

The Path Forward for Lung Cancer Screening

**Prevent Cancer Foundation Lung Cancer
Workshop IX**

**Hyattsville, MD
03 May 2012**

**Robert A. Smith, Ph.D.
American Cancer Society**

The Top Ten Locations for Lung Imaging Workshops, and Overdiagnosis in Lung Cancer Screening

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Disclosure

- I have no conflicts to disclose

Today, Three Positions on the Introduction of Lung Cancer Screening are Evident Around the Globe

1. Current evidence is **insufficient** to meet the evidence-based requirements of *all* relevant parties necessary to establish screening policy and practice.
2. Current evidence is **sufficiently persuasive** of the ability to detect lung cancers at early curable stages, *but there is uncertainty about the potential and how to begin.*
3. **We know enough.... *Full speed ahead!***

Screening: The Real Thing....*or Just Going Through the Motions*

- It is quite easy to screen the population and achieve mediocre outcomes..., or worse
- Poor performance, or highly variable performance, in screening not only fails to fulfill the potential of early detection for those with the disease:
 - it wastes resources;
 - it causes excess harms in people without cancer *and* with cancer;
 - it creates cynicism among related health professionals;
 - *it provides skeptics and pseudo-skeptics with evidence to argue against screening.*

Elements of a Successful Screening Program

- Participation by the target population
- Participation by health care providers
- Adherence with recommendations, *especially* the screening interval
- Adherence to quality assurance standards

Elements of a Successful Screening Program (continued)

- Timely and thorough follow-up of positive tests
- State of the art treatment
- A comprehensive surveillance system to measure program performance, *with feedback to participants*



While planning for the implementation of lung cancer screening, what lessons can be learned from the experience of screening for other cancers?

Evolution in the Guidelines Process

- Compared with guidelines a decade ago....
 - More emphasis on the balance of benefits and harms
 - More emphasis on modeling, and a preference for modeling vs. observational studies (specifically USPSTF)
 - More emphasis on meta-analysis (USPSTF)
 - More emphasis on cost-effectiveness (NNT, NNS, \$)
 - More emphasis on the importance of informed decisions

Guidelines for Lung Cancer Screening in the U.S.

- American Cancer Society (interim guidance)
- National Comprehensive Cancer Network
- American Lung Association
- Joint Guidelines from American College of Chest Physicians & ASCO (in press)
- United States Preventive Services Task Force (in progress)

Guidelines are important, but commonly are unknown or ignored

- Physician awareness of guidelines and adherence with guidelines is poor
- **Key Point — Small differences in guidelines can result in inertia among primary care physicians**
- **Differences can be explained by:**
 - Different orientation towards risk
 - Different orientation towards evidence
 - Different methodology in estimating benefit vs. harms
 - Timing



Communication with the Target Audience

- The target population generally does not fully understand screening, including the requirements, benefits, limitations, and potential harms. This leads to:
 - Failure to adhere to screening protocols, including both under- and over- screening
 - Both unrealistically *low* and *high* expectations
 - Little understanding that screening evolves with the evolution of evidence
 - Expectations among critics of screening that *the target population should adopt a defensive, consumerist position about testing for early detection*

Educating the Population

- This is more difficult than it would seem
- Conventional strategies (i.e., mass media, print materials, etc.) have some, but limited impact
- Tailored strategies...(1) generally delivered in the clinical setting, (2) at a time when the information is relevant, tend to work best

The Role of Referring Clinicians, usually the Primary Care Provider

- Depending on the national context, GPs have a role on gate keeping, or information transfer, or both, including:
 - Risk assessment
 - Shared decision making
 - Referral to screening
 - Reminders for repeat screening
 - Managing positive findings
- Commonly, *they are poorly prepared for these roles*
- It also is a challenge for them to fulfill this role given competing priorities in a high volume sick care oriented system

U.S. Primary Care MD's Lung Cancer Screening Beliefs and Recommendations

U.S. Primary Care Physicians' Lung Cancer Screening Beliefs and Recommendations

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Background: No high-quality study to date has shown that screening reduces lung cancer mortality, and expert groups do not recommend screening for asymptomatic individuals. Nevertheless, lung cancer screening tests are available in the U.S., and primary care physicians (PCPs) may have a role in recommending them to patients.

