

# CT Lung Screening Implementation Challenges: ALA/ATS Implementation Microsite

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Bloomberg

Business

# America's Heaviest Smokers Don't Want to Know if They Have Cancer

Screening could save 12,000 lives annually, but fewer than 2 percent of those eligible take advantage of it.

2016 data, 3 years after ACS recommendation and one year after CMS coverage

Mammography -28% in 1987, 11 years after ACS recommendation

Colonoscopy -32% in 1980, 20 years after ACS recommendation

Lung cancer screening Lahey– 65% in 2018, 6 years after NCCN recommendation 65% of eligible population screened – Changed the conversation



## HEALTH NEWS

## ✓ Fact Checked

# Why Only 2 Percent of Heavy Smokers Get Lung Cancer Screenings

## Why so slow?

Reimbursement Stigma Infrastructure Who does what Misinformation Terminology Resources Quality Training Silos





# **Reimbursement and Messaging**

| 70498 | Ct Angio, Neck<br>Combo, Incl Image<br>Process | \$2,586.00 | \$300.14 | \$160.27 | \$1,163.70 | \$345.16 |
|-------|--|------------|----------|----------|------------|----------|
| 71010 | Chest X-Ray 1 Vw                               | \$150.00   | \$58.96  | \$31.48  | \$67.50    | \$67.80  |
| 71020 | Chest X-Ray 2 Vw                               | \$150.00   | \$58.96  | \$31.48  | \$67.50    | \$67.80  |
| 71035 | Chest X-Ray Spec<br>Views                      | \$298.00   | \$58.96  | \$31.48  | \$134.10   | \$67.80  |
| 71110 | X-Ray Ribs 3 Vw Bilat                          | \$448.00   | \$93.44  | \$49.90  | \$201.60   | \$107.46 |
| 71111 | X-Ray Ribs, Chest 4+<br>Vw                     | \$448.00   | \$93.44  | \$49.90  | \$201.60   | \$107.46 |
| 71250 | Ct Scan, Thorax, w/o<br>Contrast               | \$1,671.00 | \$130.01 | \$69.43  | \$751.95   | \$149.51 |
| 71260 | Ct Chest Contrast                              | \$2,586.00 | \$255.98 | \$136.69 | \$1,163.70 | \$294.38 |
| 71275 | Ct Angio, Chest,<br>Combo, Incl Image<br>Proc  | \$2586.00  | \$300.14 | \$160.27 | \$1,163.70 | \$345.16 |
| 72040 | X-Ray Exam Neck<br>Spine 3/Or Less             | \$298.00   | \$58.96  | \$31.48  | \$134.10   | \$67.80  |

CTLS Medicare Payment 2016 -\$112.49 2017 - \$59.84 2018 -\$52.56

2018 TC - \$189.71 2018 Global - \$242.28



"Don't mess with lung screening"

# Stigma and Big Tobacco





Competition has been tough - tobacco industry, Hollywood, press

Guard against withholding of health care services or advocacy based on social history – slippery slope



## Revenues and Expenses Different Silos





# Training

Radiology- Make the radiologist comfortable

Mevis Lung Academy

IELCAP VA PALS

European 18 month implementation plan

Primary Care – Make primary care comfortable

SDM Massachusetts Medical Society

SDM tools Grannis

Specialist

Navigator

State Quality Collaborative

Technologist

**Smoking Cessation** 



## **Program Access and Structure**

## **Centralized vs Decentralized**



McKee, B et al. Low-dose Computed Tomography Screening for Lung Cancer in a Clinical Setting: Essential Elements of a Screening Program. J Thorac Imaging. 2015 Mar;30(2):115-29.



## **ACR Registry Requirements**

#### **Required Elements**

Exam details:

Facility ID number, patient name, exam date

#### General:

Smoking status in pack years Smoking cessation counseling Documentation of shared decision making Height, weight, comorbidities, cancer history Radiologist name, ordering provider and NPI Indication for the exam Exam modality, manufacturer, radiation exposure CT exam results by Lung-RADS™ category Other abnormalities- CT exam result S modifier Prior history of lung cancer and years since diagnosis

#### Follow-up within 1 year

Documentation of an exam anytime within prior 12 months and date Follow-up diagnostic for tissue:

- Tissue Diagnosis
- Tissue diagnosis method
- Location from which sample was obtained
- Histology
- Stage- Clinical or pathologic
- Overall stage
- T, N, M status
- Period of follow-up for incidence (in months)

#### Additional Risk Factors:

Education level, radiation exposure, occupational exposures, history of cancers associated with a higher risk of lung cancer, lung cancer in first-degree relative, other family history of lung cancer, COPD, pulmonary fibrosis, secondhand smoke exposure.

