CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare Evidence Development Consensus Advisory Committee
Lung Cancer Screening with Low Dose CT

April 30, 2014

Laurie Fenton Ambrose
President & CEO

LUNG CANCER ALLIANCE

Disclosures and Conflicts of Interest

I have no personal conflicts to disclose.

Lung Cancer Alliance received the following grants:

Siemens Healthcare USA - $80,000 in FY 2013 for Give A Scan, a web-based patient donated and open access research program.

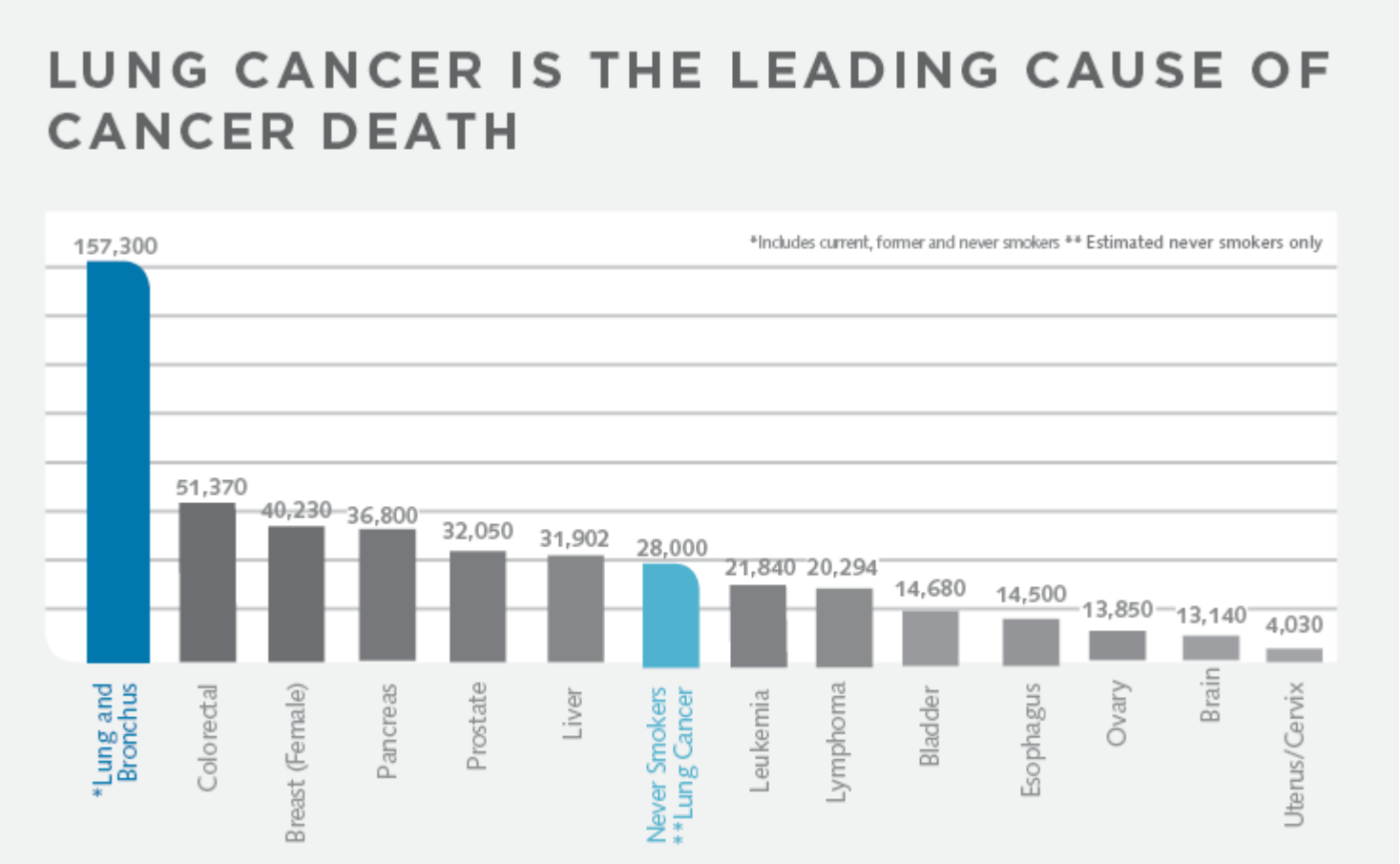
Covidien/SuperDimension - $60,500 in FY 2014 for patient education and support program; $1,803 in FY 2011 unrestricted grant; $115,000 between 2008-2010 for patient education and support program.

