

Rescue Lung, Rescue Life CT Lung Screening Implementation

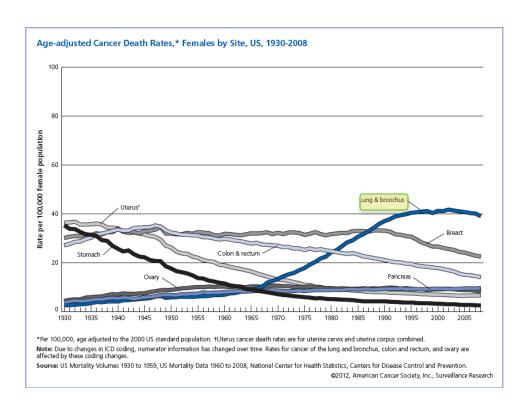
Prevent Cancer
May 2013

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Lung Cancer Incidence/Mortality: US

Number one cause of cancer-related death in the US and World

Kills more women than Breast, Ovarian, and Uterus Cancer Combined

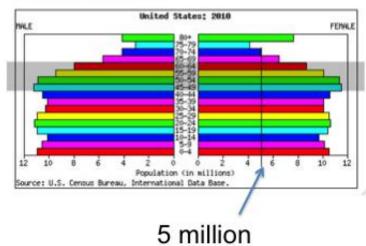


Lung Cancer Incidence/Mortality: US

- Primary Prevention (Smoking Cessation) significant success
 - Decreasing deaths by decreasing incidence
 - ❖Now most people dying from lung cancer are FORMER SMOKERS
 - ❖BUT 160K still die each year and that number appears ready to rise....

United States Population Pyramid for 2010

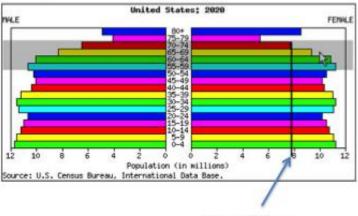
Age and sex distribution for the year 2010:



Average age at lung cancer diagnosis is 71

United States Population Pyramid for 2020

Predicted age and sex distribution for the year 2020:



8 million

NLST NEJM 6/29/2011

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

The National Lung Screening Trial Research Team*

NLST Summary

- ❖ At least 20% lung cancer specific mortality benefit
- ❖ 7% overall mortality benefit
- 1 in 100 has lung cancer (prevalence)
- **❖** NNS = 320
- ❖7,000,000 patients at high-risk
- 6 deaths in false positive interventions

NCCN Guidelines® 10/26/2011

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Lung Cancer Screening

Version 1.2012

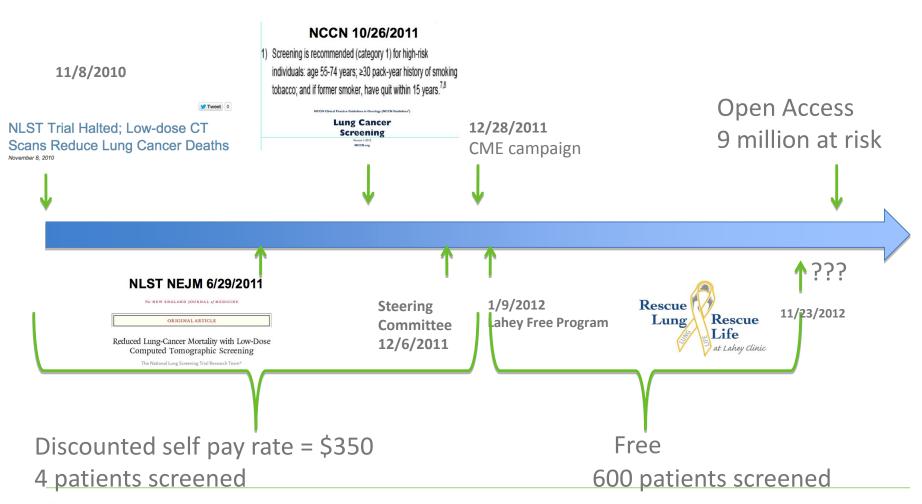
NCCN.org







Timeline





Rescue Lung, Rescue Life Steering Committee

Radiology

- **❖Brady McKee, MD**
- ❖Sebastian Flacke, MD
- **❖Robert French, MD**
- Christoph Wald, MD

Oncology

- **❖Andrea McKee, MD**
- ❖Paul Hesketh, MD

&GIM

- ❖Guy Napolitana, MD
- ❖Brendan Connell, MD

***Pulmonary**

- ❖Andrew Villanueva,MD
- **❖Anthony Campagna, MD**
- **❖Jeffrey Klenz, MD**
- ❖Carla Lamb, MD

Administration

- ❖Richard Guarino
- ❖Patricia Grady
- ❖Patricia Doyle
- ❖Nancy VonBorzestowski
- **♦** Angela Tambini
- ❖Fatima Laurenza
- Stacey Scott
- Christina Derochers

Marketing

- Erika Clapp
- **❖Finance**
 - ***Kevin Bennett**

***Business Development**

- Robert Toporoff
- Philanthropy
 - ❖Derik Bellin



Why Free?

Ethical

Only way to make lung screening available for all high-risk patients regardless of socioeconomic status without established reimbursement

Power of Free

- Motivation
 - ❖No one shows up @ self-pay rate
- **❖**Word of mouth marketing
 - Commercial marketing not required

How Free?

Low cost model requires downtime on installed CT scanners

- **❖30** slots/wk on our PET/CT without adding tech staff.
- Significant additional capacity by adding one 8 hour off hours shift (200 pts/wk, 10K/yr)

Decentralized

- ❖PCP order & patient and physician education to conduct informed consent
- **❖** Cannot see every patient with Multidisciplinary Care Team − Target the suspicious cases

Costs are unavoidable – some revenue is needed

- ❖ Database
- **❖Database management**
- **❖Patient navigator**
- ❖1 Radiologist & 3 tech staff for 8000 exams
- ❖Program literature

Program revenue

- **❖Work up of positive findings billed to patient in customary fashion**
- **❖Need certain percentage of patients to return for treatment to breakeven**
- **❖** Motivated to make screening a comfortable positive experience.