Name of person performing data collection for the exam, submission date.



# Systems Approach

Division of labor cost efficient/effective volume for PCP, specialist, radiology Triage to manage specialty volume





# **Additional Challenges**

Who to screen

Identifying the high risk population

Scheduling

Quality metrics and benchmarking

Tracking

Compliance

Workflow and division of labor

Smoking cessation

Community outreach

Radiology

Care escalation

Smoking cessation

Access

Primary Care engagement

Identification of the high risk population

Who to compare to?

Who tracks and reviews metrics

Metric feedback

Workflow and division of labor

Community outreach



# **Shared Decision Making**

Editorials Exaggerating Radiation Harm and FPR What is the false positive rate in modern clinical practice CTLS?

98%, 60%, 50%, 23%, 12%, 7%, 2%

Patient Anxiety – Little/No Evidence

"Permission to Smoke" - Little/No Evidence

Overdiagnosis

What is the rate of overdiagnosis in the NLST when using modern reporting and work up algorithms?

70%, 50%, 18%, 3%

Significant Incidental Findings

What is the rate of significant incidental findings in clinical CTLS practice?

70%, 40%, 10%, 6%, 4%, 2%



## "False" False Positive Rates



# What is the False Positive Rate?

"On a population-based level, the FP rate is traditionally defined as the probability of receiving a positive result, given an absence of the disease. In this review, the FP rate will be defined as the number of FPs as a proportion of the total number of screening examinations conducted (i.e. accounting for cases of both the presence and absence of malignant disease). The definition has been modified from the true technical definition as a result of an observed trend, whereby the FP rate is reported in the latter manner by most of the publications concerning mammographic screening." -British Journal of Radiology

## What is NOT the False Positive Rate?

"In 1995, Benjamini and Hochberg introduced the concept of the False Discovery Rate (FDR) as a way to allow inference when many tests are being conducted. The FDR is the ratio of the number of false positive results to the number of total positive test results." -Partnership for Assessment and Accreditation of Scientific Practice

|               | Disease or<br>Condition | No Disease or<br>Condition |
|---------------|-------------------------|----------------------------|
| Test Positive | A<br>True Positive      | B<br>False Positive        |
| Test Negative | C<br>False<br>Negative  | D<br>True<br>Negative      |

- False positive rate = B / (A + B + C + D)
- False discovery rate = B / (A + B)



"Of the 2106 screened patients, 1257 (59.7%) had nodules, and 1184 (56.2%) required tracking. Only 42 (2.0%) patients required further evaluations that did not result in a lung cancer diagnosis, and only 31 (1.5%) were diagnosed with lung cancer within 330 days. Overall, researchers calculated a false-positive rate of 97.5%. Incidental findings such as emphysema, other pulmonary abnormalities, and coronary artery calcification were observed on the scans of 857 patients (40.7%). Wide variation in processes and patient experiences among the 8 sites was also noted."

# This is the false discovery rate

## JAMA Internal Medicine | Original Investigation

# Implementation of Lung Cancer Screening in the Veterans Health Administration

Linda S. Kinsinger, MD, MPH; Charles Anderson, MD, PhD; Jane Kim, MD, MPH; Martha Larson, BSN, MS; Stephanie H. Chan, MPH; Heather A. King, PhD; Kathryn L. Rice, MD; Christopher G. Slatore, MD, MS; Nichole T. Tanner, MD, MSCR; Kathleen Pittman, BSN, MPH; Robert J. Monte, MBA; Rebecca B. McNeil, PhD; Janet M. Grubber, MSPH; Michael J. Kelley, MD; Dawn Provenzale, MD, MSc; Santanu K. Datta, PhD; Nina S. Sperber, PhD; Lottie K. Barnes, MPH; David H. Abbott, MS; Kellie J. Sims, PhD, MS; Richard L. Whitley, BS; R. Ryanne Wu, MD, MHS; George L. Jackson, PhD, MHA

