

Decision Making in Lung Cancer Screening

Educational Need/Practice Gap

- Health Care providers have been trained to implement Shared Decision Making (SDM) when talking to patients about lung cancer screening.
- Not only this, but health care providers are now required by law to initiate shared Decision making when counseling patients
<http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAid=274>
- LCS is a new preventive health service with significant potential benefits and harms..

Shafir, A., & Rosenthal, J. (2012). Shared Decision Making: Advancing Patient-Centered Care Through State and Federal Implementation. National Academy for State Health Policy, Washington, DC
http://www.nashp.org/sites/default/files/shared_decision_making_report.pdf

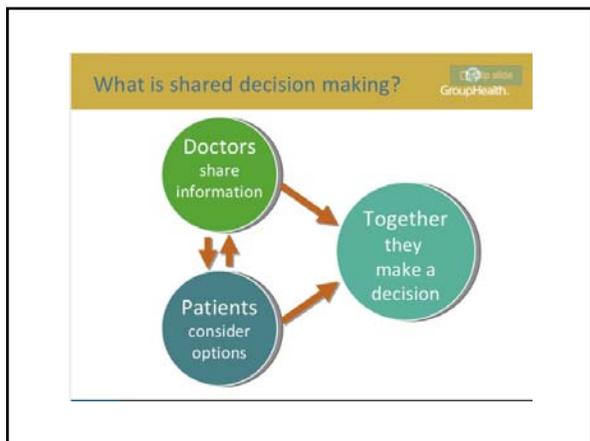


What is Shared Decision Making?

- SDM is a collaborative process that health care providers and patients use to make health care decisions.
- Goals of SDM are to provide patients with the best scientific research available while also satisfying their values and preferences.



<http://www.youtube.com/watch?v=9PmSEK0R8Uc>
<http://www.informedmedicaldecisions.org/what-is-shared-decision-making/>



Why Shared Decision Making?

- **High Quality Care**
 - **The Patient Perspective:** Patients who have been through the SDM process report better outcomes and increased satisfaction with their providers.
 - **The Provider Perspective:** Providers who successfully implement SDM find that they can more accurately assess individual patients and tailor their care to improve each patient's outcomes.
<http://www.informedmedicaldecisions.org/>

Who Qualifies for LCS?

Specifics of CMS Regulations related to SDM in Lung Cancer Screening

- 55-77 years old
- Asymptomatic
- Tobacco of 30+ years
- Currently smoking or has quit in past 15 years
- **Written LDCT order obtained via SDM from physician**
 - Eligibility
 - SDM consultation
 - Documentation of adherence/screening counseling
 - Tobacco Cessation Intervention
 - Use of a Decision Aid/Decision Support Tool

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

CMS Justification for SDM

- There is adequate evidence that annual LCS decreases lung cancer mortality. *(benefit)*
- However, there are notable side effects of LCS *(harms)*
 - False positive/false alarms=unnecessary testing, costs, and distress
 - False negatives=false sense of security and delay diagnosis
 - Exposure to radiation may cause harm
- Additionally, LCS is new in medicine... *(unknowns)*
 - Optimal screening intervals and ages are not yet known
 - Long-term benefits and harm are unknown
 - Improvements in screening and treatment may arise that change the diagnosis and treatment of lung cancer

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

CMS on SDM for Lung Cancer Screening

Determination of Eligibility

- In order to be considered for LCS, patients must meet these criteria:
 1. 55-77 years old
 2. Asymptomatic
 3. Tobacco of 30+ years
 4. Currently smoking or has quit in past 15 years
 5. Written LDCT order obtained via SDM from physician

Delivery of SDM

- CMS now requires SDM with all patients considering LCS who have met the aforementioned requirements.

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

CMS on Patient Counseling for LCS

Counseling Topics

- Benefits
- Harms
- Unknowns
- Patient's Wants and Preferences
- Importance of Continuity of Screening
- How a LCS is performed
- What results mean
- Follow-up

Tobacco Treatment

- CMS requires that tobacco treatment be integrated as a component of a LCS program.
- Current tobacco users must be offered tobacco treatment.
 - Continued smoking among LCS participants is likely to undermine the value of lung cancer screening.

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

Lung Cancer Screening: The Data on Benefits, Harms, and Unknowns

Unlike other disease that can easily be diagnosed with a quick and simple inspection, lab, or scan, LCS can require more invasive techniques and these must be considered.

Lung Cancer Screening

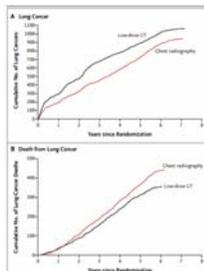
- Low-Dose Computed Tomography (LDCT) is initially used to for LCS
- If a pulmonary nodule is detected from the initial LDCT, a lung biopsy is taken to further assess the nodule for identification.
- Identification of the nodule as lung cancer, requires surgical removal of the nodule in order to treat.

