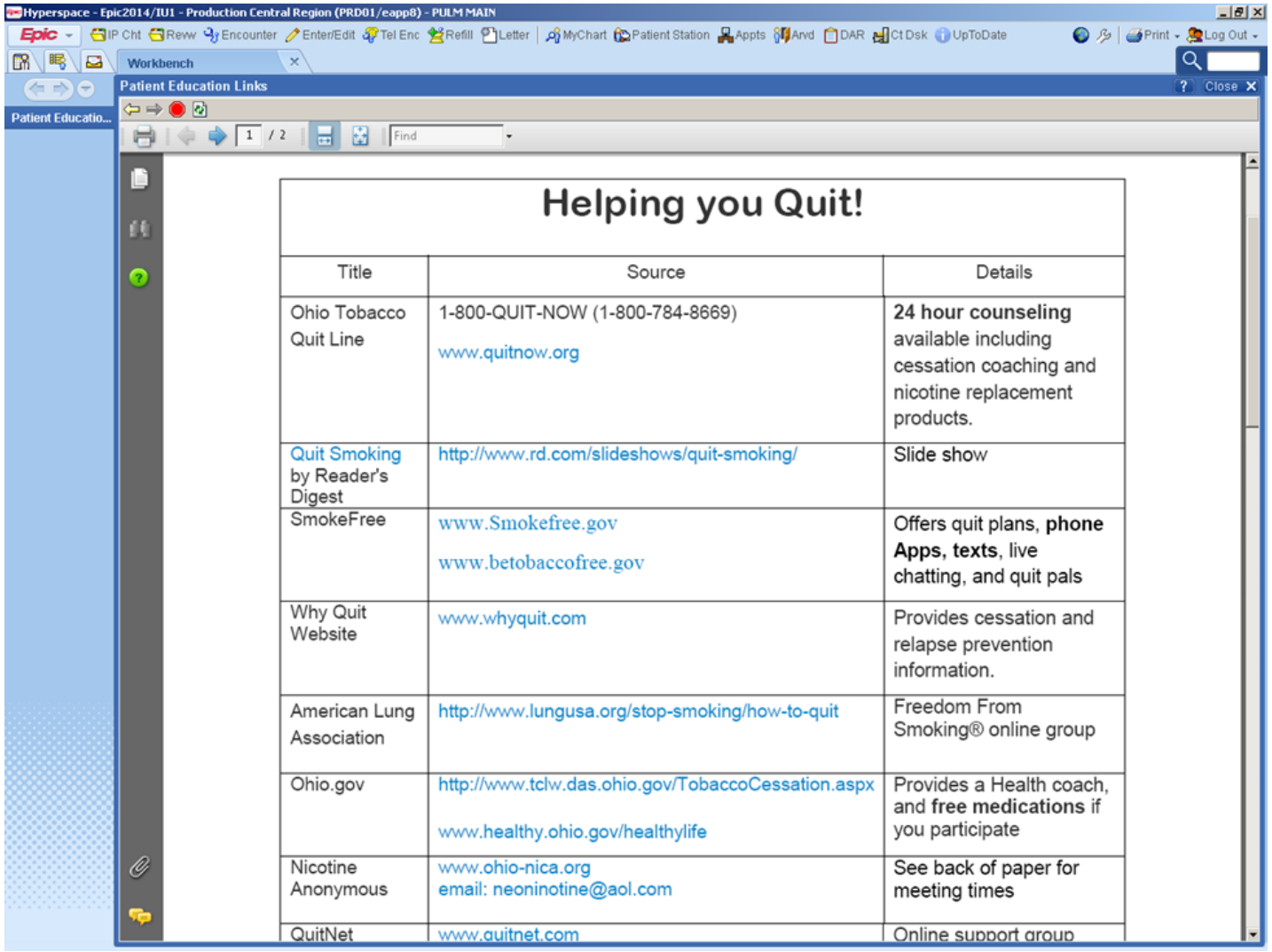
To Consider	Our Approach
How to insure compliance	• Internal **registry** • Management **tracking system** • Letters, calls

Whether to include a SDM visit	• Believe this is of value
	  • improve the patient's understanding of their choices
	  • allow new information to be presented
	  • another opportunity for smoking cessation interventions
	  • reassess patient eligibility

Incorporating Smoking Cessation

To Consider	Our Approach
Approach to smoking cessation guidance	• Incorporate into **SDM visit** • Connect with **tobacco cessation programs** • Information sheet about **community resources** • **Program personnel trained** to be certified smoking cessation counselors

Incorporating Smoking Cessation



Collect, Report, and Review Data

To Consider	Our Approach
How to collect relevant and required data	• Developed a **registry** • Built orders, structured report, SDM visit note for automated data abstraction • Automate **data abstraction** from EHR • **Commercial software**
How to communicate data to national registry	• Data pulled from our registry and other sources • Commercial software being tested
How to use data for program improvement	• Program meetings q2 weeks • Meetings with key collaborators q1-2 months • Annual program review

Cleveland Clinic Screening Program

	Initial Plan	Evolution
Who to screen	NLST, Risk predictor	NLST to age 77, USPSTF
How to identify	Education, EHR	Education, EHR
How to schedule	Test order, Smartset	Consult order, Coordinate
Shared decision making	Ordering provider	Screening program
Scan details	1.5 mGy CTDLP	3.0 mGy CTDIVol
Communicate results	Internal, provider	LungRads, program
Nodule evaluation	Carepath	LungRads, Carepath
Management of findings	Ordering provider	Screening program
Annual follow-up	Ordering provider	Screening program
Smoking cessation	Ordering provider	Screening program
Data collection	Registry	Registry, National, Automation

Disciplines Involved in Program

Discipline	Role
Primary Care Providers	Identify eligible patients and order screening
Radiologists	Imaging protocols, results reporting
Pulmonary/IP	SDM visit, nodule evaluation
Thoracic Surgery	Nodule evaluation, cancer care
Other subspecialists	Other findings, cancer care
Advanced practice provider	SDM visit, communication, tracking
Administrator	Infrastructure support
Marketing	Program awareness, education
Billing	Billing compliance, financial data
Scheduling	Schedule coordination
EHR/IT specialist	Order sets, structured reports, and registries; assist with test follow-up, quality management, and data reporting

Summary

- Balance of Benefit and Harm
- Implementation Considerations