| Patients screened  | 2106 (85.9) | 442 (81.0) | 228 (92.3) | 213 (82.9) | 444 (90.8) | 247 (96.9) | 135 (76.3) | 258 (89.0) | 139 (72.8) |
|--|-------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Patients with nodular<br>findings on scans <sup>c</sup>                              | 1257 (59.7) | 340 (76.9) | 70 (30.7)  | 181 (85.0) | 248 (55.9) | 153 (61.9) | 63 (46.7)  | 112 (43.4) | 90 (64.7)  |
| Patients with nodules to<br>be tracked <sup>d</sup>                                  | 1184 (56.2) | 323 (73.1) | 64 (28.1)  | 176 (82.6) | 225 (50.7) | 143 (57.9) | 61 (45.2)  | 108 (41.9) | 84 (60.4)  |
| Patients with suspicious<br>findings not confirmed to<br>be lung cancer <sup>e</sup> | 42 (2.0)    | 10 (2.3)   | 2 (0.9)    | 2 (0.9)    | 13 (2.9)   | 10 (4.0)   | 0          | 1 (0.4)    | 4 (2.9)    |
| Patients with confirmed<br>lung cancer   | 31 (1.5)    | 7 (1.6)    | 4 (1.8)    | 3 (1.4)    | 10 (2.3)   | 0          | 2 (1.5)    | 3 (1.2)    | 2 (1.4)    |

> 2106 patients screened; 1257 positive\* exams; 31 confirmed lung cancers

➤ False positive\* rate = (1257 - 31) / 2106 = 58.2%

➤ False suspicious rate = (73 - 31) / 2106 = 2%

"There was wide variation among sites in the percentage of screening test results that were positive for nodules or possible lung cancer. Overall, 1257 of the 2106 patients (59.7%) screened had a positive test result (site range, 70 of 228 [30.7%] to 181 of 213 [85.0%]) (Table 1), including 1184 patients (56.2%) who had 1 or more nodules needing to be tracked (site range, 64 of 228 [28.1%] to 176 of 213 [82.6%]). Most nodules were small (<5 cm; 710 of 1293 [54.9%]) and solid (1079 of 1293 [83.4%]) (Table 3). A total of 73 patients (3.5% of all patients screened) had findings suspicious for possible lung cancer and underwent further diagnostic evaluation. Lung cancer was confirmed for 31 of those patients (1.5%; site range, 0 of 247 to 10 of 444 [2.3%]) within the 330-day follow-up period; 20 (64.5%) of the cancers were stage I (Table 4). The mean number of days from initial LDCT scan to cancer diagnosis was 137 (range, 5-330 days). The remaining 42 patients (2.0%; site range, 0 of 135 to 10 of 247 [4.0%]) who underwent evaluation were not confirmed to have lung cancer during that time frame. The rate of false-positive test results for lung cancer was 97.5% (1226 of 1257) during the 330-day follow-up period (Table 1)."

false discovery rate \* "Since only about one-third of nodules identified as needing to be tracked in the LCSDP were 6 mm or greater, the positive rate might decline from nearly 60% to about 20%."

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- Jan 2017 JAMA Internal Medicine article:
  - "The rate of false-positive test results for lung cancer was 97.5% (1226 of 1257) during the 330-day follow-up period"
  - "The reason for the overall high rate of initially positive examination results in the VHA sites is not certain but may be owing, in part, to the older age and heavier smoking history of veterans screened."
  - "Since only about one-third of nodules identified as needing to be tracked in the LCSDP were 6 mm or greater, the positive rate might decline from nearly 60% to about 20%"



## **Editorial**

October 2018

# Failing Grade for Shared Decision Making for Lung Cancer Screening

Rita F. Redberg, MD, MSc<sup>1,2</sup>

> Author Affiliations | Article Information

JAMA Intern Med. 2018;178(10):1295-1296. doi:10.1001/jamainternmed.2018.3527

"Even in the highest-rated discussions, there was no mention of possible harms from the screening by the physicians, even though these harms include a 98% falsepositive rate, which may lead to anxiety; additional testing including imaging or procedures, such as biopsy or lobectomy; and radiation from the LDCT with the small increased risk of cancer. Some evidence suggests that a more-rigorous and informative SDM discussion about lung cancer screening is occurring in the Veterans Administration system."