<http://www.lung.org/lung-disease/lung-cancer/lung-cancer-screening-guidelines/lung-cancer-screening.pdf>

National Lung Screening Trial

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

National Lung Screening Trial



- Primary Results
 - 20% relative reduction in lung cancer mortality with LDCT
 - 6.7% reduction in all-cause mortality with LDCT
- Additional Results
 - Positive/False Positive Screens
 - LDCT: 39% had 1+ pos. screen
 - CXR: 16% had 1+ pos. screen

Figure 1. Cumulative Numbers of Lung Cancers and of Deaths from Lung Cancer.
 The number of lung cancers (panel A), includes lung cancers that were diagnosed from the date of randomization through December 31, 2009. The number of deaths from lung cancer (panel B), includes deaths that occurred from the date of randomization through January 31, 2010.

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

CMS Eligibility

CMS recommends annual LCS for current smokers who are:

1. 55-77 years old
2. Asymptomatic
3. Tobacco of 30+ years
4. Currently smoking or has quit in past 15 years
5. Written LDCT order obtained via SDM from physician

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

USPSTF Eligibility

USPSTF recommends annual LCS for current smokers who are:

1. 55-80 year of age
2. 30 packs per year history of cigarette smoking
3. OR have quit cigarette smoking in the past 15 years.
4. Screening should cease after person has not smoked for 15 years, develops a health problem that significantly reduces life expectance, or willingness/ability to have invasive lung surgery

<http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/lung-cancer-screening>

USPSTF Final Guideline for Lung Cancer Screening



Shared Decision Making

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

Tobacco/Smoking Cessation

- "All persons enrolled in a screening program should receive smoking cessation interventions."
- "Because many persons may enter screening through pathways besides referral from primary care, the USPSTF encourages incorporating such interventions into the screening program."

(Humphrey et al., 2013, Annals of Internal Medicine, Online)
(Moyer et al., 2013, Annals of Internal Medicine, Online)
<http://www.uspreventiveservicestaskforce.org/uspsft13/lungcan/lungcancfact.pdf>

ACS Eligibility

• ACS recommends annual LCS for current smokers who are:

1. 55-74 years of age
2. 30 packs per year history of cigarette smoking
3. OR have quit cigarette smoking in the past 15 years.
4. Otherwise in relatively good health, without other significant illnesses that significantly reduce lifespan

<http://www.cancer.org/healthy/informationforhealthcareprofessionals/acsguidelines/lungcancerscreeningguidelines/index>

Potential Benefits of LCS

- Early detection of adenocarcinoma and squamous cell carcinoma can sometimes be cured and increase of life expectancy.
- Detection of small-cell carcinoma can allow patient and provider to make changes to improve outcomes.
- Negative readings can provide peace-of-mind to individuals worried about lung cancer.

<http://www.cancer.org/cancer/news/expertvoices/post/2013/01/11/weighing-the-benefits-and-risks-of-lung-cancer-screening.aspx>

Potential Harms of LCS

- LDCT does cause exposure to radiation, but this risk is generally considered minimal and disregarded unless there is a reason to consider it otherwise.
- False positives can put the patient at risk of invasive and unnecessary procedures to biopsy/surgically remove nodules that are of no harm.
- False negatives can provide the patient with a false sense of security.

<http://www.cancer.org/cancer/news/expertvoices/post/2013/01/11/weighing-the-benefits-and-risks-of-lung-cancer-screening.aspx>

Unknowns of LCS

- Optimal screening intervals
- Optimal screening ages
- Long-term benefits
- Long-term harms
- Improvement in screening
- Improvement in treatment
- Optimal combination of screening approaches

Example Case

- “A 60-year-old woman comes for high blood pressure. She has no symptoms other than mild, long-standing shortness of breath on exertion; she specifically reports that she has no cough or chest pain and that her weight has not changed. There is no personal history of cancer or family history of lung cancer. She reports smoking one pack of cigarettes per day since 16 years of age.

Gould, M. (2014). Lung Cancer Screening with Low-Dose Computed Tomography. *The New England Journal of Medicine*, 371(19), 1814-1820. doi:10.1056/NEJMcp1404071

- She is interested in her risk of lung cancer. Should she ask her doctor about LCS with low-dose computed tomography (CT)?”

Let's review her eligibility

- **60-year-old woman**
- **No symptoms**
 - no cough or chest pain and that her weight has not changed
- **No personal history of cancer or family history of lung cancer**
- **one pack of cigarettes per day since 16 years of age**
 - 44 pack-years

An Example of SDM & LCS

- Meets CMS, USPSTF, and ACS eligibility requirements
- Use of a Decision making tool shows her risk of dying from lung cancer in the next 6 years is 2%
- Assuming that the 20% risk reduction of LDCT is consistent in the patients risk group, her personal probability of benefit from LDCT is slightly higher than average
- Absolute risk reduction of 0.4% or Number needed to save=4/1000

Gould, M. (2014). Lung Cancer Screening with Low-Dose Computed Tomography. *The New England Journal of Medicine*, 371(19), 1814-1820. doi:10.1056/NEJMcp1404071

- **Based on this, this patient should be encouraged to participate in a SDM process about LCS.**

Summary & Conclusions

- Lung cancer screening using Low-Dose Computed Tomography has the potential reduce lung cancer morbidity.
- However, lung cancer screening is a new approach and requires a different approach to patient education and counseling.
- Shared Decision Making must be paramount in the approach to facilitate informed patient decisions about lung cancer screening.