GE Healthcare - $195,000 between 2005-2008 in unrestricted grants

Lung Cancer Alliance

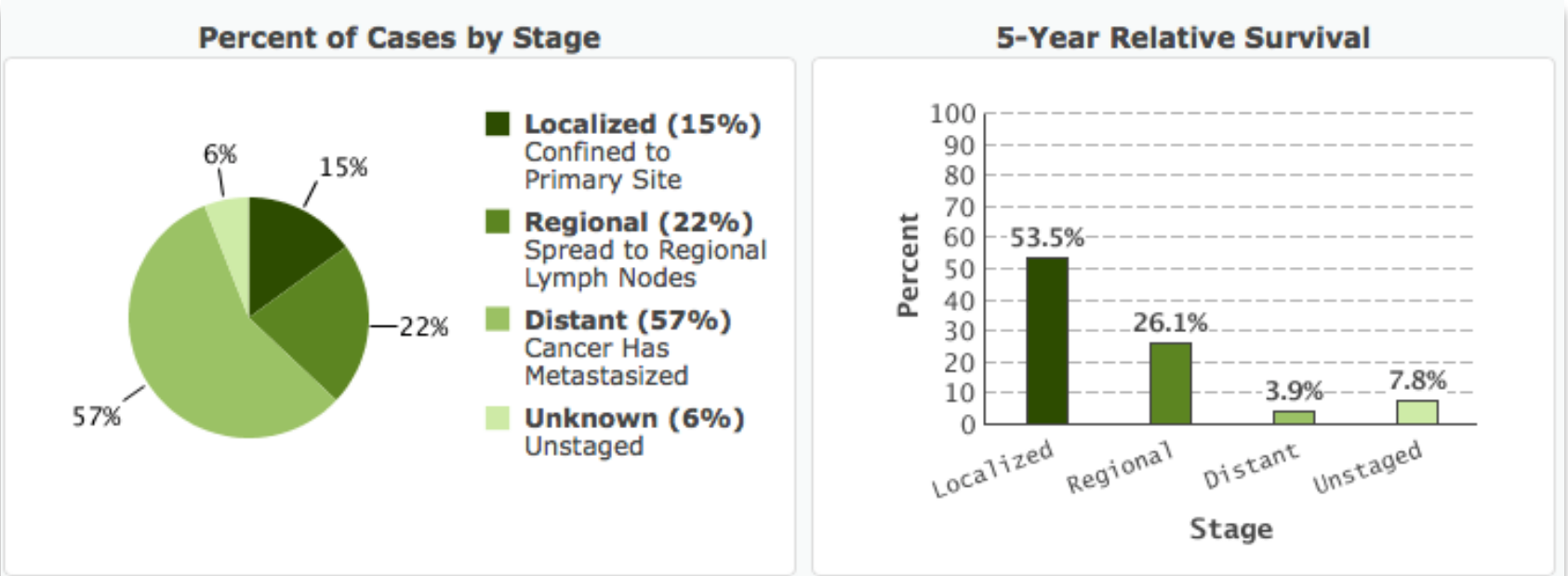
- Leading organization dedicated to saving lives and advancing research by empowering those living with or at risk for lung cancer.
- Offering personalized support, information and referral services at no cost through a team of trained, dedicated staff members to help patients, their loved ones and those at risk.
- Advocate for increased lung cancer research funding and equitable access, coverage and reimbursement for screening, treatment, diagnostics and testing.
- Conduct nationwide education campaigns about the disease, risk and early detection.