Purpose: This study describes U.S. PCPs' beliefs about and recommendations for lung cancer screening and examines characteristics of PCPs who recommend screening.

Methods: A nationally representative survey of practicing PCPs was conducted in 2006–2007. Mailed questionnaires were used to assess PCPs' beliefs about lung cancer screening guidelines and the effectiveness of screening tests and to determine whether PCPs would recommend screening for asymptomatic patients. Data were analyzed in 2009.

Results: Nine hundred sixty-two PCPs completed the survey (absolute response rate=70.6%; cooperation rate=76.8%). One quarter said that major guidelines support lung cancer screening. Two thirds said that low-radiation dose spiral computed tomography (LDCT) screening is very or somewhat effective in reducing lung cancer mortality in current smokers; LDCT was perceived as more effective than chest x-ray or sputum cytology. Responding to vignettes describing asymptomatic patients of varying smoking exposure, 67% of PCPs recommended lung cancer screening for at least one of the vignettes. Most PCPs recommending screening said they would use chest x-ray; up to 26% would use LDCT. In adjusted analyses, PCPs' beliefs and practice style were strongly associated with their lung cancer screening recommendations.

Conclusions: Many PCPs' lung cancer screening beliefs and recommendations are inconsistent with current evidence and guidelines. Provider education regarding the evidence base and guideline content of lung cancer screening is indicated.

(Am J Prev Med 2010;39(5):411–420) Published by Elsevier Inc. on behalf of American Journal of Preventive Medicine

Introduction

More deaths in the U.S. are caused by lung cancer than by cancers of the breast, prostate, and colon and rectum combined.^{1,2} The 5-year survival rate for lung cancer, 16%, is substantially lower than those for breast (89%); prostate (99%); and colorectal cancer (64%).³ Because of the propensity to diagnose lung cancer at a late stage, the high mortality from the disease, and the U.S.' large population of former and current smokers, there is periodic debate about the utility of screening patients for lung cancer.^{4–7} Lung cancer screening, however, is highly controversial. Chest x-ray and sputum cytology were studied as screening tests in RCTs in the 1970s and 1980s,^{8,9} but those tests were not shown to significantly reduce lung cancer mortality.