Compliance Requirements for Free Screening

All patients must meet our established program guidelines

No charge for any patient that fits the criteria regardless of insurance coverage

• (ICD-9 code V76.0, CPT 71250)

No requirement for any patient to return for followup testing

No "tying" or "quid pro quo"

If we decide to charge once CMS covers this we must charge all patients and insurance equally based on contracted or self pay rate



Lung Screening Then and Now

10/2011

Recommendations to Screen
1. NCCN

Reimbursement None

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Lung Cancer Screening

Version 1.2012 NCCN.org

4/2013

- Recommendations to Screen
 - 1. NCCN
 - 2. ACCP
 - 3. ASCO
 - 4. ATS
 - 5. AI A
 - 6. AATS
 - 7. ACS
- Reimbursement
 - Mass BC/BS
 - Wellpoint
 - Multiple state plans



NCCN Guidelines® High-Risk Groups

Group 1 (Category 1 Recommendation)

- 55-74 years old
- Are currently a smoker or have quit within the past 15 years
- Have smoked at least a pack of cigarettes a day for 30+ years

Group 2 (Category 2B Recommendation)

- □ 50-74 years old
- Have smoked at least a pack of cigarettes a day for 20+ years
- Have one additional lung cancer risk factor, not to include secondhand smoke exposure



NCCN High-Risk Group 2 Risk Factors

Personal Cancer History

Lung, lymphoma, smoking related cancers

Family History Lung Cancer in 1st Degree Relative

Chronic Lung Disease

- Emphysema
- Pulmonary Fibrosis

Carcinogen Exposure

 Arsenic, asbestos, cadmium, chromium, diesel fumes, nickel, radon, silica



Making a case to screen: Education Campaign

Save lives

Enhance revenue

Save money

Attract patients

Teamwork



In other words: Fulfill Hospital Mission

Save Lives, Growth, Innovation, Sustainability, Teamwork



Making a case to screen

Save lives

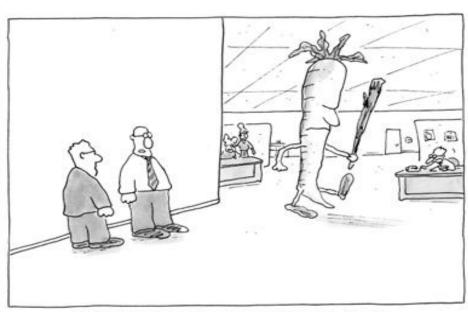
Enhance revenue

Save money

Attract patients

Teamwork

Fulfill mission



"This is their new big carrot and stick method."

Help avoid future litigation?



Failure to Screen Lawsuits

Although abundant scientific literature raises concerns about the efficacy of, and in some cases suggests risks to obtaining, certain screening tests, the public is generally exposed at a disproportionately greater degree to the benefits of these tests. As a result, juries confronted with a plaintiff patient who develops cancer or other serious disease for which a screening test was available but not ordered by the patient's physician, tend to find that the physician's failure to order the test was negligent.

Berlin, L. AJR December 2002 vol. 179 no. 6 1401-1405

Lawsuit Follows Death Of Woman When Doctors Failed To Screen Her As Per Cancer Screening Guidelines



JUNE 25, 2012

D.C. Jury Awards \$5M for Failure to Screen for Cancer Updated at 6:12 p.m.

A District of Columbia Superior Court jury recently awarded more than \$5 million to the family of a man who died of colon cancer last year, finding that his doctor was liable for failing to properly screen him for cancer for 16 years.

Ronald Berger, 69, died in December following four years of chemotherapy treatment. From 1992 until his diagnosis in 2008, however, Berger's family claimed that his Washington-based doctor, Dr. Francis Chucker, failed to perform the full scope of screening laid out in guidelines from national health organizations. Berger's family filed a lawsuit alleging malpractice against Chucker in July 2010.

"Right to Know"



THE RIGHTS OF THE PEOPLE

- You have the right to know if you are at risk for lung cancer.
- You have the right to know that wellorganized low-dose CT screening has been shown to significantly reduce the possibility of dying from lung cancer.
- You have the right to clear and unbiased information on the risks and benefits of CT screening.
- You have the right to fair and equitable access to medically appropriate CT screening.

- You have the right to timely and compassionate care if you are diagnosed with lung cancer.
- You have the right to donate your scans and biological specimens to lung cancer research to help find additional life-saving cures.
- You have the right to ask screening sites if they follow the Guiding Principles for Lung Cancer Screening Excellence and provide care in a multidisciplinary continuum.



PCP Reassurance

Example Individual PCP: 2500 Patient Panel

~75 patients: Qualify for lung screening (NCCN high-risk)

~20 patients: Positive for a lung nodule

~5 patients: Potentially significant incidental findings





NLST

Results: False Positive Workup/Adverse Events

False Positive Rate:

- **❖20-25%:** Chance you will end up with a false positive
- **❖~10-12%** for Mammography ("Call back")

False Discovery Rate (1-PPV):

- **❖96%:** Chance if you are positive you do not have cancer
- **❖Same as mammography**

False Positive Biopsy Rate

- **❖**0.4-2.4%: Chance if screened you will have an unnecessary invasive procedure (LDCT)
- ❖7-15%: Chance if you end up having a biopsy it will be negative (mammography).



Lung vs Breast Screening

	Lung Cancer	Breast Cancer	
5 Yr Overall Survival 1975	12%	75%	
5 Yr Overall Survival 2007	15%	89%	
Screening Modality	LDCT	Mammogram	
Screening Frequency	Annual	Annual/Biannual	
Patient Population	30PY, 55-74y	Females 40-80y	
Patient Number Estimates	9,000,000	60,000,000	
Cost of Exam	\$300	\$100	
Per Year Cost of 1 Screen	\$2.1 B	\$6 B	
Radiation Exposure	0.5-1.7 mSv	0.7 mSv	
Mortality Reduction	20%	10-35%	
NNS	320	1250 (40-49y)	
Overdiagnosis	< 17% vs CXR*	5-50%	
False Positive Rate	~35%/ 3 years	30-35%/10 years (annual)	
Cost/QALY	< \$50,000	\$38K - 58K (40-80y)	



Program Activities →

Publications/Abstracts
Public Outreach
Lobbying for Reimbursement
Institutional Guidance
Research

