Screening for Lung Cancer with Low-Dose Computed Tomography in Adult Smokers

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Cancer of the Lung and Bronchus

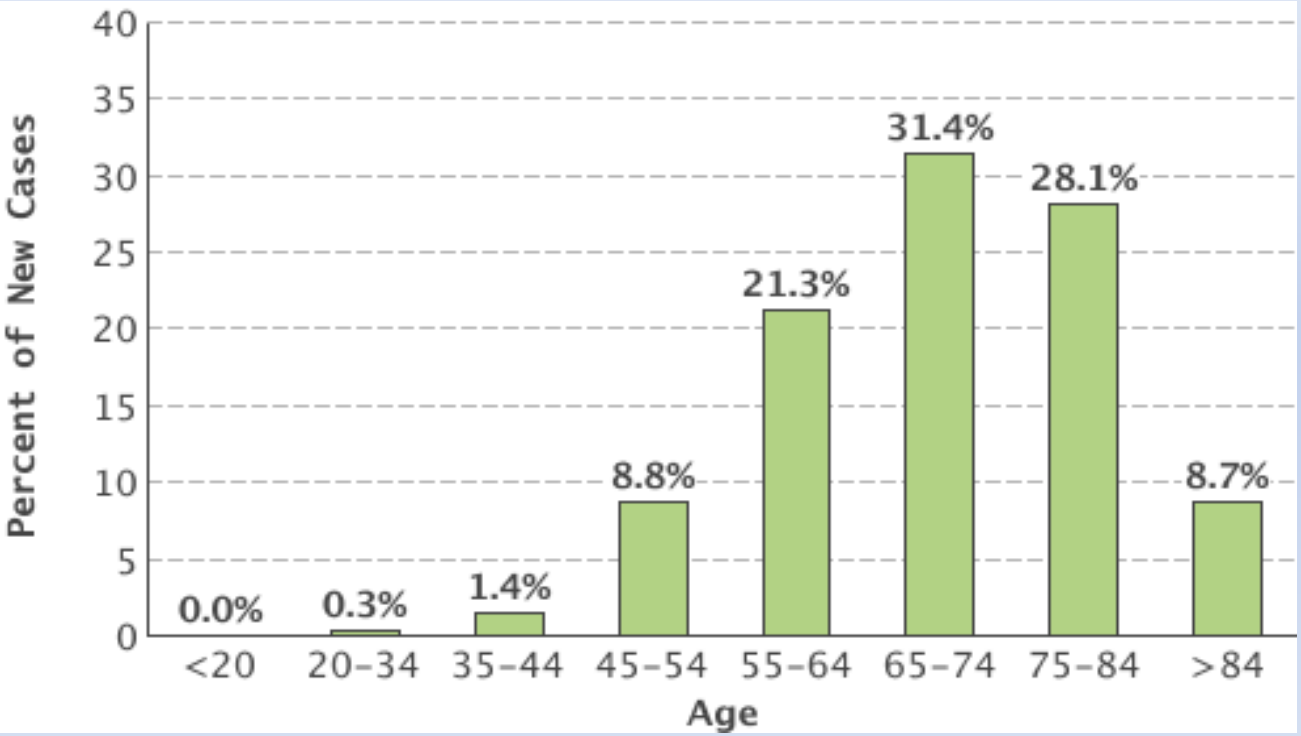
	Common Types of Cancer	Estimated New Cases 2013	Estimated Deaths 2013
1	Prostate Cancer	238,590	29,720
2	Breast Cancer	232,340	39,620
3	**Lung and Bronchus Cancer**	**228,190**	**159,480**
4	Colon and Rectum Cancer	142,820	50,830
5	Melanoma of the Skin	76,690	9,480
6	Bladder Cancer	72,570	15,210
7	Non-Hodgkin Lymphoma	69,740	19,020
8	Kidney and Renal Pelvis Cancer	65,150	13,680
9	Thyroid Cancer	60,220	1,850
10	Endometrial Cancer	49,560	8,190

Source: http://seer.cancer.gov/statfacts/html/lungb.html

Lung and bronchus cancer represents 13.7% of all new cancer cases in the U.S.