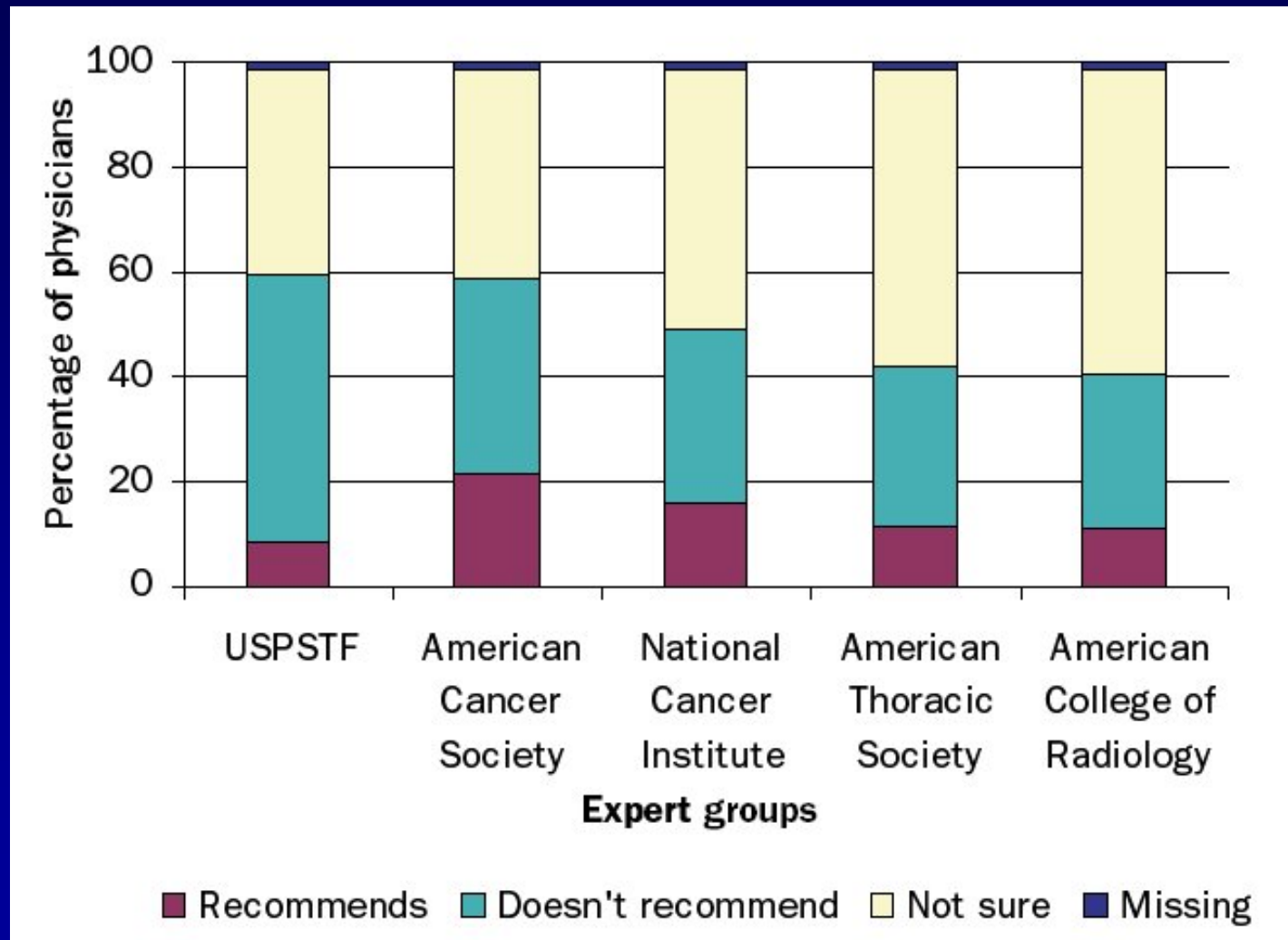
The recent introduction of low radiation–dose spiral computed tomography (LDCT) has sparked renewed interest in

- Nationally representative mailed survey of practicing PCPs was conducted in 2006 –2007.
- 962 PCPs completed the survey
- Response rate = 70.6%
- 68% reported that > 1 patient had inquired about lung cancer screening