9/21/2011 Docs For Dinner	ABM, BM
1/5/2012 Steering Committee Meeting	ABM, BM
1/19/2012 Sg2	ABM, BM
1/19/2012 Radiology Working Group Meeting	BM
1/19/2012 Lahey Executive Health & Philanthropy	ABM
1/23/2012 Lahey Board of Governors	ABM
1/24/2012 Lahey North Leadership	ABM
1/24/2012 Radiology Working Group Meeting	BM
1/24/2012 Steering Committee Meeting	ABM, BM
1/25/2012 Burlington GIM	ABM
1/25/2012 Lahey Tumor Board	ABM
1/27/2012 Radiology Working Group Meeting	BM
1/31/2012 Radiology Working Group Meeting	BM
2/2/2012 MPU Committee	ABM
2/7/2012 Radiology Working Group Meeting	BM
2/8/2012 Steering Committee Meeting	ABM, BM
2/9/2012 Beverly CGP	ABM
2/17/2012 Radiology Working Group Meeting	BM
2/27/2012 Radiology Working Group Meeting	BM
3/8/2012 Steering Committee Meeting	ABM, BM
3/19/2012 Lahey BDI CGPs	ABM
3/20/2012 Pilot Program Review Meeting	ABM, BM
3/20/2012 Colleague Health Fair	ABM
3/23/2012 Lahey Grand Rounds	ABM
3/28/2012 Radiology Working Group Meeting	BM
4/3/2012 Radiology Working Group Meeting	BM
4/4/2012 Beverly MITS Conference	ABM
4/5/2012 Pentucket Medical Group	ABM
4/9/2012 Radiology Working Group Meeting	BM
4/12/2012 Steering Committee Meeting	ABM, BM
4/23/2012 Radiology Working Group Meeting	BM
4/24/2012 Frisbee Conference Call	ABM, BM
5/8/2012 Radiology Working Group Meeting	BM
5/9/2012 Lahey CT Surgery Meeting	ABM
5/15/2012 Varian Webinar	ABM, BM
5/18/2012 LCN CT Tech Protocol Review	BM
5/18/2012 Mass Firefighters Union	ABM
5/30/2012 ACR Conference Call (J. Brink)	ABM, BM
5/30/2012 Radiology Working Group Meeting	BM
6/2/2012 Lahey Cancer Walk	
6/5/2012 Phillips Research Conference Call	ABM, BM
	ABM, BM
6/6/2012 Hanscom Airforce Base	ABM DM
6/12/2012 Program CD Created (Now over 220 distributed internationally)	ABM, BM
6/14/2012 Catholic Medical Center	ABM DM
6/26/2012 Steering Committee Meeting	ABM, BM

7/18/2012 Mass Firefighters (Danvers FD)	ABM	
7/20/2012 Phillips Research Meeting	ABM, BM	
7/29/2012 Varian Centerline Cover Story	ABM	
8/16/2012 Congressman Tierney Visits Program	ABM	
8/21/2012 Mass DCP and DPH Director Meeting	ABM	
8/27/2012 LCA and Brookings Insitutute Conf Call	ABM, BM	
8/29/2012 Radiology Working Group Meeting	BM	
9/6/2012 Rescue Lung, Rescue Life Poster @ Chicago	MSTO ABM, BM	
9/6/2012 Initial Program Results Poster @ Chicago M	STO ABM, BM	
9/11/2012 Radiology Working Group Meeting	BM	
9/14/2012 Centers of Excellence CHEST 2012 Conf Ca	II ABM, BM	
9/18/2012 Harvard Vanguard PCPs	ABM	
9/20/2012 KEMH Lung Screening Presentation (Neumo		
9/25/2012 Candidate Tisei Visits Program	ABM	
9/28/2012 ASCR Presentation	(BM)	
9/29/2012 Aunt Minnie LungRADS Interview/Writeup	BM	
10/19/2012 SWOG Presentation	BM	
10/22-10/24 CHEST 2012 Center of Excellence Booth	ABM, BM	
10/26/2012 MD Anderson Conference Call	ABM, BM	
10/29/2012 Initial Results Poster @ ASTRO	ABM. BM	
11/3/2012 Breathe Deep Boston Rescue Lung Rescue		
11/6/2012 UTSW Conference Call	ABM, BM	
11/7/2012 Steering Committee Meeting	ABM, BM	
11/8/2012 Veteran's Day Lung Screening Event w/LCA		
11/13/2012 SWOG Research Proposal Meeting	ABM, BM	
11/13/2012 Shine a Light Presentation	ABM	
11/29/2012 LungRADS Oral Presntation @ RSNA	BM	
11/29/2012 Richard Duszak Meeting (HNI)	BM	
11/29/2012 University of Illinois @ Chicago Presentation	BM	
11/30/2012 Kathleen Sebelius Response Petition for Rei		
12/3/2012 SWOG Conference Call re: Comparative Effe		
12/6/2012 Achieving Excellence in Lung Screening Mee	ting (Speaker) ABM	



Referral Sources

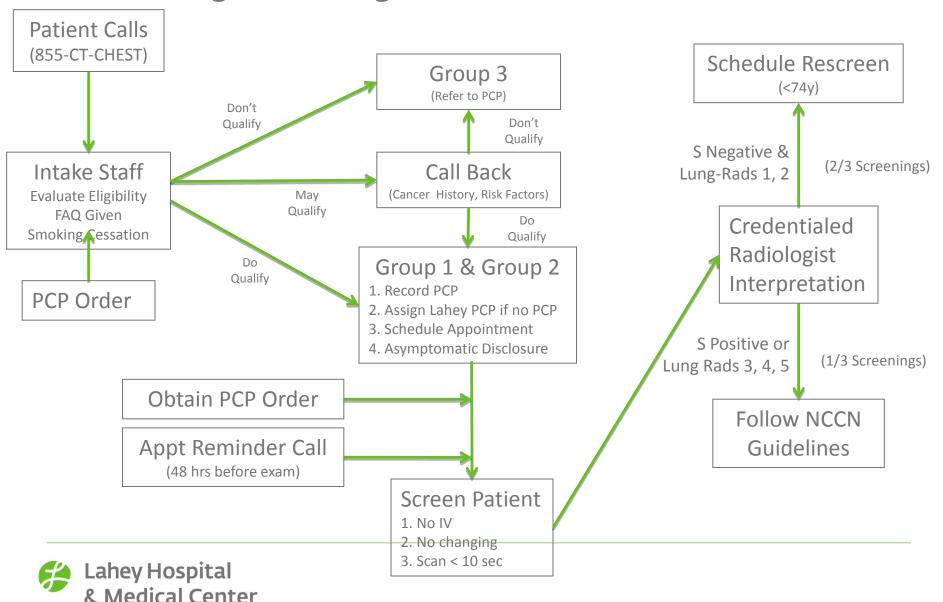
(First 12 Months ~700 patients)

- **❖Lahey PCP 463 (65%)**
- **❖Lahey Spec. Provider** − 92 (13%)
 - ❖Pulmonary 63
 - ❖Radiation Oncology 11
 - ❖Cardiovascular 3
 - ◆Breast 2
 - **♦EIH 13**
- **❖Outside MD 21 (3%)**
 - ❖ Outside PCP 20
 - ❖ Outside Pulmonary MD 1
- **❖Lahey Employees** − 33 (5%)
- ❖Lahey Web/Facebook 11 (1.5%)