# This is the false discovery rate



"A pair of studies in JAMA Internal Medicine illustrate the difficulties of implementing lung cancer screening.

In the first, eight Veterans Health Administration medical centers identified and screened patients using low-dose computed tomography (LDCT). Over 2100 patients who were eligible for screening based on smoking history and other factors completed LDCT. Overall, 60% had nodules, but just 1.5% had lung cancer diagnosed within 330 days. The researchers calculate a false-positive rate of 97.5%."

# This is the false discovery rate





## Inhalation Toxicology International Forum for Respiratory Research

ISSN: 0895-8378 (Print) 1091-7691 (Online) Journal homepage: http://www.tandfonline.com/loi/iiht20

## Screening tests: a review with examples

L. Daniel Maxim, Ron Niebo & Mark J. Utell

Reported false positives as % Remarks Source National Lung Screening Trial Research Team, p. 399 (Exhibit A again) 96.4 National Lung Screening Trial Research Team (2011) Swensen et al. (2003) 96.1 Study also reports 90% sensitivity 95.5 106 false positives among 111 with nodules >0.5 cm Tiitola et al. (2002) D 92.9-96.0 Rates depended on nodule size, p. 260. Swensen et al. (2005) 86.6-96.4 Rates depend upon assumed nodule size from 5.0 to 9.0 mm Henschke et al. (2013) Based on 14 detected cancers among 259 patients with abnormal CT scans 94.6 Ε McWilliams et al. (2003) 94.1 F From Table 2, 1773 false positives among 1883 nodules detected Mahadevia et al. (2003) 93 Based on 8 lung cancers among 114 subjects with nodules >5 mm Novello et al. (2005) G 92.6 Based on 22 lung cancers among 298 patients with nodules Pastorino et al. (2003) н 92.1 Based on 22 cancers in 279 with suspicious nodules Sone et al. (2001) 88.5-97 From Table 3, rate dependent upon risk Kovalchik et al. (2013) Based on 29 malignancies among 233 positive results 87.6 Henschke et al. (2002) 75 Percent of patients with non-calcified nodules on CT Manos (2013) 73.4 Based on 163 benign nodules among 222 evaluated by thin section CT Li et al. (2004) >70Reported value derived from Mayo clinic and ELCAP trials Patz et al. (2004) 62.1 Based on 18 false positives among 29 subjects; for nodules >10 mm Diedrerich et al. (2002) 43.75 Based on 36 confirmed lung cancer cases among 64 patients Nawa et al. (2002) 21 - 33Rates depend upon number of tests, p. 509. Of participants with a false-positive CT scan, 7% Croswell et al. (2010) had an unnecessary invasive procedure and 2% had major surgery for benign disease. Gohagan et al. (2004) 19 p. 119 p. 612. Includes multi-stage process with classification of nodules by size and calcification Pedersen et al. (2009), 7.9 with follow-up. Saghir et al. (2012) Sensitivity reported to range between 84.6% W to 90.6% M 7.9 M/5.6 F Toyoda et al. (2008) Sensitivity reported at 94.6%, based on Volume CT scanning 1.7 van Klaveren et al. (2009)

Table 5. Reported false positive rates for CT scans for lung cancer.

| <b>D</b> : 95.5% = 106 / 111 ≠ false positive rate | E: 94.6% = (259 – 14) / 259 ≠ false positive rate |
|--|---|
| F: 94.1% = 1773 / 1883 ≠ false positive rate       | G: 93% = (114 – 8) / 114 ≠ false positive rate    |
| H: 92.6% = (298 – 22) / 298 ≠ false positive rate  | I: 92.1% = (279 – 22) / 279 ≠ false positive rate |
| THESE ARE ALL FALSE DISC                           | COVERY RATES                                      |

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NIH NATIONAL CANCER INSTITUTE https://www.cancer.gov/types/breast/hp/breast-screening-pdq

#### • False Positives with Additional Testing and Anxiety.

**Magnitude of Effect**: In the United States, approximately 10% of women are recalled for further testing after a screening examination, however, only 0.5% of tested women have cancer; thus, approximately 9.5% of tested women will have a false-positive exam.[8,9] Approximately 50% of women screened annually for 10 years in the United States will experience a false positive; of these, 7% to 17% will undergo biopsies.[10,11] Additional testing is less likely when prior mammograms are available for comparison.