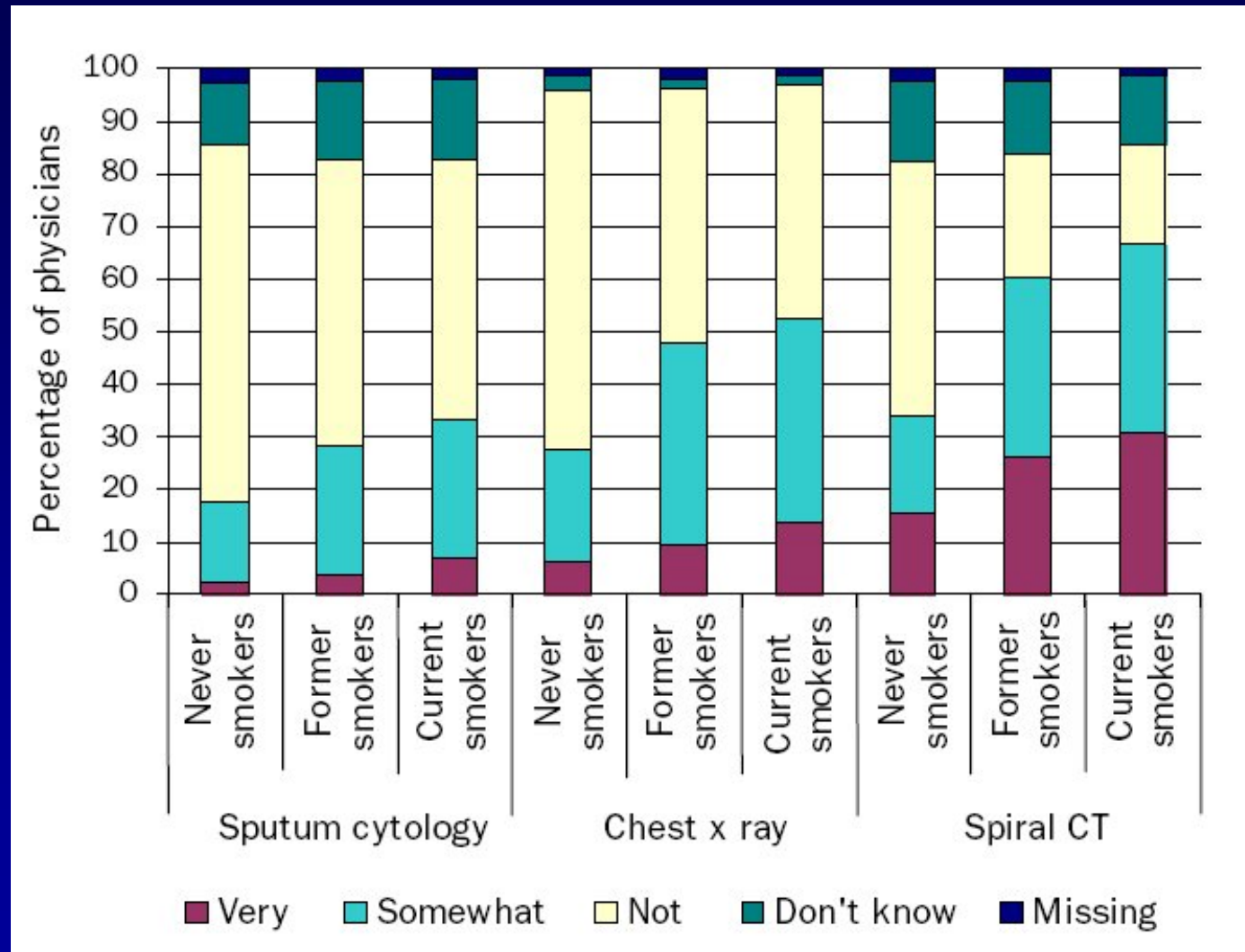
From the Applied Research Program, Division of Cancer Control and Population Sciences (Klabunde, Han, S. Marcus), Division of Cancer Prevention (P. Marcus), National Cancer Institute, Bethesda, Maryland; Division of Cancer Prevention and Control (Richards), Centers for Disease Control and Prevention, Atlanta, Georgia; Information Management Services, Inc. (Yuan), Silver Spring, Maryland; Division of Pulmonary and Critical Care Medicine (Silvestri), Medical University of South Carolina, Charleston, South Carolina; Division of Health Promotion and Behavioral Sciences (Vernon), University of Texas School of Public Health, Houston, Texas.