Impact: 27.5% of All Cancer Deaths



The Heart of the Issue: Only 15% Diagnosed at Early Stage

Lung Cancer Screening Can Change This

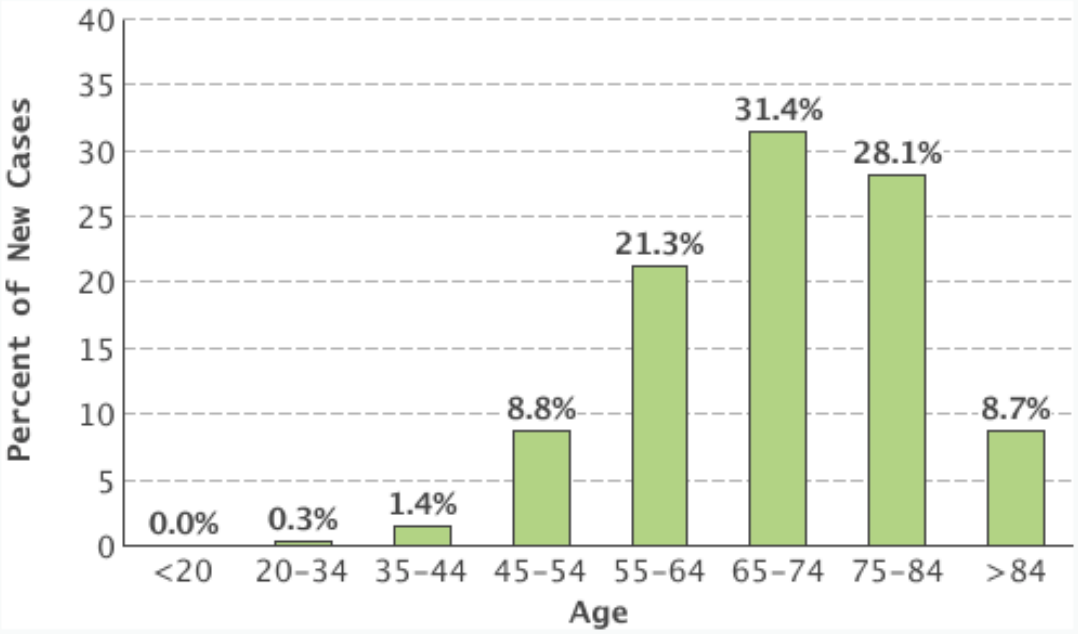


SEER 18 2003-2009, All Races, Both Sexes by SEER Summary Stage 2000

Impact: On Medicare Aged Population

Expeditious Action: "Reasonable and Necessary"… and Warranted

Percent of New Cases by Age Group: Lung and Bronchus Cancer



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

Median Age At Diagnosis

70

SEER 18 2006-2010, All Races, Both Sexes

LDCT Screening Has Been More Rigorously Tested and Reviewed Prior to Implementation Than Any Other Screening Method: Combined Total of Over 30 Years

- National Lung Screening Trial (NLST): The largest randomized controlled cancer trial in NCI history 53,434 participants at 33 sites over 8 years at a cost of $225M, confirmed that CT screening would reduce lung cancer deaths at a minimum of 20% with three rounds of screening.
- International Early Lung Cancer Action Program (I-ELCAP): 20 years of observational studies at 64 sites around the country half of which are community-based centers.
- National Comprehensive Cancer Network (NCCN): Rigorous evidence review and annual clinical guideline updates.
- U.S. Preventive Services Task Force (USPSTF): Two year evidence review resulting in a B grade for a population that specifically includes 55-80 year olds.

Consensus Request Co-Signed by Over 40 Multi-Society and Multi-Disciplinary Stakeholders Call for National Coverage of Lung Cancer Screening of High Risk Individuals.

LUNG CANCER ALLIANCE

The Society of Thoracic Surgeons

ACR AMERICAN COLLEGE OF RADIOLOGY
QUALITY IS OUR IMAGE

March 12, 2014

Tamara S. Syrek Jensen, J.D.
Acting Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

By Online Submission

Re: National Coverage Analysis for Lung Cancer Screening with Low Dose Computed Tomography (CAG-00439N)

Dear Ms. Syrek Jensen:

The undersigned organizations are pleased to provide a joint consensus document and comment on the National Coverage Analysis (NCA) for lung cancer screening with low dose computed tomography (LDCT). Echoing our January 10th, 2014, letter to Administrator Tavenner, our Joint Societies strongly support national coverage for lung cancer screening of high risk individuals with low dose computed tomography in light of the robust scientific evidence outlined in the United States Preventive Services Task Force's (USPSTF) final recommendation (Grade B).

