May 3, 2013

James L. Mulshine, MD

Dean (Acting)
Graduate College
Associate
Provost for
Research

RUSH UNIVERSITY
MEDICAL CENTER

IT'S HOW MEDICINE

SHOULD BE





## Disclosures 12/11

- Board of Trustees: Lung Cancer Alliance & Prevent Cancer Foundation
- Scientific Advisory Board to I-ELCAP, Roy Castle Foundation, Biodesign Institute, Arizona State U and Illinois Institute of Technology, Associate Council, U of C Inst of Translatl Med
- Chair, MD Anderson DOD External Review Committee for lung cancer research
- Member and National Steering Committee, Quantitative Biomarker Alliance, RSNA; Prevention Committee, IASLC & ASCO
- Consultant to NHRI, UK, Collaborator European Institute, Milan
- I have no financial relationships to disclose
- I will discuss the following investigational use in my presentation: lung cancer screening

Workshop X is a pre-competative forum addressing public health issues in improving lung cancer and related outcomes thru Quantitative Imaging



25 Years of progress through prevention

#### AND A SPECIAL THANKS ALSO GOES TO THE

## **WORKSHOP X SPONSOR**

Carolyn R. "Bo" Aldigé

Prevent Cancer Foundation

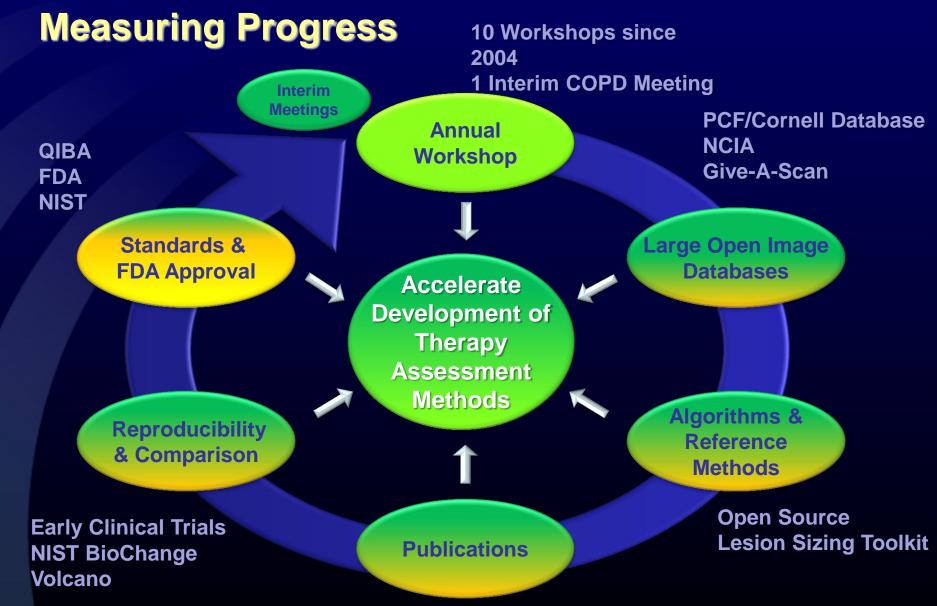
## STEERING COMMITTEE

#### Chair:

- James L Mulshine, Rush University Members:
  - Laurie Fenton Ambrose

Lung Cancer Alliance

- Ricardo S. Avila *Kitware, Inc.*
- Thomas M. Baer Stanford Photonics Research Center
- Raul San Jose Estepar
   Brigham and Women's Hospital
- David F. Yankelevitz
   Mount Sinai Medical Center







## **Why Cost Benefit Matters**

- USPSTF grades cancer screening services based on strength of evidence for clinical benefit and cost efficiency (http://www.uspreventiveservicestaskfo rce.org/uspstf/grades.htm).
- Only Grade A or B is reimbursed by Medicare (http://www.healthcare.gov/law/features /rights/preventive)



## **Workshop X**

- Suppose USPSTF recommend spiral CT (B recommendation)
  - are we ready for national implementation?
  - If LD CT is to be implemented, how do we optimize evaluation of nodules to reduce overdiagnosis—a role for phantoms?
- How do we optimize the yield of clinically useful information from a LD CT study?
- What can we accomplish now?
  - Role of the Two Breakout Groups
    - Policy or Imaging Considerations



## Improve Diagnostic Work-up

- NELSON published diagnostic work up efficiency in NEJM and found a sensitivity of 95%, specificity of 99% using a Siemens Lung Care volume measurement tool to implement the nodule growth criteria proposed by I-ELCAP\*
- I-ELCAP (Toronto) use a nodule growth criteria to separate clinically significant from nonmalignant behaving nodules using quantitative imaging (filter for overdiagnosis)^
- RSNA (QIBA) is defining imaging protocols and QC/QS criteria to ensure robust measurements

\*van Klaveren RJ et al NEJM, 2009

^Wagnetz et al AJR, 2012



## **Moving To Rapid Learning**

 Institute of Medicine (IOM) Roundtable suggested that a new clinical paradigm be developed that takes better advantage of data generated in the course of healthcare delivery which would speed and improve the development of evidence for real-world decision making for complex management processes