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Primary care provider beliefs about the lung cancer screening recommendations of expert groups



Perceived effectiveness of tests to screen for lung cancer, by patients' smoking status

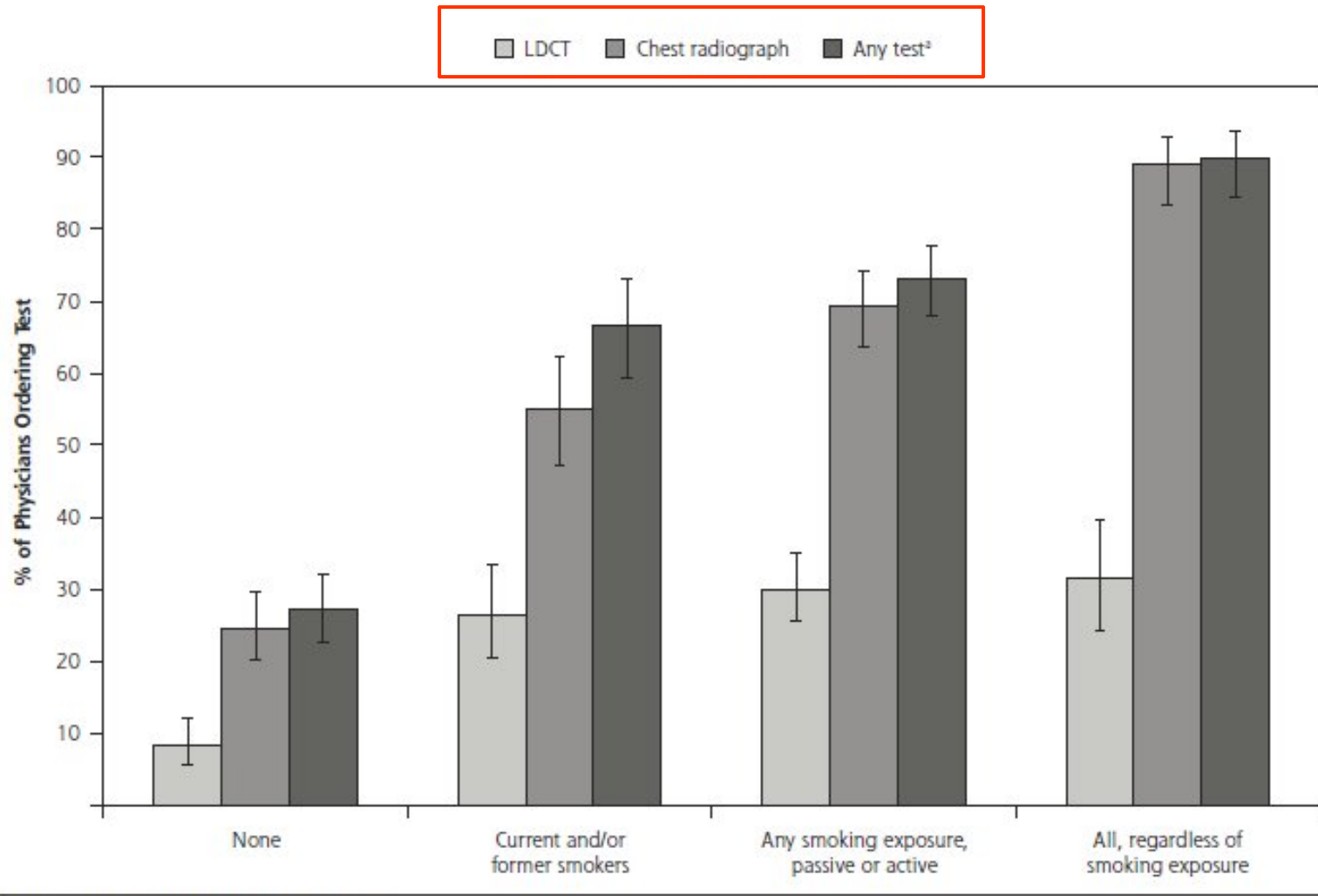


Primary care physicians' recommendations for lung cancer screening, by patients' smoking status

Vignette	% Recommending Screening
Healthy never smoker aged 50 years	17.4
Healthy never smoker aged 50 years with smoking spouse	48.3
Otherwise healthy former smoker aged 50 years with 20 pack-year history who quit smoking 15 years ago	52.8
Otherwise healthy former smoker aged 50 years with 20-packyear history who quit smoking 1 year ago	63.8
Otherwise healthy current smoker aged 50 years who has smoked 1 pack of cigarettes per day for 20 years	66.3

Source: Am J Prev Med 2010;39(5)411–4

Percentage of primary care physicians who ordered lung cancer screening tests by types of patients



LDCT = low-dose spiral computed tomography.