RESPONSIBLE SCREENING IN PRACTICE TODAY

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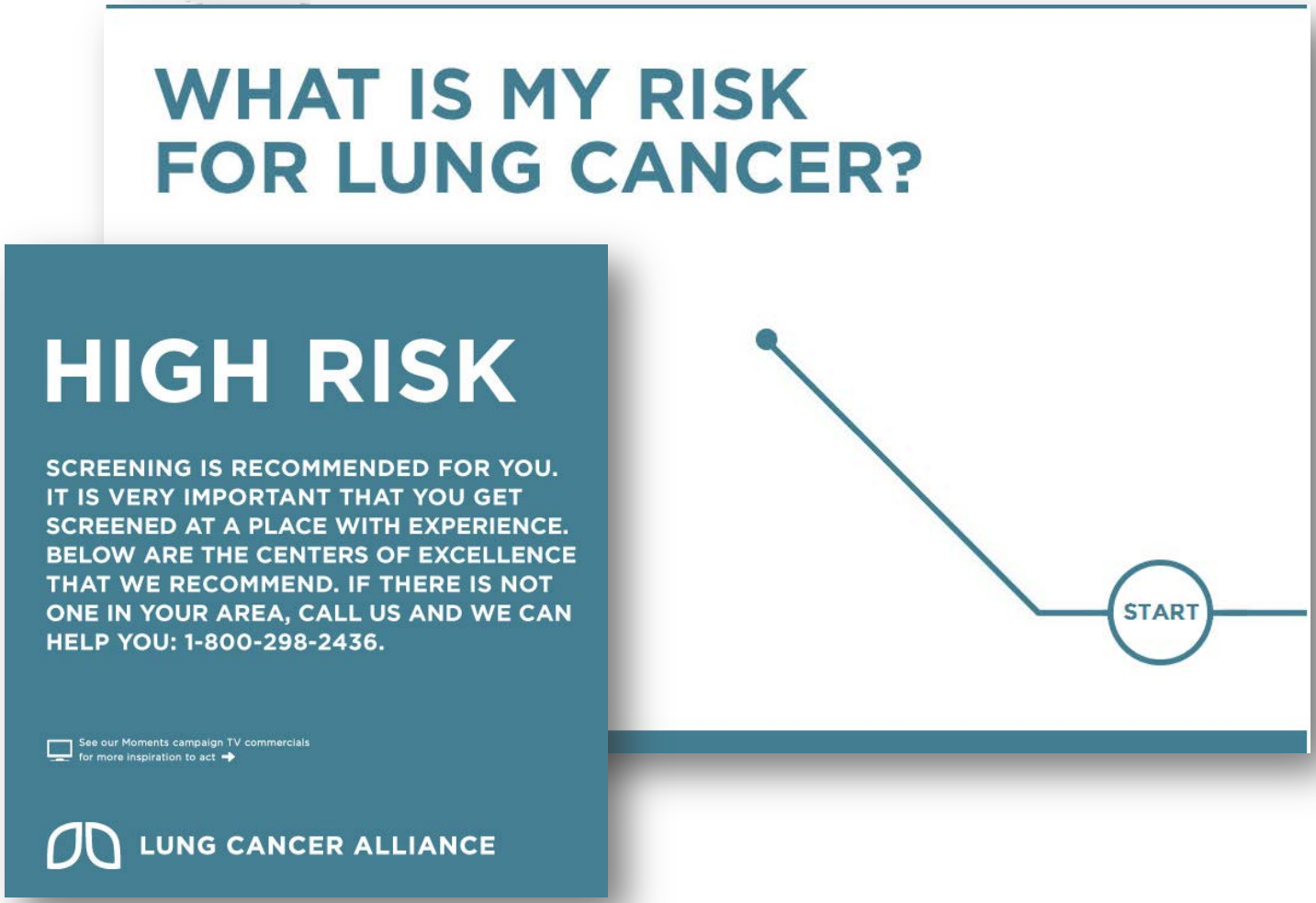
Key Elements of Responsible Screening

- Educating Those at Risk
- Implementing Best Practices
- Supporting Continuous Quality Improvements Through the Collection of Data

Educating Those At Risk: Risk Navigator and Informed Decision Making



Educating Those At Risk: Live More Moments National Campaign

Educating Those At Risk: Military Men and Women

HONORING OUR VETERANS

Offering Responsible Screening & Care for Veterans At Risk for Lung Cancer

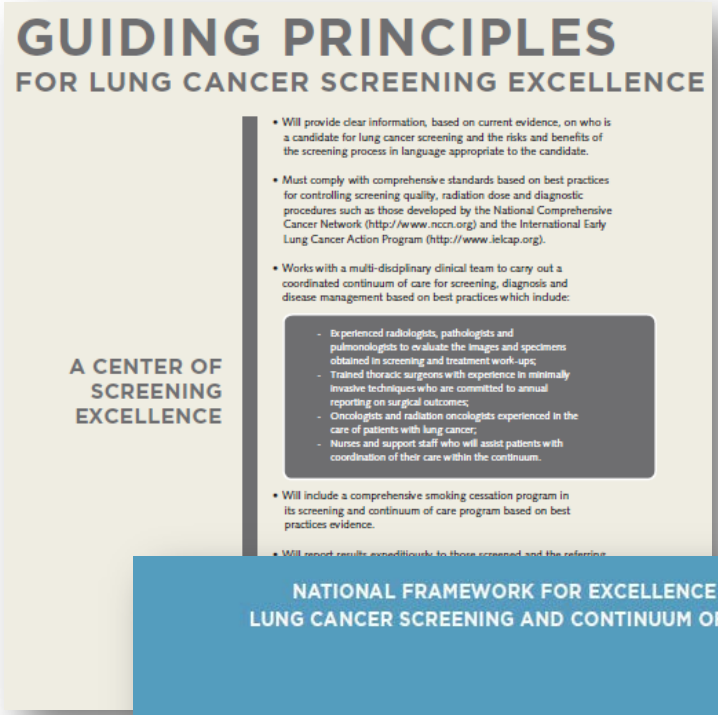
Implementation of Best Practices

High quality lung cancer screening is already being carried out safely and effectively in a variety of settings, from large metropolitan hospitals to community settings.