13.7%

New Cases of Lung and Bronchus Cancer

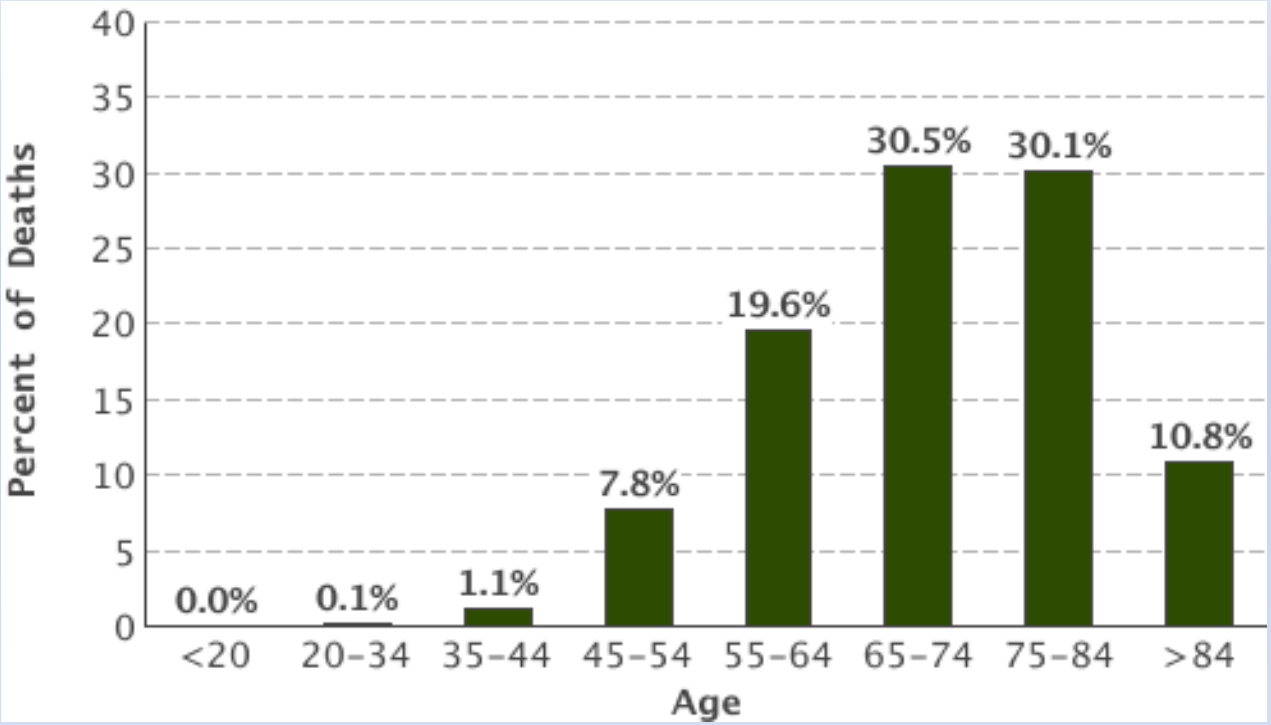


Lung and bronchus cancer is most frequently diagnosed among people aged 65-74.