➤ False discovery rate = (10 - 0.5) / 10 = 95%

False positive rate = 50%

### **Editorial**

June 2017

## Physician Adherence to Breast Cancer Screening Recommendations

Deborah Grady, MD, MPH<sup>1,2</sup>; Rita F. Redberg, MD, MSc<sup>1,3</sup>

» Author Affiliations ∣ Article Information

JAMA Intern Med. 2017;177(6):763-764. doi:10.1001/jamainternmed.2017.0458

"It is estimated that 50% of women who undergo 10 mammography screens will have a false-positive finding."

Not using false discovery rate when discussing breast cancer screening

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# Is This Misrepresentation Happening for All Cancer Screening?

JAMA | US Preventive Services Task Force | EVIDENCE REPORT Screening for Ovarian Cancer Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

Jillian T. Henderson, PhD; Elizabeth M. Webber, MS; George F. Sawaya, MD

Not using false discovery rate when discussing ovarian cancer screening

| Source   | Quality <sup>b</sup> | False-Positive Screening Rate Across Entire<br>Program, No. With False-Positive Screen/<br>No. Without Cancer (%) <sup>c</sup> |
|--|----------------------|--|
| UKCTOCS, 2016 <sup>22,31,34</sup><br>(CA-125 ROCA) | Good                 | 20 340/46 067 (44.2) across 2-11 rounds of screening <sup>e</sup>  |
| UKCTOCS, 2016 <sup>22,31</sup><br>(TVU)            | Good                 | NR <sup>h</sup>  |
| PLCO, 2011 <sup>20,21,27</sup>                     | Good                 | 3285/34041 (9.6) across 1-6 rounds of screening  |
| UK Pilot, 1999 <sup>33</sup>                       | Good                 | 462/10 942 (4.2) across 1-3 rounds of screening <sup>m</sup>   |
| QUEST, 2007 <sup>29</sup>                          | Fair                 | NA   |

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JAMA | US Preventive Services Task Force | EVIDENCE REPORT

Screening for Cervical Cancer With High-Risk Human Papillomavirus Testing Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

Joy Melnikow, MD, MPH; Jillian T. Henderson, PhD; Brittany U. Burda, DHSc, MPH; Caitlyn A. Senger, MPH; Shauna Durbin, MPH; Meghan S. Weyrich, MPH

## Not using false discovery rate when discussing cervical cancer scre¢ning

Table 3. Colposcopy Referrals and False-Positive Rates as Harms of hrHPV Screening, Based on Randomized Clinical Trials (Key Question 2)