- NCCN Centers
- I-ELCAP Sites
- DOD and VA Centers
- Lung Cancer Alliance National Framework Centers of Excellence

The National Framework for Excellence in Lung Cancer Screening and Continuum of Care

- Launched February 2012
- Developed by LCA's Medical Advisory Board
- Three component parts:
  - Consumer bill of rights
  - Guiding principles for best practice care
  - Data collection quality improvement

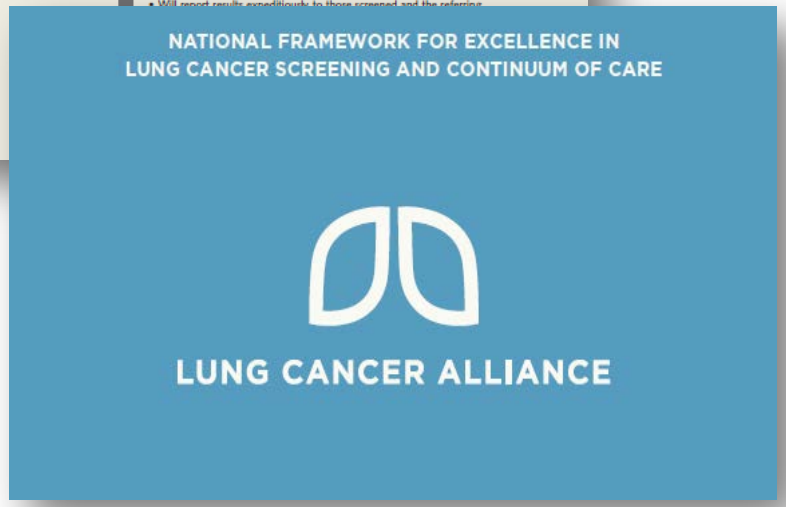


GUIDING PRINCIPLES

FOR LUNG CANCER SCREENING EXCELLENCE

A CENTER OF SCREENING EXCELLENCE

- Will provide clear information, based on current evidence, on who is a candidate for lung cancer screening and the risks and benefits of the screening process in language appropriate to the candidate.
- Must comply with comprehensive standards based on best practices for controlling screening quality, radiation dose and diagnostic procedures such as those developed by the National Comprehensive Cancer Network (http://www.nccn.org) and the International Early Lung Cancer Action Program (http://www.ielcap.org).
- Works with a multi-disciplinary clinical team to carry out a coordinated continuum of care for screening, diagnosis and disease management based on best practices which include:
  - Experienced radiologists, pathologists and pulmonologists to evaluate the images and specimens obtained in screening and treatment work-ups;
  - Trained thoracic surgeons with experience in minimally invasive techniques who are committed to annual reporting on surgical outcomes;
  - Oncologists and radiation oncologists experienced in the care of patients with lung cancer;
  - Nurses and support staff who will assist patients with coordination of their care within the continuum.
- Will include a comprehensive smoking cessation program in its screening and continuum of care program based on best practices evidence.



NATIONAL FRAMEWORK FOR EXCELLENCE IN LUNG CANCER SCREENING AND CONTINUUM OF CARE

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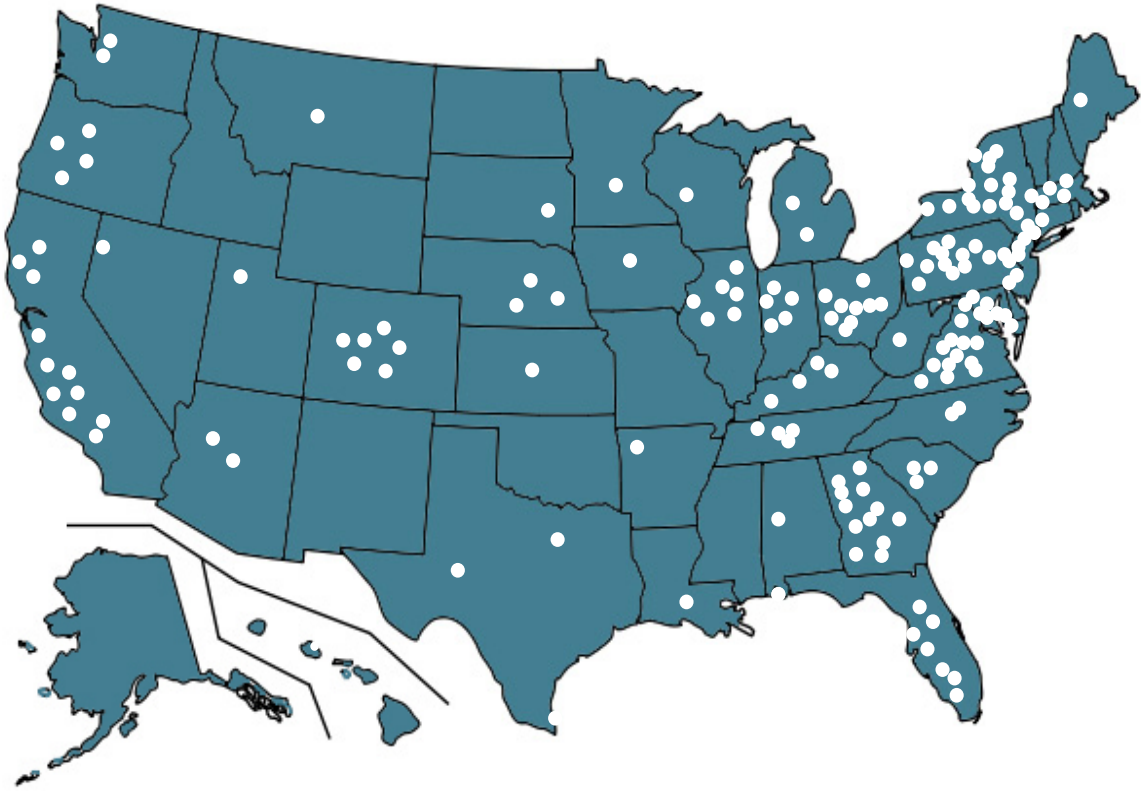
National Framework for Excellence in Lung Cancer Screening and Continuum of Care

