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MD Anderson
Cancer Center
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National Lung Cancer Roundtable Shared Decision-Making Task Group Plenary Session Overview of Shared Decision Making

December 11, 2017

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Funding and disclaimers

This work was supported by a Patient-Centered Outcomes Research Institute (PCORI) Award (CER-1306-03385), and a grant from The University of Texas MD Anderson Cancer Center Duncan Family Institute for Cancer Prevention and Risk Assessment.

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CA CANCER J CLIN 2013;63:106-117

American Cancer Society Lung Cancer Screening Guidelines

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Findings from the National Cancer Institute's National Lung Screening Trial established that lung cancer mortality in specific high-risk groups can be reduced by annual screening with low-dose computed tomography. These findings indicate that the adoption of lung cancer screening could save many lives. Based on the results of the National Lung Screening Trial, the American Cancer Society is issuing an initial guideline for lung cancer screening. This guideline recommends that clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should initiate a discussion about screening with apparently healthy patients aged 55 years to 74 years who have at least a 30-pack-year smoking history and who currently smoke or have quit within the past 15 years. A process of informed and shared decision-making with a clinician related to the potential benefits, limitations, and harms associated with screening for lung cancer with low-dose computed tomography should occur before any decision is made to initiate lung cancer screening. Smoking cessation counseling remains a high priority for clinical attention in discussions with current smokers, who should be informed of their continuing risk of lung cancer. Screening should not be viewed as an alternative to smoking cessation. CA Cancer J Clin 2013;63:106-117. ©2013 American Cancer Society.

All professional societies endorse SDM for lung cancer screening

“...clinicians...should initiate a discussion about screening with apparently healthy patients aged 55 years to 74 years who have at least a 30-pack-year smoking history and who currently smoke or have quit within the past 15 years. A process of informed and shared decision-making with a clinician related to the potential benefits, limitations, and harms associated with screening for lung cancer with low-dose computed tomography should occur before any decision is made to initiate screening.”
(emphasis added)

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!

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

Solution to low value care

- 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!

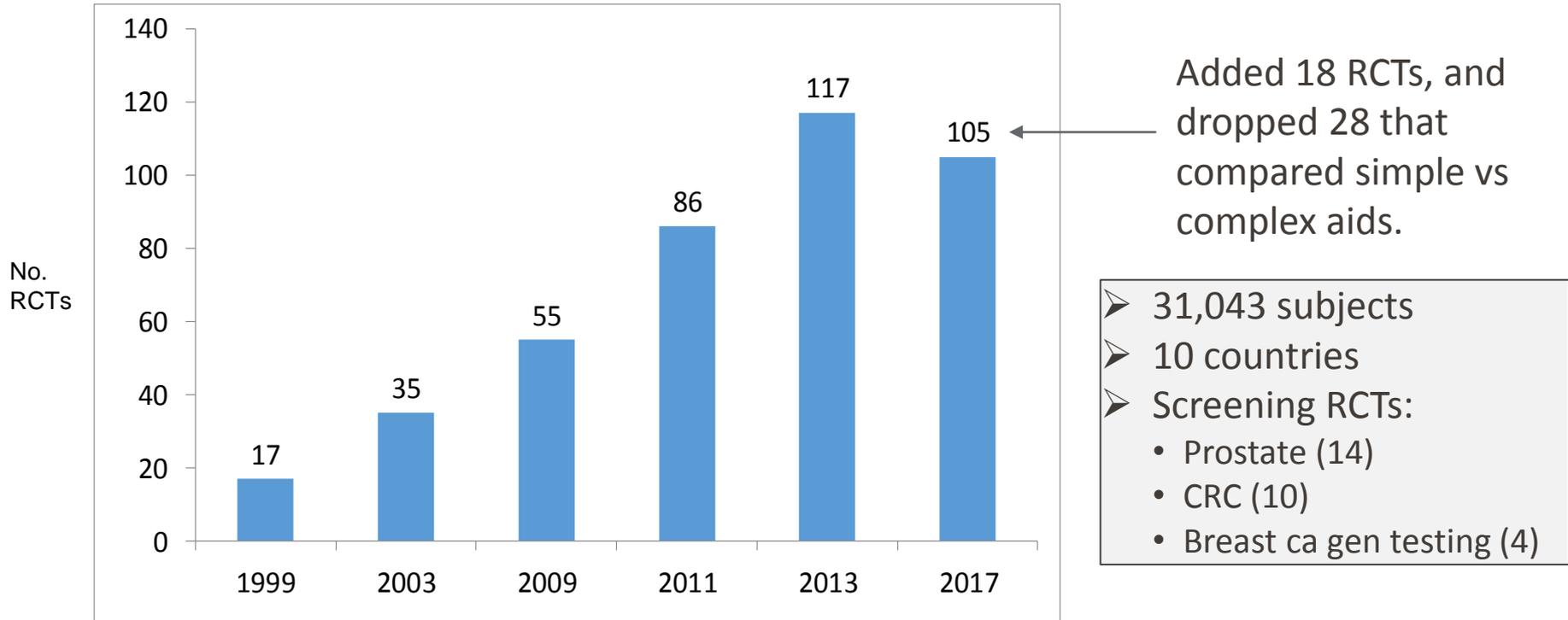
Shared Decision Making, defined

Shared decision making (SDM) is a collaborative process that allows patients and their health care providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.