Median Age At Diagnosis
70 years

Source: http://seer.cancer.gov/statfacts/html/lungb.html

Deaths from Lung and Bronchus Cancer



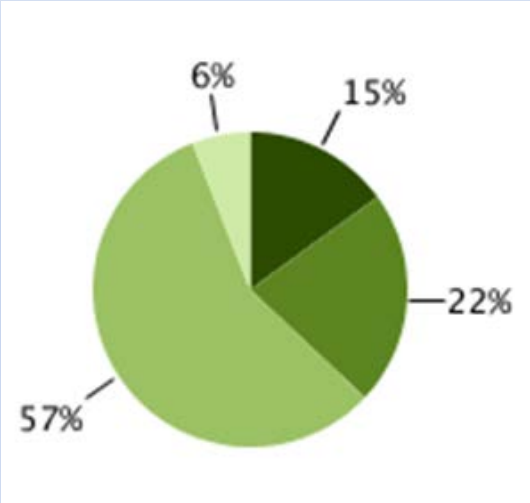
The percent of lung and bronchus cancer deaths is highest among people aged 65-74.

Median Age At Death
72 years

Source: http://seer.cancer.gov/statfacts/html/lungb.html

Stage of Diagnosis and Survival

Percent of Cases by Stage



Percent of Cases by Stage

Localized (15%)

Confined to Primary Site

Regional (22%)

Spread to Regional Lymph Nodes

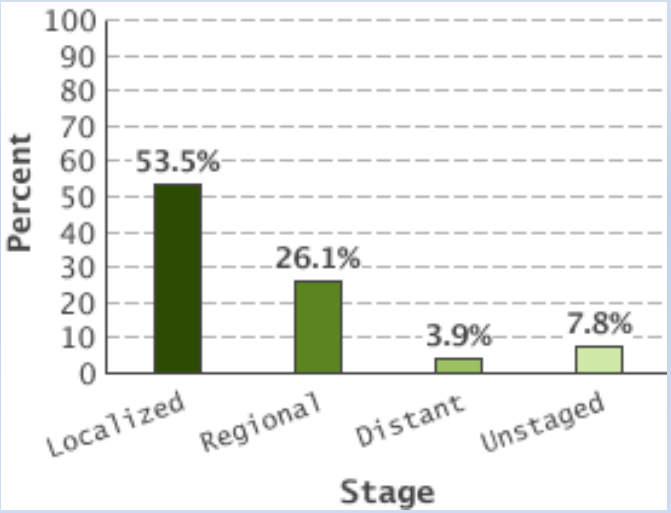
Distant (57%)

Cancer Has Metastasized

Unknown (6%)

