SHARED DECISION MAKING IN MEDICARE COVERAGE

Kate Goodrich, MD MHS
Director, Center for Clinical Standards and Quality
CMS
April 2, 2016

Disclaimer: Views and comments in this presentation are those of the presenter and do not represent the official positions and views of the Centers for Medicare and Medicaid Services.
This presentation is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings.

This presentation was prepared as a service to the public and is not intended to grant rights or impose obligations. This fact sheet may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

This presentation was current at the time it was published or uploaded to the web. Medicare policy changes frequently so links to the source documents have been provided within the document. The Centers for Medicare & Medicaid Services employees, agents, and staff make no representation, warranty, or guarantee that this compilation of Medicare information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.
WHAT IS SHARED DECISION MAKING (SDM)?

• Defined model of decision making
• Important characteristics (Charles, Gafni, Whelan, 1997)
  • at least two participants--physician and patient
  • sharing of information by all participants
  • emphasis on patient preferences
  • consensus building about the preferred screening or treatment option
  • an agreement on the plan and implementation
• Evidence-based decision aid or support tool
  • visual presentation of outcomes, benefits, harms (e.g., video, pictogram)

EVIDENCE-BASED DECISION AID
(DECISION SUPPORT TOOL)

• Provides evidence about options
• Presents relevant attributes of the options
• Improves knowledge
• Results in more accurate risk perceptions
• Helps patients be more assured about their decisions
• Increases active participation in decision making
• Results in decisions consistent with patients’ values

PMID: 24624947

BREAST CANCER EARLY DETECTION
(HARDING CENTER FOR RISK LITERACY)

---

**Breast Cancer Early Detection**

by mammography screening

Numbers for women aged 50 years or older who participated in screening for 10 years or more

<table>
<thead>
<tr>
<th>1000 women without screening:</th>
<th>1000 women with screening:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Women who died from breast cancer:</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>Women who died from all types of cancer:</strong></td>
<td>21</td>
</tr>
<tr>
<td><strong>Women who learned after a biopsy that their diagnosis was a false-positive:</strong></td>
<td>-</td>
</tr>
<tr>
<td><strong>Women who were diagnosed and treated for breast cancer unnecessarily:</strong></td>
<td>-</td>
</tr>
<tr>
<td><strong>Remaining women:</strong></td>
<td>979</td>
</tr>
</tbody>
</table>

Source: Gøtzsche, PC, Jørgensen, KI (2013). Cochrane Database of Systematic Reviews (6): CD001877

Numbers in the facts box are rounded. Where no data for women above 50 years of age are available, numbers refer to women above 40 years of age.

www.harding-center.mpg.de/en/health-information/fact-boxes/mammography
Prostate Cancer Early Detection
by PSA testing and palpation of the prostate gland
Numbers are for men aged 50 years and older, not participating vs. participating in early detection for 11 years

1000 men without early detection:

- Men who died from prostate cancer: 7
- Men who died from any cause: 210
- Men who learned after a biopsy that their diagnosis was a false-positive: –
- Men who were diagnosed and treated for prostate cancer unnecessarily: –
- Remaining men: 783

1000 men with early detection:

- Men who died from prostate cancer: 7
- Men who died from any cause: 210
- Men who learned after a biopsy that their diagnosis was a false-positive: 160
- Men who were diagnosed and treated for prostate cancer unnecessarily: 20
- Remaining men: 603

Source: Ilic et al. (2013) Cochrane Database of Systematic Reviews, Art. No.:CD004720.

www.harding-center.mpg.de/en/health-information/fact-boxes/psa
• New technologies and innovation may present multiple recommended screening or equivalent treatment options for important conditions in older adults
  • Example: anticoagulation or device therapy for non-valvular atrial fibrillation
• Development of patient centered screening and/or treatment plan incorporating patient preferences and considering benefits and harms (pros and cons)
  • Example: choice of fecal based screening tests versus screening colonoscopy
SDM IN MEDICARE COVERAGE: LUNG CANCER SCREENING WITH LOW DOSE COMPUTED TOMOGRAPHY (LDCT)
LUNG AND BRONCHUS CANCER (2013)

New Cases of Lung and Bronchus Cancer

- Median Age At Diagnosis: 70 years

Deaths from Lung and Bronchus Cancer

- Median Age At Death: 72 years

Lung and bronchus cancer is most frequently diagnosed among people aged 65-74.

The percent of lung and bronchus cancer deaths is highest among people aged 65-74.