- **❖Global Email** 36 (5%)
- ❖Newspaper Articles 18 (2.5%)
 - **❖Lowell Sun 16**
 - ❖Burlington Times 1
 - ❖Other newspaper 1
 - •
- **♦ Other 37 (5%)**
 - **❖Family Member/Friend 20**
 - ❖Brochure/Flyer/Spectrum 11
 - ❖Women's Fair at Mall 1
 - ❖Word of Mouth 1
 - ❖Wellness fair 3
 - **♦** Smoking Cessation 1



LDCT Lung Screening - Patient Flow





CT Lung Screening Reporting and Data System "LungRADS"

Lung RADS Lung Screening Specific Category (Part 1)

CT Lung Screening Reporting and Data System (LungRADS)

Lung Cancer Specific Category (BI-RADS® Based)		NCCN-Guidelines® Based	
Category	Assessment	Followup Recommendation	
1	Negative	Routine annual LDCT screen (age < 75)	
2	Benign	Routine annual LDCT screen (age < 75)	
3	Probably Benign Interval short-term diagnostic LDC (1, 2, 3, 6, 12 months)		
4	Suspicious	Pulmonary consultation/ Multidisciplinary Clinic Review	
5	Known Malignancy	PCP/Oncology referral	



Followup Schedule Stable solid nodule (4-6mm)

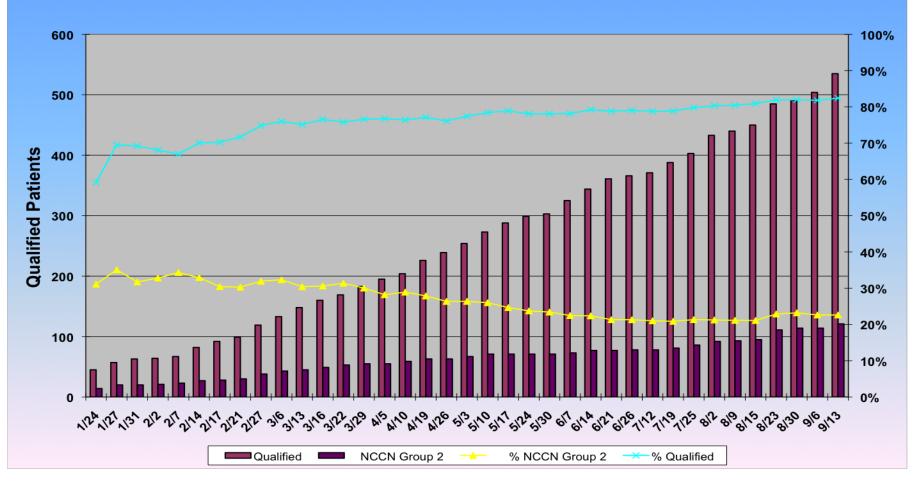
Time (Months)	LDCT Exam	Nodule Size	LungRADS
0	Screening	5-6mm	3nN
6	Diagnostic	5-6mm no △	3nN
18	Diagnostic	5-6mm no △	3nN
30	Diagnostic	5-6mm no △	2N
42	Screening	5-6mm no △	2N