Screening Centers of Excellence



There are 169 total screening Centers of Excellence (scalable and replicable) and 80+ in progress

Guiding Principles

- Information on risk/benefits
- Adhere to best practices
- Multidisciplinary team
- Smoking cessation
- Prompt results reporting
- Quality improvement
- Data collection available

Implementation of Best Practices: Smoking Cessation

- While nearly half of those diagnosed are former smokers, studies have shown that for those still smoking screening can improve quit rates.
- Screening provides a teachable moment to address smoking cessation and to provide the patient with a more personalized and targeted regimen to achieve success.
- As importantly, there is no evidence of an increase in rates of recidivism among those who had previously quit.
- Incorporation of smoking cessation significantly increases the cost effectiveness of lung cancer screening.

A Cost-Utility Analysis of Lung Cancer Screening and the Additional Benefits of Incorporating Smoking Cessation Interventions

Andrea C. Villanti, Yiding Jiang, David B. Abrams, Bruce S. Pyenson, published August 7, 2013, PLOS ONE

Table 2. Projected 15-year costs and quality-adjusted life years saved by lung cancer screening and treatment with and without smoking cessation using stage shifts from the NY-ELCAP and NLST in authors' actuarial model.

	NY-ELCAP stage shift	NLST stage shift
Screening		
Lung cancer screening and treatment costs	$27,824,282,242	$34,054,299,361
QALYs saved by screening and treatment	985,284	722,795
Cost per QALY saved	$28,240	$47,115
Screening + light smoking cessation intervention		
Additional costs for cessation	$1,361,556,665	$1,361,556,665
Additional QALYs saved by cessation	273,566	273,566
Cost per QALY saved	$23,185	$35,545
Screening + intensive smoking cessation intervention		
A. NRT generic plus behavioral		
Additional costs for cessation	$3,212,191,737	$3,212,191,737
Additional QALYs saved by cessation	930,754	930,754
Cost per QALY saved	$16,198	$22,537
B. Bupropion generic plus behavioral		
Additional costs for cessation	$4,088,822,965	$4,088,822,965
Additional QALYs saved by cessation	930,754	930,754
Cost per QALY saved	$16,656	$23,067
C. Chantix plus behavioral		
Additional costs for cessation	$5,342,861,783	$5,342,861,783
Additional QALYs saved by cessation	930,754	930,754
Cost per QALY saved	$17,310	$23,826

NY-ELCAP, New York Early Lung Cancer Action Project; NLST, National Lung Screening Trial; QALY, quality-adjusted life year.

doi:10.1371/journal.pone.0071379.t002

Supporting Continuous Quality Improvements: Collection and Analysis of Data Through Established Registries

Agreement by Joint Societies to coordinate and build upon existing databases to provide ongoing quality assessment and to make continuous improvements to the screening process.

The registries include but are not limited to:

- **STS** – Ongoing patient registry of surgical outcomes.
- **ACR** – Developing a structured reporting process for lung cancer imaging, which builds on over 20 years of experience with breast cancer imaging.
- **I-ELCAP** – Over 20 years of data collection and refinement of screening protocols based on data from over 60,000 individual patients and 100,000 scans with 60 participating centers around the world including community based hospitals.
- **NATIONAL FRAMEWORK** – Launching data collection and quality improvement reporting.

Example: How Coordination Has Already Improved and Refined the Screening Process

- February 2013: The publication of a I-ELCAP paper on the nodule size and malignancy based on fifteen years of structured reporting and analyses led to the recommendation of a 6mm threshold for a positive scan.

- Summer 2013: The recommendation was carefully considered and incorporated into the NCCN Clinical Guidelines.

- RESULT: The new threshold will significantly reduce the number of false positives without a significant reduction in efficacy.