Note: Brackets indicate 95% CIs.

^a Chest radiograph, sputum cytology, or LDCT.

Lung Cancer Screening and the Primary Care Provider

Lung Cancer Screening Practices of Primary Care Physicians: Results From a National Survey

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Conflicts of interest: authors report none.

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ABSTRACT

PURPOSE Although current practice guidelines do not recommend screening asymptomatic patients for lung cancer, physicians may still order lung cancer screening tests. No recent national survey of health care professionals has focused on lung cancer screening. In this study, we examined the lung cancer screening practices of US primary care physicians and characteristics of those who order lung cancer screening tests.

METHODS We conducted a nationally representative survey of practicing primary care physicians in 2006-2007. Mailed questionnaires assessed the physicians' knowledge of lung cancer screening guidelines, beliefs about the effectiveness of screening tests, and ordering of screening chest radiograph, low-dose spiral computed tomography, or sputum cytology in the past 12 months. Clinical vignettes were used to assess the physicians' intentions to screen asymptomatic 50-year-old patients with varying smoking histories for lung cancer.

RESULTS A total of 962 family physicians, general practitioners, and general internists completed questionnaires (cooperation rate = 76.8%). Overall, 38% had ordered no lung cancer screening tests; 55% had ordered chest radiograph, 22% low-dose spiral computed tomography, and less than 5% sputum cytology. In multivariate modeling, physicians were more likely to have ordered lung cancer screening tests if they believed that expert groups recommend lung cancer screening or that screening tests are effective; if they would recommend screening for asymptomatic patients, including patients without substantial smoking exposure; and if their patients had asked them about screening.

CONCLUSIONS Primary care physicians in the United States frequently order lung cancer screening tests for asymptomatic patients, even though expert groups do not recommend it. Primary care physicians and patients need more information about lung cancer screening's evidence base, guidelines, potential harms, and costs to avert inappropriate ordering.

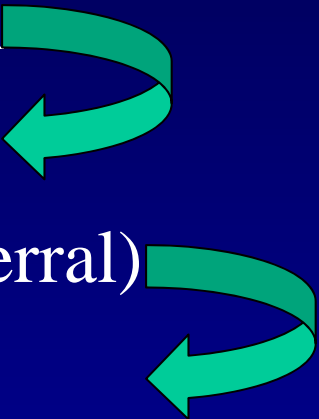
Ann Fam Med 2012;10:102-110. doi:10.1370/afm.1340.

INTRODUCTION

Lung cancer is the leading cause of cancer death in the United States,^{1,2} with a 5-year survival rate (16%) that is substantially lower than that for other common cancers.³ Despite periodic debate about the utility of screening patients for lung cancer,⁴⁻⁷ no randomized controlled trial has demonstrated that screening with chest radiograph or sputum cytology reduces mortality from lung cancer.⁸⁻¹¹ In the United States, a large, randomized controlled trial comparing chest radiograph vs usual care has completed accrual, results assessing impact on lung cancer mortality are expected in late 2015.¹² A second large, randomized controlled trial comparing low-dose spiral computed tomography (LDCT) vs chest radiograph in current and former heavy cigarette smokers, the National Lung

- “Our results showing gaps in primary care physicians’ knowledge of lung cancer screening and use of unproven screening modalities suggest that in the United States—where most cancer screening occurs opportunistically rather than through organized programs”
- This means that there is real potential for both underscreening and overscreening

Screening is a Cascade of Events

- A target population
 - Referring MD's
 - (information & referral)
 - The Test
 - High quality image
 - High quality interpretation
 - High quality evaluation of positive results
- 

The Quality of Lung Cancer Screening

- a) Do we know that all CT imaging systems meet high standards of quality?
- b) Do we know that all radiologists are competent to screen for lung cancer?
- c) Do we know that all radiologists are aware of their level of performance in screening for lung cancer?
- d) Are all residency programs adequately preparing radiologists to screen for lung cancer?
- e) Are the key organizations who should take a systematic approach to addressing these issues engaged to do so?