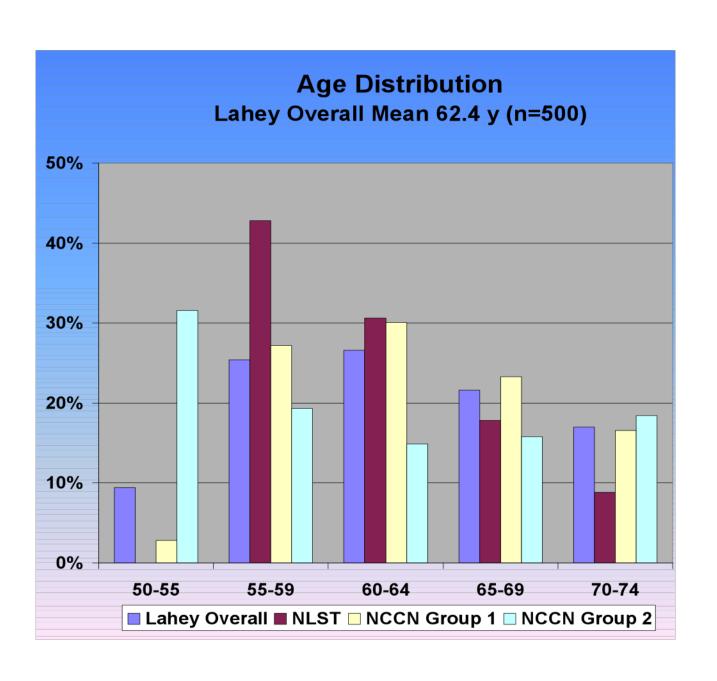


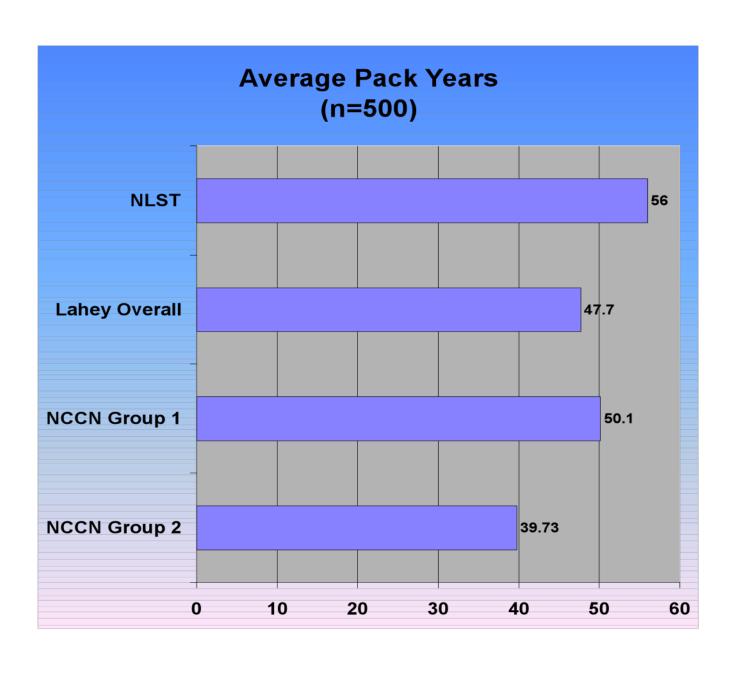
Results First 500 patients

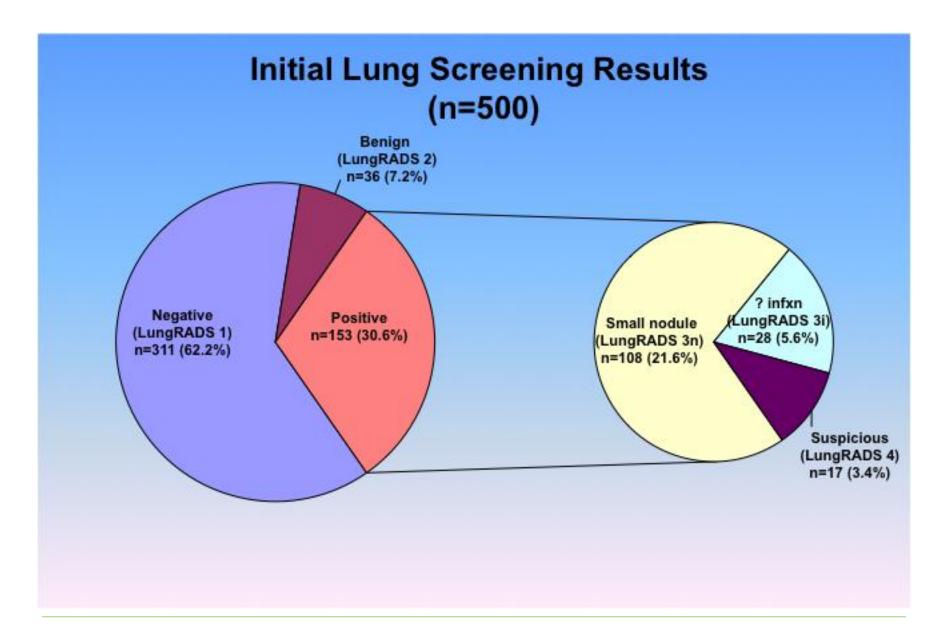
Lahey Clinic Lung Screening Program Volume and Percentages







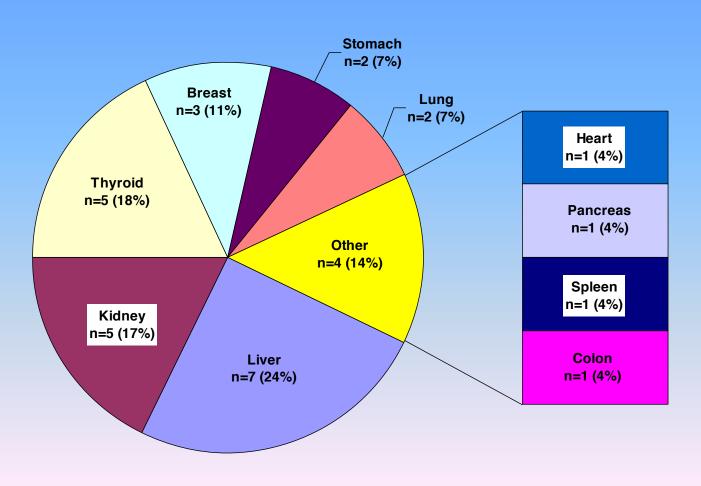






Initial Lung Screening Results

Significant Incidental Findings (n=28)





Initial Experience With a Free, High-Volume, Low-Dose CT Lung Cancer Screening Program

Brady J. McKee, MD^a, Andrea B. McKee, MD^b, Sebastian Flacke, MD, PhD^a, Carla R. Lamb, MD^c, Paul J. Hesketh, MD^d, Christoph Wald, MD, PhD^a

The National Lung Screening Trial demonstrated a significant mortality benefit for patients at high risk for lung cancer undergoing serial low-dose CT. Currently, the National Comprehensive Cancer Network and several United States—based professional associations recommend CT Lung screening for high-risk patients. In the absence of established reimbursement, the authors modeled and implemented a free low-dose CT lung cancer screening program to provide equitable access to all eligible patients. Elements of the program reported in this article include a decentralized referral network, centralized program coordination, structured reporting, and a patient data management system. The experience and initial results observed in this clinical setting closely match the performance metrics of the National Lung Screening Trial with regard to cancer detection and incidental findings rates. To eliminate health care disparities a vigorous lobbying effort will be needed to expedite reimbursement and make CT lung screening equally available to all patients at high-risk.

Key Words: Lung cancer screening, low-dose chest CT, National Lung Screening Trial, NLST

J Am Coll Radiol 2013;xx:xxx. Copyright © 2013 American College of Radiology



Key Lung Screening Program Elements

Physician champions (at least 2 disciplines)

Free or very low cost access until established reimbursement

- Available CT scanner downtime
- Decentralization
- Primary care physician/public education & outreach

Database

Program coordinator/navigator

Standardized reporting system (LungRADS) – Guideline approach

Integrated smoking cessation counseling

Multidisciplinary steering committee (oversight mechanism)



Rescue Lung, Rescue Life Movement Mission:

- Save lives through the early detection of lung cancer with responsible CT lung screening
- Encourage the government to establish reimbursement for CT lung screening
- Encourage other centers of excellence in the treatment of lung cancer to offer FREE CT lung screening until CMS establishes reimbursement
- Break down barriers and prejudice faced by those at risk for lung cancer
- Raise public awareness of the power of CT lung screening to save lives
- Provide a platform to explore relevant research questions

CT Lung Screening Reporting and Data System "LungRADS" - NCCN Guidelines® based

Overall exam assessment system

Nodule lexicon

Structured reporting system



LungRADS Overall Exam Assessment

Part 1: Lung cancer specific findings

- Nodules, masses, mediastinal/hilar lymph nodes, effusions
- BI-RADS®-like numeric assignment 1-5 based on NCCN Guidelines® Recommendations

Part 2: Significant incidentals findings: "Category S"

• "P" – positive or "N" – negative.

10 possible LungRADS final assessments

- Part 1 + Part 2
- 1P, 1N, 2P, 2N, 3P, 3N, 4P, 4N, 5P, 5N



LungRADS Category 1 – "Negative"

Findings:

- No findings or minor findings
 - Morphologically benign nodules
 - Micronodules
 - Non-calcified solid/part-solid nodules with mean diameter ≤ 4m
 - Ground glass nodules with mean diameter < 5mm

Impression: Negative, no evidence of malignancy

Recommendation: Normal interval follow-up LDCT screening recommended in 12 months (if age < 75)



LungRADS Category 2 – "Benign"

Findings:

- Solid nodules > 4mm which are stable for > 2 yrs
 - Need prior imaging
- Biopsy proven benign lesions.