STAGE OF DIAGNOSIS AND SURVIVAL (2013)

Percent of Cases by Stage:
- Localized (15%)
- Regional (22%)
- Distant (57%)
- Unknown (6%)
- Unstaged

5-Year Relative Survival:
- Localized: 53.5%
- Regional: 26.1%
- Distant: 3.9%
- Unstaged: 7.8%

CMS authority to add preventive services established by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Section 101).

May add using national coverage determination process if the service meets all of the following:

- Reasonable and necessary for the prevention or early detection of illness or disability.
- Recommended with a grade of A or B by the United States Preventive Services Task Force.
- Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.
- “Secretary [HHS] may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination”
NLST AND USPSTF

• National Lung Screening Trial (NLST, 2011) - large randomized controlled trial sponsored by the National Institutes of Health
  • “screening with the use of low-dose CT reduces mortality from lung cancer” in adults, 55-74 years old, who have at least a 30 pack year smoking history with 3 annual LDCTs”

• U.S. Preventive Services Task Force (2013)
  • “annual screening for lung cancer with LDCT in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years” (B recommendation)
LUNG CANCER SCREENING WITH LDCT

• Based on the NLST & USPSTF, CMS added Medicare coverage of lung cancer screening with LDCT for certain beneficiary performed at qualified radiology centers with data collection
• Beneficiary eligibility
  • Asymptomatic, age 55 – 77 years (NLST)
  • Tobacco smoking history of at least 30 pack-years
  • Current smoker or one who has quit smoking within the last 15 years
• Radiologist and imaging center criteria for performance, quality and consistency
• Specific requirement for initial shared decision making visit prior to starting long term screening
SHARED DECISION MAKING VISIT

- First formal Medicare coverage requirement of SDM
- Furnished by a physician or qualified non-physician practitioner and includes:
  - Determination of beneficiary eligibility;
  - Shared decision making, including the use of one or more evidence-based decision aids or tools;
  - Counseling on adherence, impact of comorbidities and ability or willingness to undergo diagnosis and treatment;
  - Counseling on cigarette smoking abstinence if former smoker or the importance of smoking cessation if current smoker.
IMPORTANCE OF SDM & DATA COLLECTION

- Narrow window of evidence of benefit (eligibility)
  - NLST identified a well defined high risk population to screen
  - 2 other trials were negative

<table>
<thead>
<tr>
<th>Study</th>
<th>Age (inclusion criterion)</th>
<th>Smoking history (inclusion criterion)</th>
<th>Positive result LDCT (false positive rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DANTE; n = 2472</td>
<td>mean age = 64.6; (60-74 years)</td>
<td>mean = 47 pack-years; (≥ 20 pack-years)</td>
<td>non-calcified nodule ≥ 10 mm, etc; (291/351, 83%)</td>
</tr>
<tr>
<td>CTx5 vs no screening</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DLSCT; n = 4104</td>
<td>91% 50-64 years; (50-70 years)</td>
<td>mean = 36 pack-years; (≥ 20 pack-years)</td>
<td>nodule ≥ 5 mm; (542/611, 89%)</td>
</tr>
<tr>
<td>CTx5 vs no screening</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NLST; n = 53454</td>
<td>73% 55-64 years; (55-74 years)</td>
<td>mean = 56 pack-years; (≥ 30 pack-years)</td>
<td>non-calcified nodule ≥ 4 mm; (17497/18146, 96 %)</td>
</tr>
<tr>
<td>CTx3 vs CXR</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Patient-centered decisions and care
- Coverage with Evidence Development (CED)
  - Provides access to important new technology and services
  - Data collection to demonstrate results in broad population screening outside of controlled trial settings (implementation science)
Several evidence-based decision aids and support tools have been developed and published since our NCD requiring SDM and use of decision aid, including but not limited to:

- **NIH National Cancer Institute**

- **Memorial Sloan Kettering**

- **University of Michigan**
  (http://news.thoracic.org/ats-develops-lung-cancer-screening-decision-aid/)

- **American Thoracic Society**
  (http://news.thoracic.org/ats-develops-lung-cancer-screening-decision-aid/)
SUMMARY & NEXT STEPS

• New formal concept for Medicare coverage
  • Recognizes and emphasizes the role of the patient
• Monitor, evaluate and refine structure of patient SDM visit and appropriate implementation
• Engage stakeholders including beneficiaries on important applications of SDM
• Foster development of additional evidence-based decision aids or support tools
• Consider formal shared decision making in future coverage decisions, quality activities