|   |                      |                         |  | No./Total (%)  |   |                                   | False-Positive Rate,<br>No. Screened Positive<br>Without CIN 2+/Total No. |                                 |                             |
|---|----------------------|-------------------------|--|--|---|-----------------------------------|---|---------------------------------|-----------------------------|
|   |                      | Screening Round         |  | Test Positivity <sup>c</sup>                           | 8   | Colposcopy Referrals <sup>d</sup> |   | Screened Without CIN            | 2+ (%) <sup>d</sup>         |
| Source  | Quality <sup>a</sup> | Period, y) <sup>b</sup> | Screening Approach   | Intervention   | Control                                   | Intervention                      | Control   | Intervention                    | Control                     |
| hrHPV Primary Screening   | 1                    |                         |  |  |   |                                   |   |                                 |                             |
| NTCC Phase II<br>Ronco et al, <sup>20</sup> 2008<br>Ronco et al, <sup>14</sup> 2010                                   | Good                 | 1 (3.5)                 | hrHPV vs conventional<br>cytology                                      | hrHPV+:<br>1936/24661 (7.9)                            | ASCUS+:<br>825/24353 (3.4)                | 1936/24661 (7.9)                  | 679/25 435 (2.8)  | 1799/24 428 <mark>(7.4)</mark>  | 770/24038 (3.2)             |
| HPV FOCAL<br>Ogilivie et al, <sup>22</sup> 2010   | Fair                 | 1 (1) <sup>c</sup>      | hrHPV with LBC triage<br>vs LBC  | hrHPV+:<br>771/9540 (8.1) <sup>d,e</sup>               | ASCUS+:<br>334/9408 (3.5) <sup>d,e</sup>  | 544/9540 (5.7) <sup>e,g</sup>     | 290/9408 (3.1) <sup>e,g</sup>   | 624/939 <mark>3 (6.6)</mark>    | 244/9318 (2.6)              |
| Cook et al, <sup>19</sup> 2015<br>Ogilvie et al, <sup>21</sup> 2017<br>Ogilvie et al, <sup>13</sup>                   |                      | 2 (4) <sup>c</sup>      | Cotesting vs cotesting <sup>f</sup>                                    | hrHPV+:<br>469/8296 (5.7)                              | ASCUS+:<br>513/8078 (6.4) <sup>d,e</sup>  | 469/9540 (4.9) <sup>e,g</sup>     | 660/9408 (7.0) <sup>e,g</sup>   | 421/824 <mark>8 (5.1)</mark>    | 413/7978 (5.2)              |
| FINNISH<br>Leinonen et al, <sup>23</sup> 2012   | Fair                 | 1 (5)                   | hrHPV with conventional<br>cytology triage<br>vs conventional cytology | hrHPV+:<br>4971/62 106 (8.0) <sup>h</sup>              | ASCUS+:<br>4506/65 747 (6.9) <sup>h</sup> | 796/66 410 (1.2)                  | 755/65 784 (1.1)  | 4462/61 597 <mark>(7.2)</mark>  | 4239/65 480 (6.5)           |
| Compass<br>Canfell et al, <sup>12</sup> 2017  | Fair                 | 1 (5)                   | hrHPV with LBC triage<br>vs LBC <sup>I</sup>                           | hrHPV+:<br>277/4000 (6.9)                              | ASCUS+:<br>67/995 (6.7)                   | 154/4000 (3.8)                    | 27/995 <mark>(</mark> 2.7)  | NR                              | NR                          |
| hrHPV Cotesting With Cyt  | tology               |                         |  |  |   |                                   |   | _                               |                             |
| NTCC Phase I<br>Ronco et al, <sup>25</sup> 2006<br>Ronco et al, <sup>26</sup> 2006<br>Ronco et al, <sup>14</sup> 2010 | Good                 | 1 (3.5)                 | Cotesting vs conventional<br>cytology                                  | hrHPV+ or ASCUS+:<br>2830/22708 (12.5)                 | ASCUS+:<br>855/22 466 (3.8)               | لإ10.9% 2470/22 708               | 738/22 466 (3.3)  | 2702/22 042 (12.3)              | 771/21972 (3.5)             |
| POBASCAM<br>Bulkmans et al, <sup>27</sup> 2004  | Good                 | 1 (4)                   | Cotesting vs conventional<br>cytology                                  | hrHPV+ or ASCUS+:<br>1406/19 999 (7.0)                 | ASCUS+:<br>706/20 106 (3.5)               | NR                                | NR  | 1149/19742 <mark>(5.8)</mark>   | 513/19913 (2.6)             |
| Rijkaart et al, <sup>26</sup> 2012<br>Dijkstra et al, <sup>29</sup> 2016  |                      | 2 (5)                   | Cotesting vs cotesting   | hrHPV+ or ASCUS+:<br>742/19 579 (3.8)                  | hrHPV+ or ASCUS+:<br>774/19731 (3.9)      | NR                                | NR  | 610/957 <mark>2 (6.4)</mark>    | 612/9450 (6.5)              |
| Swedescreen<br>Naucler et al, <sup>30</sup> 2008<br>Elfström et al, <sup>31</sup> 2014                                | Fair                 | 1 (3)                   | Cotesting vs conventional cytology                                     | hrHPV+:<br>433/6257 (6.9)<br>ASCUS+:<br>146/6257 (6.9) | ASCUS+:<br>150/6270 (2.4)                 | NR                                | NR  | NR                              | 72/6192 (1.2)               |
| ARTISTIC<br>Kitchener et al, 32 2008  | Fair                 | 1 (2)                   | Cotesting vs LBC   | hrHPV+ or ASCUS+:<br>4019/18 386 (21.9)                | ASCUS+:<br>786/6124 (12.8)                | 1247/18 386 (6.8)                 | 320/6124 (5.2)  | 3566/17 933 <mark>(19.9)</mark> | 653/5991 (10.9)             |
| Kitchener et al, <sup>33</sup> 2009<br>Kitchener et al, <sup>34</sup> 2009<br>Kitchener et al, <sup>35</sup> 2014     |                      | 2 (2)                   | Cotesting vs LBC   | hrHPV+ or ASCUS+:<br>1258/11862 (10.6) <sup>k</sup>    | ASCUS+:<br>210/3928 (5.3) <sup>k</sup>    | 284/10716 (2.7) <sup>k</sup>      | 74/3514 (2.1) <sup>k</sup>  | 1178/10512 (11.2) <sup>k</sup>  | 176/3832 (4.6) <sup>k</sup> |