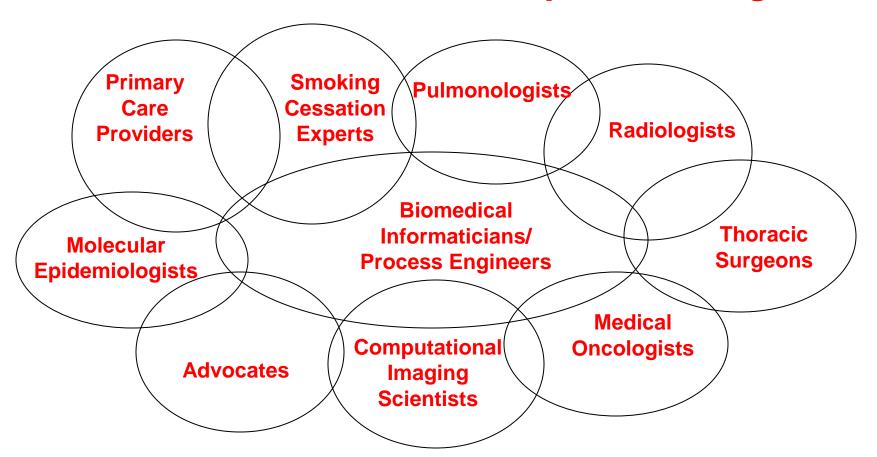
### **Conclusion:**

 Congruence on refining components of the screening process could accelerate progress with improving screening management outcomes



## "Framework": Screening as a Process

## Chain of Care & Research as a Rapid Learning Matrix

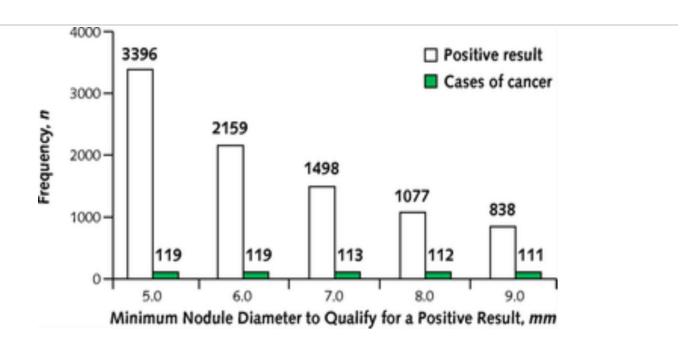


I-ELCAP 73 Institutions with 60,869 Participants and 131,942 CT scans





# From: Definition of a Positive Test Result in Computed Tomography Screening for Lung Cancer: A Cohort Study



Frequency of a positive result and cases of lung cancer diagnosed within 12 mo of baseline enrollment.

Ann Intern Med. 2013;158(4):246-252



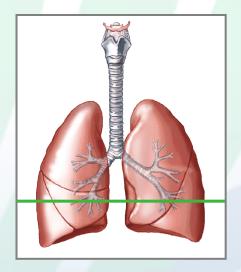
## **Improving Public Policy**

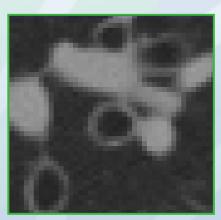
- Challenge with over reliance on RCT
  - Concern with external validity—evidence from "there, then applied over "here"
  - methodological conclusions from evidence-based clearing house difficult to apply in real world settings
- Challenges in communicating academic concepts through the filter of the political process
- Suggests better characterization of the provenance of the data in justifying a policy recommendation
- Tension between science and politics in defining health policy

Brian Baird, Book Review, Science 340:432-3, 2013

# **COPD** and Lung Cancer

- Common Technical Challenges
  - Gathering Large Clinical Datasets
    - Open image archives
    - Along with additional metadata
  - Common Data and Analysis Methods
    - High resolution CT
    - Spirometry (LC Risk)
  - Common Phantom Goals
    - Image Acquisition Quality and Repeatability
- How can we leverage the common work we are doing?
  - Imaging Datasets
  - Source Code
  - Anatomical Models
  - Phantoms & Findings





## If Lung CA Saves Lives, What Next?

- NLST reported a 20.3% reduction compared to CXR arm (NCI website)
- Long-term follow up from NY-ELCAP associated with a 36%, 64% mortality reduction compared to CPS or CARET outcomes (Henschke et al Cancer, 2011)
- CISNET Modeling of NY-ELCAP outcomes suggested 46% mortality (Foy et al Cancer, 2011)
- USPSTF is proposing to use modeling to develop their LD CT recommendation

How to responsibly move from research to public health?



## Consider

- Implement screening such as proposed by the Screening "Framework"
- Use optimized imaging protocol for LDCT"
  - "Rapid Learn" COPD in standardized pilot
  - "Rapid Learn" Calcium scores in standardized pilot
  - Consider piloting thoracic spine density and adiposity measure
- Evaluate new disease site screening by rapid learning principles to provide evidence for eventual inclusion as clinically actionable data



## **Further Consider**

- In post ACA world of capitated care, why is LDCT not developed as a normative health evaluation tool at least in tobacco smokeexposed populations
- Preventive care for major chronic diseases in this population is anchored by dynamic changes in serial data provided by integrated quantitative assessment of periodic CT screening data
- This periodic health encounter bundles coaching on smoking cessation along with other health and wellness information into an efficient ambulatory encounter