SDM honors both the provider's expert knowledge and the patient's right to be fully informed of all care options and the potential harms and benefits. This process provides patients with the support they need to make the best individualized care decisions, while allowing providers to feel confident in the care they prescribe.

Cochrane Database of Systematic Reviews

Decision aids for people facing health treatment or screening decisions



Cochrane Database of Systematic Reviews

Decision aids for people facing health treatment or screening decisions

Compared to usual care, decision aids...

- 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

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,¹ Smita S. Saraykar, MBBS, MPH,¹ Viola B. Leal, MPH,¹ Michael P. Pignone, MD, MPH³

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 decision aids. Reviewers independently selected studies that quantitatively evaluated a decision aid compared to one or more conditions or within a two-group evaluation. Using a standardized form, reviewers independently extracted data.

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

Conclusions: Decision aids screening over no informative screening information. (Am J Prev Med 2016;51(5):779-784. 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

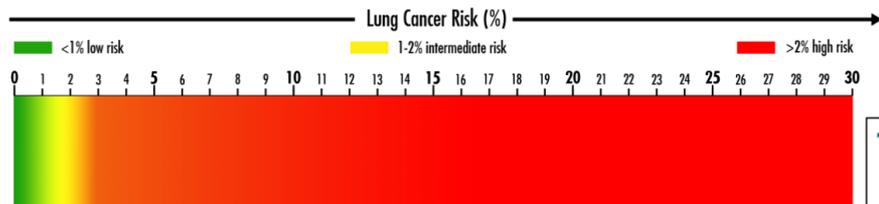
Cancer screening aid	Impact on screening behavior compared to usual care
Prostate cancer screening	Reduction 12%
Colorectal cancer screening	Increase 30%
Lung cancer screening	Unknown (probably increase)
Breast cancer screening (“younger” women, “older” women)	Unknown
Other cancer screening	Unknown

Recommendations about SDM for lung cancer screening address the content of discussions

USPSTF*	NCCN	CMS
Benefits	Benefits	Benefits
↓ lung cancer mortality	<p style="color: red; text-align: center;">Decision scientists are really good at translating knowledge.</p>	Lung cancer mortality
		Mortality
Harm	<p style="color: red; text-align: center;">Implementation of SDM is the key.</p>	Harms
False positives		False negatives
Invasive procedures	Limited impact on mortality	Follow-up diagnostic testing
Overdiagnosis	False positives	Overdiagnosis
Radiation exposure (cumulative)		Total radiation exposure

Shouldiscreen.com

The chance of you developing lung cancer in the next 6 years is 5.5%. Talk to your doctor about the option to screen or not to screen as s/he will understand your situation best.



Your Risk = 5.5%

Incidence: tailored
Benefits: tailored
Harms: not tailored

Compared to other people like you, there will be 10 fewer deaths out of 1000 in the next 6 years if you get screened.

NOT SCREENED

54 deaths from lung cancer



SCREENED

44 deaths from lung cancer
 10 fewer lung cancer deaths due to screening



BENEFITS



10 in 1000

fewer people like you will die from lung cancer among those who were screened compared to those who were not screened.

HARMS

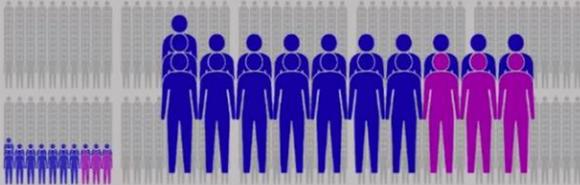
- 365 in 1000 people who were screened found a lung nodule that was not cancer.
- 18 in 1000 had an invasive procedure, such as biopsy or surgery, due to a lung nodule that was not cancer.
- 3 in 1000 had a major complication from invasive procedures.
- ◆ Of the lung cancers found by screening, about 1 in 10 would have never harmed you (overdiagnosis). This may lead to unnecessary treatment and complications.

Lung Cancer Screening: Is it right for me?



1 pack a day for 30 years
or
2 packs a day for 15 years
both = 30 pack-years

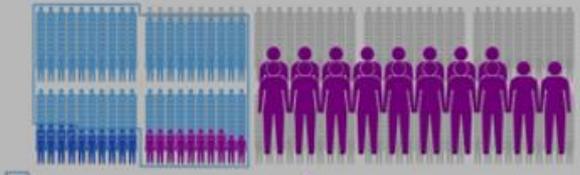
Same 1000 Smokers (55 to 74 years of age) **WERE Screened every year for 3 years**