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|                    |             | False Posit    | tive Rate   |           | <u>F</u>    | alse Discov    | ery Rate    |     |
|--------------------|-------------|----------------|-------------|-----------|-------------|----------------|-------------|-----|
| Screening<br>Round | <u>NLST</u> | <u>NLST LR</u> | <u>LHMC</u> | <u>MG</u> | <u>NLST</u> | <u>NLST LR</u> | <u>LHMC</u> | MG  |
| то                 | 26.3%       | 12.6%          | 10.6%       | 7-12%     | 96.2%       | 92.8%          | 83.1%       | 95% |
| T1                 | 27.2%       | 5.3%           | 5.2%        | ?         | 97.6%       | 90.3%          | 78.2%       | ?   |
| T2                 | 15.9%       | 5.1%           | 5.0%        | ?         | 94.8%       | 87.2%          | 84.6%       | ?   |
| Overall            | 23.3%       | 7.8%           | 7.6%        | 50% 🤇     | 96.4%       | 91.0%          | 82.1%       | ?   |

NLST: National Lung Screening Trial; NLST LR: Pinsky et al NLST conversion;

LHMC: Lahey CTLS program; MG: Mammography (nationwide)

Do you ever hear the false positive rate for mammography quoted as 95%??





"Based on solid evidence, approximately 96% of all positive, low-dose helical computed tomography screening exams do not result in a lung cancer diagnosis. False-positive exams may result in unnecessary invasive diagnostic procedures. Magnitude of Effect: Based on the findings from a large randomized trial, the average false-positive rate per screening round was 23.3%. A total of 0.06% of all falsepositive screening results led to a major complication after an invasive procedure performed as diagnostic follow-up to the positive screening result. Over three screening rounds, 1.8% of participants who did not have lung cancer had an invasive procedure following a positive screening result."

> - NIH 2 Feb 2018



# So What ARE the False Positive Rates for CT Lung Screening?

| The <b>NEW</b> | ENGLAND     |
|----------------|-------------|
| JOURNAL        | of MEDICINE |

ESTABLISHED IN 1812

AUGUST 4, 2011

VOL. 365 NO. 5

Reduced Lung-Cancer Mortality with Low-Dose Computed **Tomographic Screening** 

The National Lung Screening Trial Research Team\*

T0: 26.3% T1: 27.2% T2: 15.9% Overall: 23.3%

| Annals of Internal Medicine  | ORIGINAL RESEARCH                                    | T0: 12.6%     |
|--|--|---------------|
| Performance of Lung-RADS in the Natio  | onal Lung Screening Trial                            | T1: 5.3%      |
| A Retrospective Assessment   |  | T2: 5.1%      |
| Paul F. Pinsky, PhD; David S. Gierada, MD; William Black, MD; Reginald<br>Ella Kazerooni, MD | Munden, MD; Hrudaya Nath, MD; Denise Aberle, MD; and | Overall: 7.8% |

| Original<br>Research                                | T0: 10.6% |
|---|-----------|
|   | T1: 5.2%  |
| NCCN Guidelines as a Model of Extended Criteria for | T2: 5.0%  |
| Lung Cancer Screening                               |           |

Brady J. McKee, MD; Shawn Regis, PhD; Andrea K. Borondy-Kitts, MS, MPH; Jeffrey A. Hashim, MD; Robert J. French Jr, MD; Christoph Wald, MD, MBA, PhD; and Andrea B. McKee, MD

Overall: 7.6%

#### RESCUE LUNG RESCUE LIFE SOCIETY

## **Quality Metrics - Agreement on Terminology**



IASLC 19th World Conference on Lung Cancer September 23–26, 2018 Toronto, Canada

INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER

WCLC2018.IASLC.ORG

#WCLC2018

## Major discrepancies in the reporting of significant incidental findings in CT lung screening due to lack of both general and specific standard definitions