ETHICS AND EQUITY

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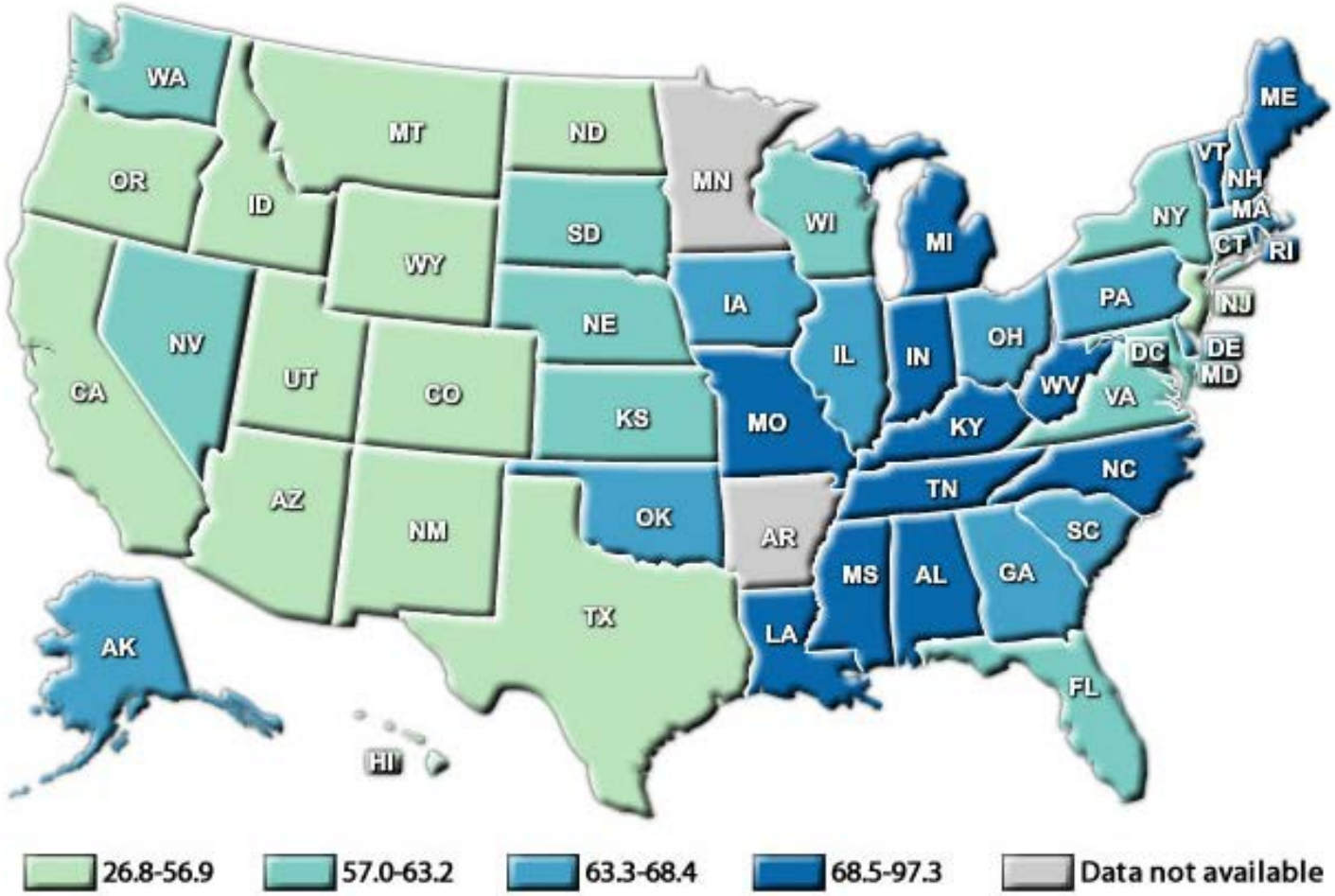
Ethics & Equity: Public Health Imperative

- Affordable Care Act makes lung cancer screening an Essential Health Benefit which means that:
  - All non-grandfathered insurance plans in the exchanges must include lung cancer screening by 2015 without co-pays or deductibles.
  - Many commercial insurers already offer the benefit to the non-Medicare population included in the USPSTF recommendation.
- Since the majority lung cancer deaths are in the Medicare population, if CMS does not cover expeditiously, this older and higher risk population will be disadvantaged.