Impression: Negative, benign findings with no evidence of primary lung cancer

Recommendation: Normal interval follow-up LDCT screening recommended in 12 months (if age < 75)



LungRADS Category 3 – "Likely Benign"

Findings: NCCN Guidelines® recommends interval LDCT followup.

- Subcategory 3n
 - > Solid and part-solid nodules 4-8mm
 - > Groundglass nodules ≥ 5mm
 - > Solid endobronchial nodules
- Subcategory 3i
 - > Infectious/Inflammatory nodules
 - > In addition to LDCT followup consider antibiotics

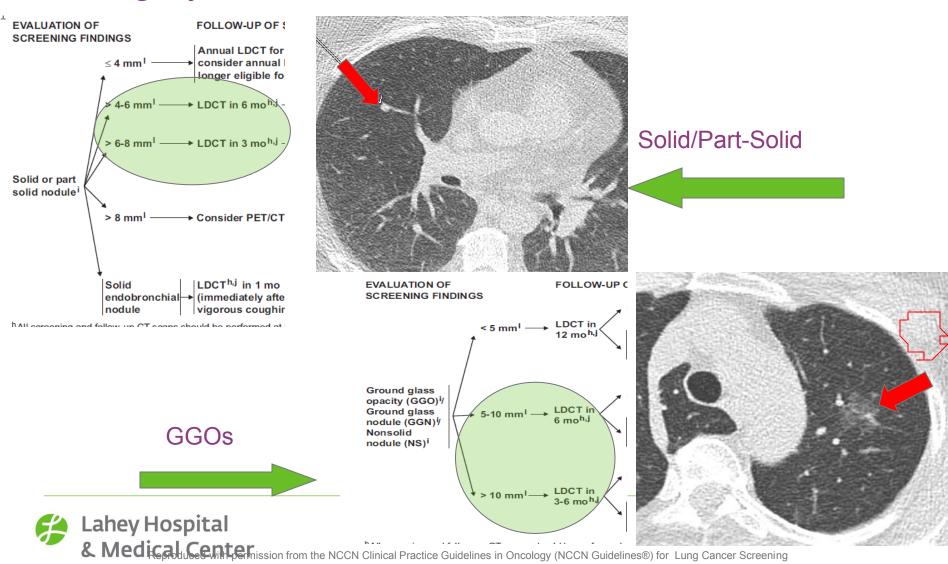
<u>Impression:</u> Positive: Indeterminate, <u>likely benign</u> finding requiring LDCT imaging follow-up.

Recommendation: LDCT imaging follow-up per NCCN guidelines

Followup months and specific date given

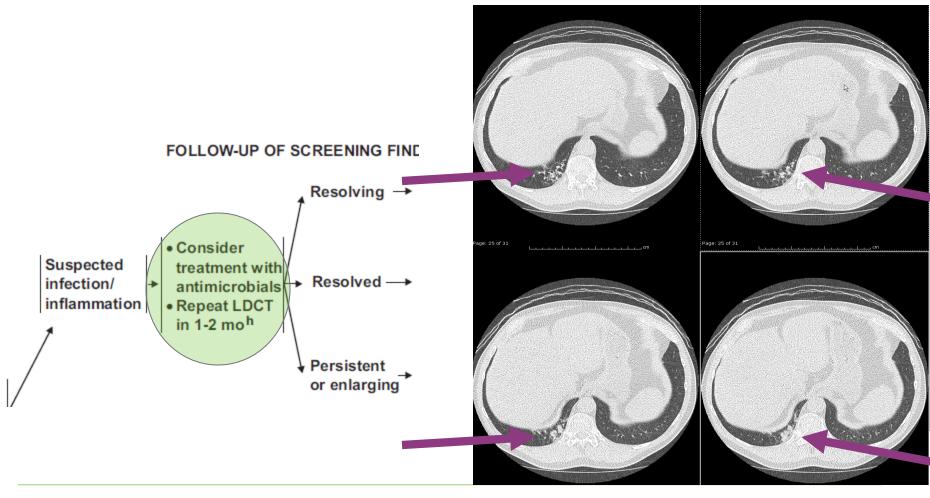


LungRADS Category 3n: Solid/Part-Solid & GGOs



LungRADS

Category 3i: Infectious/Inflammatory Nodule



LungRADS

Category 4 – "Suspicious"

<u>Findings:</u> Require more than LDCT followup (PET/CT, bronchoscopy, biopsy, surgical resection, etc)

- Solid nodule increasing in size, initially >4mm
- Solid nodule >8mm
- Persistent endobronchial nodule
- GG nodule increasing in size
- Change in ground glass component (more solid)
- Stable GG nodule >10mm at f/u

Impression: Positive, suspicious finding requiring clinical evaluation

Recommendation: Pulmonary consultation advised to determine direction of further evaluation.

- Radiologist to referring MD conversation
- Multidisciplinary care team review



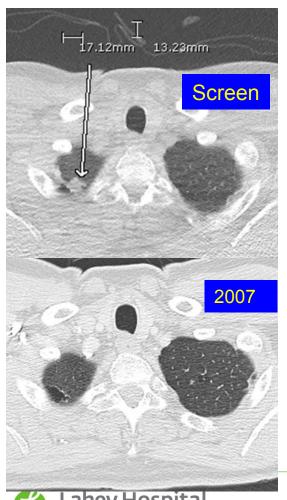
LungRADS Category 4: Pulmonary consultation

Printed by Brady McKee on 9/5/2012 12:51:56 PM. For personal use only. Not approved for distribution. Copyright © 2012 National Comprehensive Cancer Network, Inc., All Rights Reserved National Comprehensive NCCN Guidelines Version 1.2013 **NCCN Guidelines Index** LCS Table of Contents Cancer Lung Cancer Screening Network® **EVALUATION OF** FOLLOW-UP OF SCREENING FINDINGS SCREENING FINDINGS Annual LDCT for 2 years (category 1) and Annual LDCT for 2 years (category 1) and consider annual LDCT until patient no ≤4 mm^l consider annual LDCT until patient no longer eligible for definitive treatment h,j,k longer eligible for definitive treatmenth,j,k If no increase n,o in → LDCT in 6 mo^{h,j} size, LDCT in 12 mo h,j If no increase n,o in → increase → Surgical excision > 6-8 mm¹ -→ LDCT in 3 mo^{h,j} size, LDCT in 6 mo h,j in sizen,o Low suspicion Solid or part ▶ LDCT in 3 mo^{h,j} of lung cancer solid nodule Annual LDCT for 2 years (category 1) and consider → Consider PET/CT > 8 mm¹ No annual LDCT until patient no Biopsy cancer longer eligible for definitive Suspicion of treatment h,j,k Surgical lung cancer^m See appropriate excision Cancer **NCCN Guidelines** confirmed LDCTh,j in 1 mo Solid endobronchial → (immediately after → If no resolution → Bronchoscopy nodule vigorous coughing)