Unstaged

5-Year Relative Survival



Source: http://seer.cancer.gov/statfacts/html/lungb.html

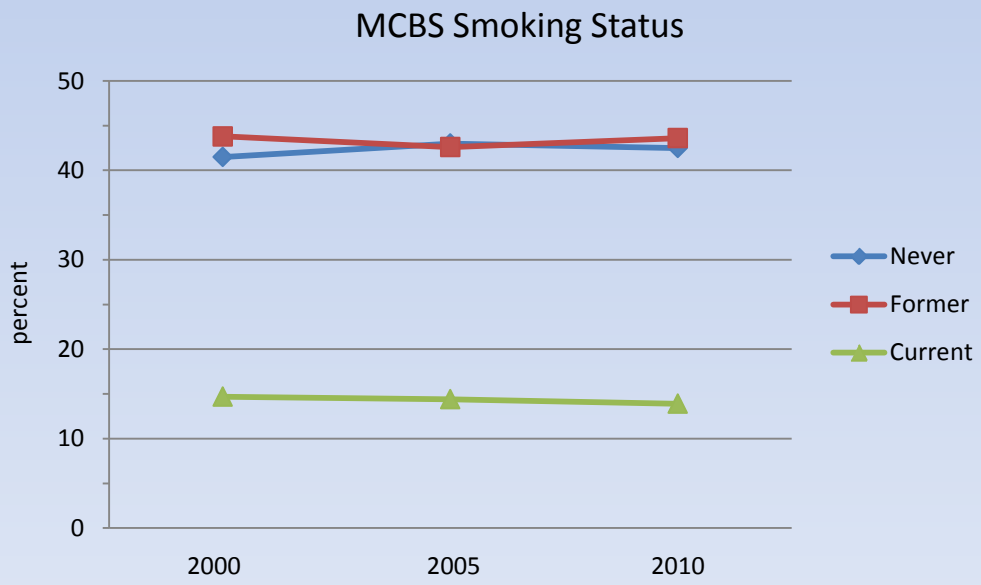
Risk Factors for Lung Cancer

- Smoking cigarettes, pipes, or cigars, now or in the past.
- Being exposed to secondhand smoke.
- Having a family history of lung cancer.
- Being treated with radiation therapy to the breast or chest.
- Being exposed to asbestos, chromium, nickel, arsenic, soot, or tar in the workplace.
- Being exposed to radon in the home or workplace.
- Living where there is air pollution.
- Being infected with the human immunodeficiency virus (HIV).
- Using beta carotene supplements and being a heavy smoker.

Source: http://seer.cancer.gov/statfacts/html/lungb.html

Current and Former Smokers in Medicare

- Medicare Current Beneficiary Survey, 2011
  - Never smoked: 42%
  - Former smoker: 44%
  - Current smoker: 14%



Lung Cancer Screening Tests

- Chest radiography
  - no strong evidence of long term health benefits; not recommended.
- Low dose computed tomography
  - initial screening studies showed LDCT could detect lung cancer at an earlier stage but did not conclusively show mortality benefits.
  - National Lung Screening Trial (NLST, 2011) showed that "[s]creening 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.

National Lung Screening Trial Research Team, Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, Gareen IF, Gatsonis C, Marcus PM, Sicks JD. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med. 2011 Aug 4;365(5):395-409. doi: 10.1056/NEJMoa1102873. Epub 2011 Jun 29.

Medicare History

- Established by the Social Security Act of 1965, Title XVIII

Photo courtesy of LBJ Presidential Library.

- "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"

Medicare Coverage of Preventive Services

- Balanced Budget Act of 1997
  - screening mammography, screening Pap, colorectal cancer screening
- Medicare Prescription Drug, Improvement and Modernization Act of 2003
  - initial preventive visit, cholesterol-lipid screening, diabetes tests
- Medicare Improvements for Patients and Providers Act (MIPPA) of 2008
  - authority to add preventive services

Improvements to Coverage of Preventive Services

MIPPA, Section 101 – Additional preventive services if the Secretary [HHS] determines through the national coverage determination process that the services meet 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 (USPSTF).
- Appropriate for individuals entitled to benefits under Medicare Part A or enrolled under Medicare Part B.

USPSTF Recommendation 2013

"Annual screening for lung cancer with low-dose computed tomography in adults ages 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery. Grade: B recommendation."

Grade B = "The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial."

http://www.uspreventiveservicestaskforce.org/uspstf/uspslung.htm

Implementation Issues

"[T]he NLST was conducted at a variety of medical institutions, many of which are recognized for their expertise in radiology and in the diagnosis and treatment of cancer. It is possible that community facilities will be less prepared to undertake screening programs and the medical care that must be associated with them. For example, one of the most important factors determining the success of screening will be the mortality associated with surgical resection, which was much lower in the NLST than has been reported previously in the general U.S. population (1% vs. 4%)."

National Lung Screening Trial Research Team, Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, Gareen IF, Gatsonis C, Marcus PM, Sicks JD. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med. 2011 Aug 4;365(5):395-409. doi: 10.1056/NEJMoa1102873. Epub 2011 Jun 29.

Voting Questions

1. How confident are you that there is adequate evidence to determine if the benefits outweigh the harms of lung cancer screening with LDCT (CT acquisition variables set to reduce exposure to an average effective dose of 1.5 mSv) in the Medicare population?