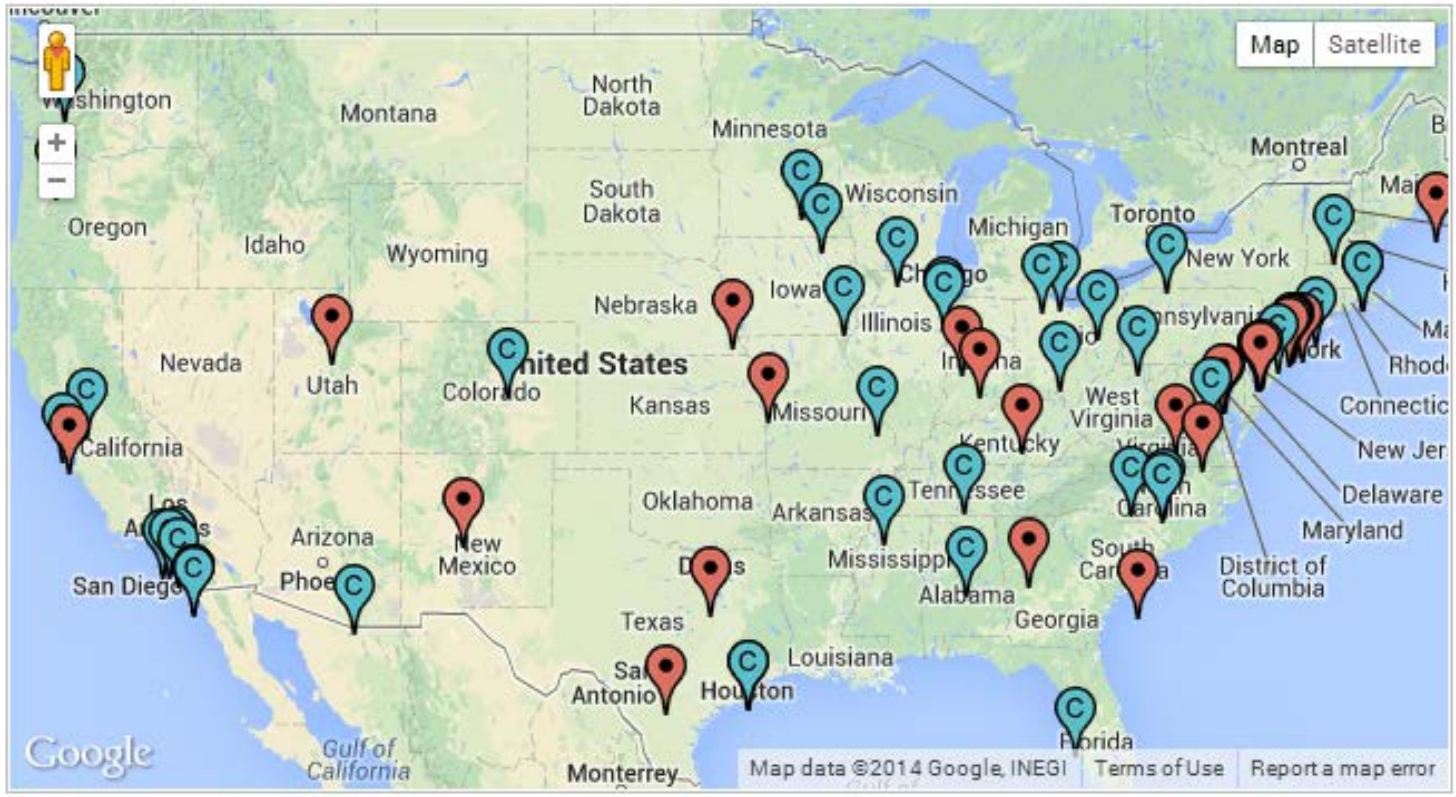
Ethics and Equity: Arbitrary Restrictions on Access

- If coverage is limited to NCI designated centers or similar sites as some have suggested, access to the life-saving benefit will not be equitably available.
  - Will be accessible primarily in coastal metropolitan areas and academic centers.
  - Will be restricted in states and sections of the country with the highest risk populations.
  - CMS would establish an unprecedented disparity of access to care.
- Rural and community centers around the country have already demonstrated that responsible screening is generalizable.

Lung and Bronchus Cancer Incidence Rates, 2010



NCI-Designated Cancer Centers



= Cancer Center 1

= Comprehensive Cancer Center 1

CLOSING THOUGHTS

Time Has Not Stood Still Since the NLST

- Lower Radiation: Exponential advances in CT scanner technology hardware and software since last screening round under the NLST in 2007 allow for higher quality imaging at lower levels of radiation exposure.
- False Positives: Refinements in protocols and adjustments in the threshold nodule size has significantly reduced false positive rates.
- Surgical Improvements and Refinements: Substantial improvements in surgical techniques, including training, experience and facilities that allow performance of minimally invasive surgery (VATS/Robotic), have improved outcomes, reduced complications and reduced hospital stays.

Lung Cancer Screening Will Save Thousands of Lives

- Yes, there are risks. All screening carries risk.
- But for smokers and former smokers the relative risk of being harmed by lung cancer screening is negligible – when compared to the risk of dying from lung cancer.
- There is no other proven way to find and detect lung cancer at early stage, when it is most treatable and even curable.

THANK YOU

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