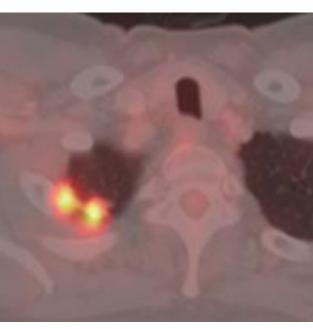


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Adenocarcinoma, Grade 3/4 T1a (2cm), N0, M0 → Stage IA

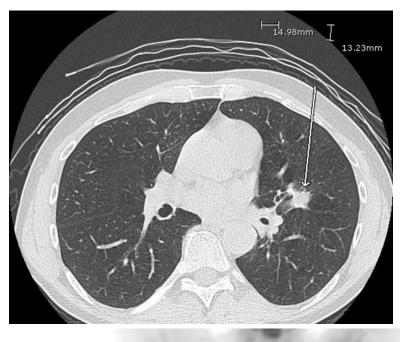




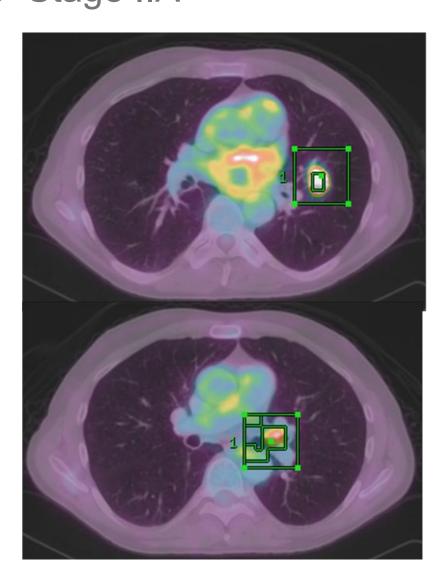




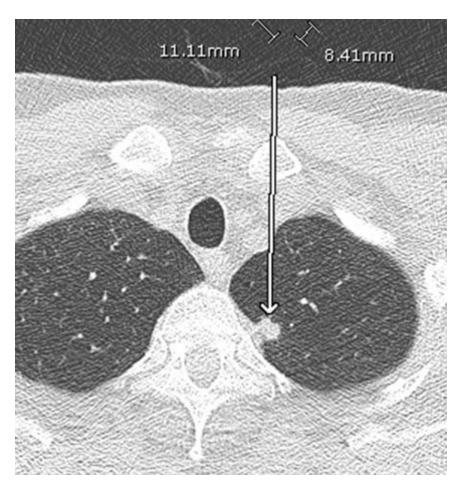
Squamous Cell Carcinoma, Grade 2/4 T1a(1.8cm), N1(10L), M0 → Stage IIA

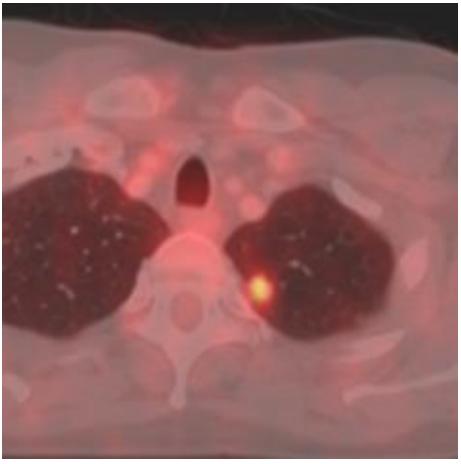






Adenocarcinoma, Grade 2/4 T1a (1.5cm), N0, M0 → Stage IA





LungRADS Category 5 – "Known Malignancy"

Findings: Cancer

Impression: Positive, Known malignancy.

Recommendation: Follow-up per clinical/oncologic protocol

- ? change to "Highly Suspicious" to match BI-RADS®
 - LungRADS Category 6: Known Malignancy

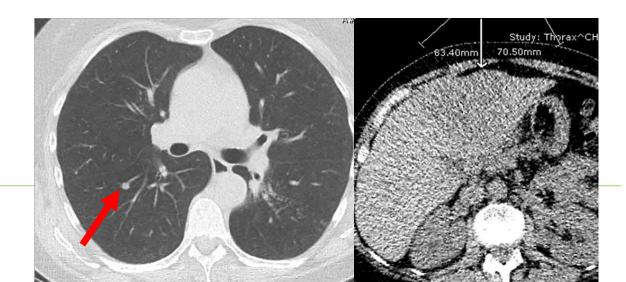


LungRADS "Category S"

Incidental findings not suspicious for lung cancer but requiring some form of clinical/imaging follow-up.

Example Case

- Liver lesion & small solid pulmonary nodules > 4mm and < 8mm
- LungRADS 3nP
- Recommend: MRI Abdomen





LungRADS "Category S"

Incidental findings not suspicious for lung cancer but requiring some form of clinical/imaging follow-up.

Example Case

- Liver lesion & small solid pulmonary nodules > 4mm and < 8mm
- LungRADS 3nP
- Recommend: MRI Abdomen
- Metastatic Cholangiocarcinoma





Nodule Lexicon



Table 2 Continued Low-Dose Computed Tomog

Low-Dood Compared Tomog
Nodule Parameters
Size
Density
Calcification
Fat
Shape
Margin
Lung location
Location in dataset
Temporal comparison

Report Example

"Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)"



Nodule Description Unique Numeric identifier

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)



Nodule Description Dataset Location

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)



Nodule Description Density

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)

Solid, Part-solid, Groundglass, infectious-inflammatory



Nodule Description Shape

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)

Ovoid, Round, Triangular



Nodule Description Margin

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)

Smooth, Lobulated, III-defined, Spiculated



Nodule Description Local environment

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)

Parenchymal, subpleural, endobronchial



Nodule Description Lung Location

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)

Lobe and segment if possible



Nodule Description Size Comparison

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)