1	—	*2*	—	*3*	—	*4*	— *5*
Low				*Intermediate Confidence*			*High*

If at least intermediate confidence (score ≥ 2.5 above),

a. how confident are you that there is adequate evidence to determine that screening in asymptomatic high risk adults over 74 years of age improves health outcomes?
b. how confident are you that there is adequate evidence to determine that annual screening beyond 3 annual LDCT screens improves health outcomes?
c. how confident are you that there is adequate evidence to determine that a lung cancer screening program implemented outside a clinical study improves health outcomes?

Voting Questions

2. How confident are you that the harms of lung cancer screening with LDCT (average effective radiation dose of 1.5 mSv) if implemented in the Medicare population will be minimized?

1	—	*2*	—	*3*	—	*4*	— *5*
Low				*Intermediate Confidence*			*High*

Discussion: What harms are likely to be relevant in the Medicare population, including (a) harms from the LDCT itself , (b) harms from follow-up diagnostic evaluation of findings in the lungs and incidental findings outside the lungs, and (c) harms from treatment arising from positive and false positive results? What provider and facility criteria or protocols are helpful in minimizing harms?

Voting Questions

3. How confident are you that clinically significant evidence gaps remain regarding the use of LDCT (average effective dose of 1.5mSv) for lung cancer screening in the Medicare population outside a clinical trial?

1	—	*2*	—	*3*	—	*4*	— *5*
Low				*Intermediate Confidence*			*High*

Discussion: If there is at least intermediate confidence (score ≥ 2.5 above), please discuss any significant gaps identified and how CMS might support their closure.

Additional Discussion Question

Please discuss whether these or other topics should be considered for further research in the beneficiary population. If yes, why?

i. Risk factors/criteria for eligibility of screening asymptomatic individuals.
ii. Frequency and duration of testing.
iii. What impact will adherence have on lung cancer detection (National Lung Screening Trial adherence was 95%)?
iv. Definition of a positive screen and variability of false positives and how false positives should be resolved.
v. The rate, classification and standard evaluation of incidental findings?
vi. Impact of lung cancer screening on smoking cessation rates?

Backup Slides

Definitions

- Sensitivity - proportion of persons with disease who have a positive test
- Specificity - proportion of persons without disease who have a negative test
- False negative rate - proportion of persons with disease who have a negative test
- False positive rate - proportion of persons without disease who have a positive test
- Positive predictive value - proportion of persons with disease among those with a positive test
- Negative predictive value - proportion of persons without disease among those with a negative test
- Number needed to screen - number of persons who would need to be screened to identify one person with the disease.

Criteria for Screening

- Wilson JMG, Jungner G. Principles and Practice of Screening for Disease. World Health Organization, 1968.
  - The condition being screened for should be an important health problem
  - The natural history of the condition should be well understood
  - There should be a detectable early stage
  - Treatment at an early stage should be of more benefit than at a later stage
  - A suitable test (highly sensitive, highly specific, etc.) should be devised for the early stage
  - The test should be acceptable
  - Intervals for repeating the test should be determined
  - Adequate health service provision should be made for the extra clinical workload resulting from screening
  - The risks, both physical and psychological, should be less than the benefits
  - The costs should be balanced against the benefits

http://whqlibdoc.who.int/php/WHO_PHP_34.pdf

USPSTF Lung Cancer Screening Recommendation 2004

The USPSTF concluded "that the evidence is insufficient to recommend for or against screening asymptomatic persons for lung cancer with either low-dose computerized tomography (LDCT), chest x-ray (CXR), sputum cytology, or a combination of these tests. This is a grade I recommendation."

U.S. Preventive Services Task Force. Lung cancer screening: recommendation statement. Ann Intern Med. 2004 May 4;140(9):738-9.

USPSTF Grade Definitions

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm#brec

Tobacco Use Cessation Services

Since 2005, Medicare Part B has covered 2 cessation attempts per year. Each attempt may include a maximum of 4 intermediate or intensive face to face counseling sessions, with the total annual benefit covering up to 8 sessions in a 12-month period.