- **Answers: (a) No, (b) No, (c) No, (d) No, (e) No**

Establishing Quality Standards and Accountability

- Quality assurance programs are expensive, and may not receive full support in both organized and opportunistic screening programs
- There will be resistance among health professionals to requirements to adhere to quality standards
- Failure to implement these programs prior to and during the implementation phase of screening programs has been enormously costly

Establishing Quality Standards and Accountability

- *However.....*
 - Failure to embrace comprehensive quality assurance standards will prove to be costly
 - There is a need for a central model of professional/regulatory oversight--*Self policing is unlikely to be successful*
 - MQSA is a reasonable model, but there is considerable room for improvement, both in terms of oversight, *but especially in the evaluation of the performance of the interpreting physician, and the provision of regular feedback*

The importance of a multidisciplinary approach to early detection

- Problems from lack of communication, consensus and collaboration re: best practices among specialty groups
 - Lack of follow-up of positive tests
 - Improper follow-up of positive tests
 - Lack of consensus on diagnostic evaluation protocols within and between professional groups
 - Cross-specialty territorialism
 - Lack of “consensus” decisions informed by different subspecialty perspectives

The Public Debate will Continue

- There will be persistent, challenge of the value of screening *vis-à-vis* alternative strategies to reduce lung cancer deaths, including:
 - Smoking prevention
 - Smoking cessation
 - Chemoprevention
- Some will argue against screening on moralistic grounds
 - Former, and especially current, smokers are undeserving
- Some will argue against screening current smokers
 - Belief that screening should only be available to *former* smokers
 - Concern that screening will be viewed as a safety net to continue smoking (data, not defensive postures, are necessary)

The Public Debate will Continue

- There will be persistent, negative appraisals of screening, calling into question the interpretation of the evidence of benefit and harms (*it will never go away*)
- New negative studies will be embraced and used to call into question all studies with favorable findings
- Some professional groups may be slow to appreciate the value of screening...the adoption of medical innovations, *including new evidence*, is slow
- Expectations will be high for near term results....inappropriate analysis of population data is common
- Don't expect the press to be friendly ... from this point forward, *negative news is more interesting*

IASLC 2011 Lung Cancer CT Screening Workshop Report

IASLC SCREENING WORKSHOP REPORT

International Association for the Study of Lung Cancer Computed Tomography Screening Workshop 2011 Report

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IASLC CT Screening Workshop 2011 Participants

Abstract: The International Association for the Study of Lung Cancer (IASLC) Board of Directors convened a computed tomography (CT) Screening Task Force to develop an IASLC position statement, after the National Cancer Institute press statement from

the National Lung Screening Trial showed that lung cancer deaths fell by 20%. The Task Force's Position Statement outlined a number of the major opportunities to further improve the CT screening in lung cancer approach, based on experience with cancer screening from other organ sites.

The IASLC CT Screening Workshop 2011 further developed these discussions, which are summarized in this report. The recommendation from the workshop, and supported by the IASLC Board of Directors, was to set up the Strategic CT Screening Advisory Committee (IASLC-SSAC). The Strategic CT Screening Advisory Committee is currently engaging professional societies and organizations who are stakeholders in lung cancer CT screening implementation across the globe, to focus on delivering guidelines and recommendations in six specific areas: (i) identification of high-risk individuals for lung cancer CT screening programs; (ii) develop radiological guidelines for use in developing national screening programs; (iii) develop guidelines for the clinical work-up of "indeterminate nodules" resulting from CT screening programmes; (iv) guidelines for pathology reporting of nodules from lung cancer CT screening programs; (v) recommendations for surgical and therapeutic interventions of suspicious nodules identified through lung cancer CT screening programs; and (vi) integration of smoking cessation practices into future national lung cancer CT screening programs.