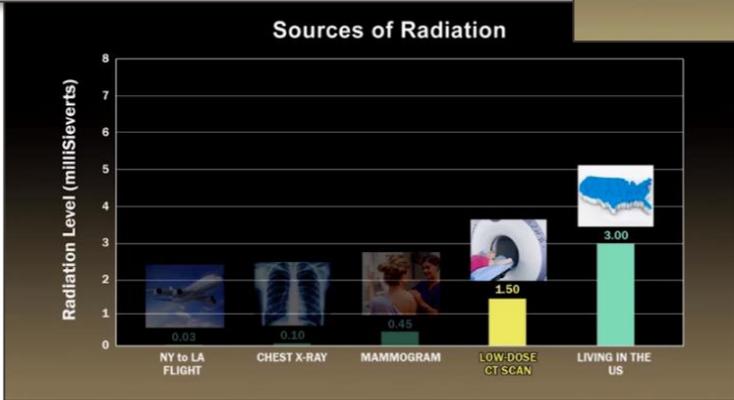
18 would die from lung cancer (within 6 1/2 years)
3 fewer smokers would die from lung cancer

Benefits	Harms
<ul style="list-style-type: none">Reducing the chance of dying from lung cancerFinding other health problems that might be treated earlier	<ul style="list-style-type: none">Exposure to radiationFalse alarms and extra testsBeing treated for a cancer that might never cause harm

1000 Smokers **ARE Screened every year for 3 years**



24 of the 380 people will have lung cancer
18 of the 356 will need a test
256 will not have lung cancer (false alarm)



How do we promote the use of SDM for lung cancer screening?

Barriers to implementing SDM

1. Overworked physicians
2. Insufficient provider training
3. Inadequate clinical information systems

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Facilitators of implementing SDM

1. Automatic triggers
2. Engaging non-physician providers

Implementation Tools for Clinicians

ELIGIBILITY CRITERIA FOR LUNG CANCER SCREENING

Criteria according to:	USPSTF	CMS*
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

*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.

^bFormer 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

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.



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

Implementation Tools for Clinicians

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? Yes No^a
(55 to 80 years old for patients with private insurance)
- » 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.

^aScreening 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.
^bSymptomatic patients may need followup and diagnostic testing, but not screening. Patients with a history of lung cancer need surveillance, but not screening.

Follows CMS eligibility criteria

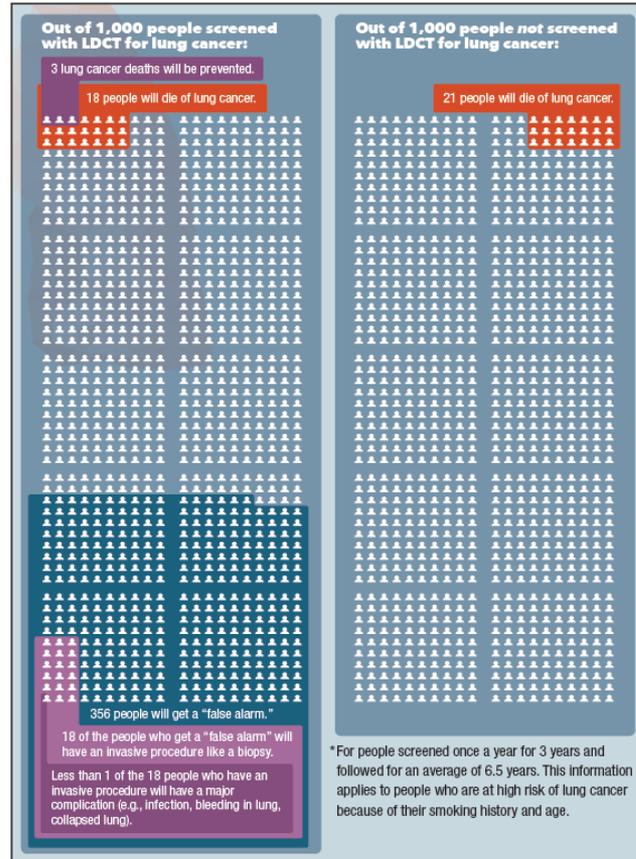
Implementation Tools: Decision Aids for Patients

Communicating benefits and harms

- Lung cancer–specific mortality benefit
- Overall mortality benefit
- “False alarms”
- Invasive procedures, and major complications

Design features – icon arrays

- Visual depiction
- Common denominator (1000)
- Clear timeframe
- Accompanying text to reinforce visual display



Remember, the best way to lower your chances of dying from lung cancer is to stop smoking.

More than 8 out of every 10 lung cancer cases in the United States are from smoking.

Lung cancer screening should not be done instead of quitting smoking. If you currently smoke, talk to your health care professional or call the nationwide quit line at

1-800-QUIT-NOW
(1-800-784-8669).

How can we promote the use of SDM in lung cancer screening?

New/better tools

Populations of greatest need:

- Low literacy/numeracy tools

Clinician training

Alternative delivery models

SDM Task Group Breakout Session: Opportunities for intervention/influence

- Create tools to aid patients and providers. Develop model informed/shared decision-making materials and content to overcome current shortcomings.
- Provide feedback to CMS to assist in verifying that a quality visit is taking place.
- Advise on strategic priorities, program direction, and scientific policy that results in the ability to empower the decision-making process for patients and providers.