Comparison size and date of comparison if available



Nodule Description Size Range

Nodule 1 (image 45, series 3): 6-7 mm solid, ovoid, lobulated, subpleural nodule in the anterior basal segment right lower lobe previously 4-5 mm (2010)



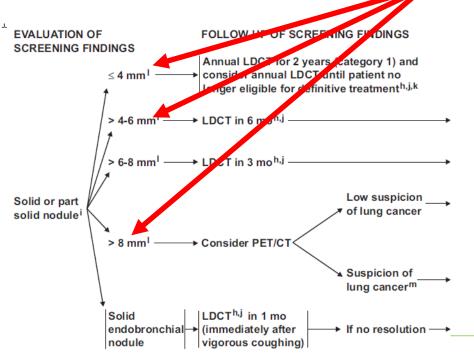
Respects spatial resolution limitation of LDCT (>0.4mm)

Fractional mm reporting = false precision



Respects spatial resolution limitation of LDCT (>0.4mm)

Avoids NCCN breakpoints: 4, 6, 8mm





Respects spatial resolution limitation of LDCT (>0.4mm)

Avoids NCCN breakpoints: 4, 6, 8mm

"Does a 6mm nodule get a 3 month or 6 month followup??"



Respects spatial resolution limitation of LDCT (>0.4mm)

Avoids NCCN breakpoints: 4, 6, 8mm

Answer: Moot Point

- 4, 6, & 8 mm nodules do not exist in this system
- Nodule ranges only: 4-5mm, 5-6mm, 6-7mm...

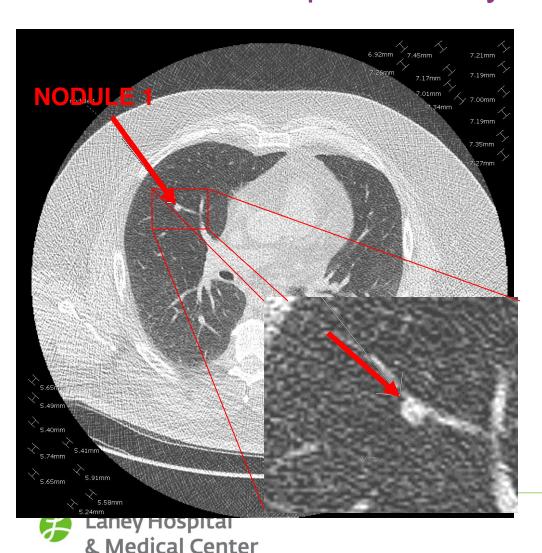
Respects spatial resolution limitation of LDCT (>0.4mm)

Avoids NCCN breakpoints: 4, 6, 8mm

Increases intraobserver and interobserver reproducibility



Nodule Lexicon Nodule Size Reproducibility



Long Axis

• 6.92-7.35 mm

Short Axis

• 5.24-5.74 mm

Sum Total

• 12.16-13.09 mm

Mean (1mm range)

• 6-7mm

Respects spatial resolution limitation of LDCT (>0.4mm)

Avoids NCCN breakpoints: 4, 6, 8mm

Increases intraobserver and interobserver reproducibility

Reduces reporting insignificant change and potential increased patient and MD anxiety

• 6.2mm nodule "grown" to 6.8mm



Respects spatial resolution limitation of LDCT (>0.4mm)

Avoids NCCN breakpoints: 4, 6, 8mm

Increases intraobserver and interobserver reproducibility

Reduces reporting insignificant change and potential increased patient and MD anxiety

Facilitates growth identification

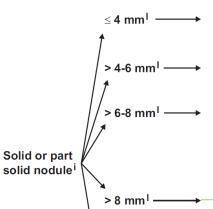


Nodule Growth NCCN Growth Definition

- Nodules < 15mm: Increase ≥ 2mm
- Nodules > 15mm: Increase 15%

4 NCCN solid nodule recommendation tranches

- 1. ≤ 4mm
- 2. 4-6mm
- 3.6-8mm
- 4. > 8 mm





Nodule Growth NCCN Growth Definition

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4 NCCN solid nodule recommendation tranches

- 1. ≤ 4mm
- 2. 4-6mm
- 3. 6-8mm

Nodule must AT LEAST move to a higher tranche to meet growth criteria

4. > 8 mm



LungRADS Structured Report FINDINGS:

Lung Screening Specific (LungRADS): []

Potentially Significant Incidentals (LungRADS category S): []

Pulmonary Incidentals: []

Other Incidentals: []

IMPRESSION:

- 1. LungRADS category []: []
- 2. <u>LungRADS category S:</u> []
- 3. Other incidental findings as above

RECOMMENDATIONS: []



Example Report LungRADS 1N

FINDINGS:

Lung Screening Specific (LungRADS): Negative.

• No findings, or minor findings not suspicious for primary lung cancer such as morphologically benign nodules, non calcified nodules with a mean diameter < 4mm, or ground glass opacities with a mean diameter < 5mm.

Potentially Significant Incidentals (LungRADS category S): None.

<u>Pulmonary Incidentals:</u> Scarring along the lateral aspect of the left lower lobe. 4 mm groundglass nodule right apex.

Other Incidentals: Marked coronary artery calcifications. Cholelithiasis. 2.4 cm left adrenal myelolipoma.

IMPRESSION:

- 1. <u>LungRADS category 1:</u> Negative, no evidence of primary lung cancer.
- 2. <u>LungRADS category S:</u> Negative, no new or unknown potentially significant incidental findings requiring urgent additional evaluation.
- 3. Left adrenal myelolipoma and other incidental findings as above.

RECOMMENDATIONS: Continued routine annual LDCT lung screening. Suggest next LDCT exam on or around 4/1/2013.



Example Report LungRADS 3nN

FINDINGS:

<u>Lung Screening Specific (LungRADS):</u> Positive.

> Nodule 1 (image 65, series 3): 4-5 mm solid, ovoid, lobulated, parenchymal nodule in the left lower lobe.

Potentially Significant Incidentals (LungRADS category S): None.

<u>Pulmonary Incidentals:</u> Mild biapical scarring.

Other Incidentals: None.

IMPRESSION:

- 1. LungRADS category 3: Positive Indeterminate, likely benign finding requiring LDCT chest imaging follow-up.
- > 4-5 mm solid pulmonary nodule left lower lobe.
- <u>2. LungRADS category S:</u> Negative, no new or potentially significant incidental findings requiring urgent additional evaluation.
- 3. Other incidental findings as above.

RECOMMENDATIONS: Follow-up LDCT lung screening in 6 months (on or around 8/2/2012).