Key Words: Lung cancer, CT screening, Radiology, CT screening recommendations, IASLC workshop 2011.

(*J Thorac Oncol.* 2012;7: 10-19)

In November 2010, results from the National Lung Screening Trial (NLST), sponsored by the National Cancer Institute (NCI) in the United States, showed that lung cancer deaths fell by 20% and all-cause mortality fell by 7% when smokers—defined as current or former smokers with 30 or greater pack years of smoking—were screened annually for 3 years using low-dose spiral computed tomography (LDCT) compared with standard chest x-ray. The study followed more than 53,000 current and former smokers aged 55 to 74 years. It was halted because the reduction in cancer deaths provided an answer to the study's main question. This announcement by the Director of NCI was significant as it

- “The recommendation was to support phased, internationally coordinated “demonstration projects,” for different geographic regions and in countries that are not currently undertaking large RCTs.”
- “....the recommendation that CT screening could be implemented at national levels is subject to local considerations.”

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Disclosure: John K. Field, PhD, FRCPath, reports that his institution received educational grants to sponsor the IASLC Workshop from the IASLC, the American Cancer Society, and GE Healthcare; a portion of these grants were used to provide travel support for attendance at the IASLC Workshop. His institution also received funds from Epigenomics. Dr. Field is a former board member of Mediavision. Denise R. Aberle, MD, serves as a science advisory board member for LUNGevity Foundation, and her institution received an NIH/NCI, U01 CA80098, American College of Radiology Imaging network grant. Jesper Holst Pedersen, MD, received lecture fees from Roche and tili Lilly. William D. Travis, MD, reports that receipt of grant R01 to his institution is pending NCI review. Ignacio I. Wisnubai, MD, serves on the board for Sanofi Aventis, Johnson & Johnson, Genentech, Champions Inc., Roche, AstraZeneca, Bristol-Myers Squibb, and GlaxoSmithKline. Jim L. Mulshine, MD, received support for travel from the Global Lung Consortium. The other authors report no conflicts of interest.

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IASLC Workshop Recommendations

- Establish a Strategic CT Screening Advisory Committee (IASLC - SSAC).
 - Chair: Prof. John K. Field, Roy Castle Lung Cancer Research Programme
- The SSAC should engage professional societies and organizations who are stakeholders in lung cancer CT Screening implementation across the globe, in order to focus on delivering guidelines and recommendations in seven specific areas:
 - (i) Identification of high risk individuals for lung cancer CT screening programs;
 - (ii) Develop radiological guidelines for use in developing national screening programs;

IASLC Workshop Recommendations

- Workshop recommendations (continued)
 - iii) Develop guidelines for the clinical work-up of ‘indeterminate nodules’ resulting from CT screening programs;
 - (iv) Guidelines for pathology reporting of nodules from lung cancer CT screening programs;
 - (v) Recommendations for surgical and therapeutic interventions of suspicious nodules identified through lung cancer CT screening programs;
 - (vi) Integration of smoking cessation practices into future national lung cancer CT screening programs
 - (vii) Promote research collaboration to improve screening outcomes while reducing the cost and complications

The path forward—we need a mission oriented approach

- Going to the moon was not achieved by waiting (and hoping) for a coincidence between NASA's needs and those of individual investigators who managed to get funded in a non-priority peer review system
- There is an urgent need to invest in coordination between committed nations and organizations, and answering high priority questions

Conclusion

- It is important to heed the lessons learned from the implementation of screening for breast, cervix, colorectal and prostate cancers.
- There is greater emphasis on harms today than ever before
- The combination of insistence on best practices, on-going program evaluation, and attempts to maximize benefits *and* minimize harms is critical to success.
- There can be no shortcuts.