Table 1. Summary Results for the Initial Ro

| Screening<br>Round |                       | Lo                 | w-Dose                                 | ст  |                                  |
|--------------------|-----------------------|--------------------|--|---|----------------------------------|
|                    | Total No.<br>Screened | Positive<br>Result | Clinically<br>Abnorn<br>Suspic<br>Lung | Significat<br>nality Not<br>cious for<br>Cancer | nt<br>No or Minor<br>Abnormality |
|                    |                       |                    | no. (%                                 | of screene                                      | (d)                              |
| то                 | 26,309                | 7191 (27.3)        | 269                                    | (10.2)  | 16,423 (62.4)                    |
| Tl                 | 24,715                | 6901 (27.9)        | 151                                    | (6.1)   | 16,295 (65.9)                    |
| T2                 | 24,102                | 4054 (16.8)        | 140                                    | (5.8)   | 18,640 (77.3)                    |

IASLC

N Engl J Med 2011; 365:395-409

"The review of the scan reveals that an abnormality is present and requires further evaluation, but is not suggestive of lung malignancy. It is up to the radiologist to determine whether an abnormality is clinically significant."

|  | No. (%)     |
|--|-------------|
| Characteristic   | All Sites   |
| Patients who met all<br>screening criteria   | 4246        |
| Patients who agreed to be screened <sup>b</sup>                                      | 2452 (57.7) |
| Patients screened  | 2106 (85.9) |
| Patients with nodular<br>findings on scans <sup>c</sup>                              | 1257 (59.7) |
| Patients with nodules to<br>be tracked <sup>d</sup>                                  | 1184 (56.2) |
| Patients with suspicious<br>findings not confirmed to<br>be lung cancer <sup>e</sup> | 42 (2.0)    |
| Patients with confirmed<br>lung cancer   | 31 (1.5)    |
| Patients with incidental,<br>non-nodule findings<br>on scans                         | 857 (40.7)  |
| Total LDCT scans completed <sup>f</sup>  | 2694        |

JAMA Intern Med. 2017;177(3):399-406

"Radiologists and coordinators were asked to record only incidental findings that would likely require followup or further evaluation. Overall, 857 patients (40.7%) had 1 or more incidental findings reported (site range, 89 of 444 [20.0%] to 135 of 213 [63.4%])"

| Table 5            |                                 |      |         |      |         |      |         |
|--------------------|---------------------------------|------|---------|------|---------|------|---------|
| Screening<br>Round | Significant Incidental Findings |      |         |      |         |      |         |
|                    | Overall                         |      | Group 1 |      | Group 2 |      | P Value |
| TO                 | 188                             | 6.4% | 150     | 6.7% | 38      | 5.4% | .23     |
| T1                 | 45                              | 2.5% | 40      | 3.0% | 5       | 1.2% | .03     |
| T2                 | 23                              | 2.1% | 20      | 2.4% | 3       | 1.1% | .32     |
| ≥T3                | 13                              | 1.9% | 10      | 1.9% | 3       | 1.9% | 1       |
| Total              | 269                             | 4.1% | 220     | 4.5% | 49      | 3.2% | .02     |

J Natl Compr Canc Netw 2018;16(4):444-449

"Unexpected findings which are either new or unknown and require some form of clinical or imaging investigation before the next recommended CTLS exam"



## Systems Approach





## LUNG CANCER SCREENING IMPLEMENTATION GUIDE

American Thoracic Society and American Lung Association LUNG CANCER SCREENING IMPLEMENTATION GUIDE

- Intended for community hospitals and healthcare systems
- Highlights potential hurdles along with resources that will aid healthcare systems in establishing their own lung cancer screening program
- Twenty-five experts from 16 institutions representing all geographic regions of the country volunteered for the panel to develop the guide and website
- Available in the Fall of 2018, the website will allow users to interact with the guide in easy to navigate sections
- For more information visit Lung.org/screening-guide-news

MERICAN



# Survey Q and A Format

- Questions submitted by participants from 16 sites
- Variety of screening settings
- Massachusetts state DPH survey
- <u>http://www.lungcancerscreeningguide.org/</u>