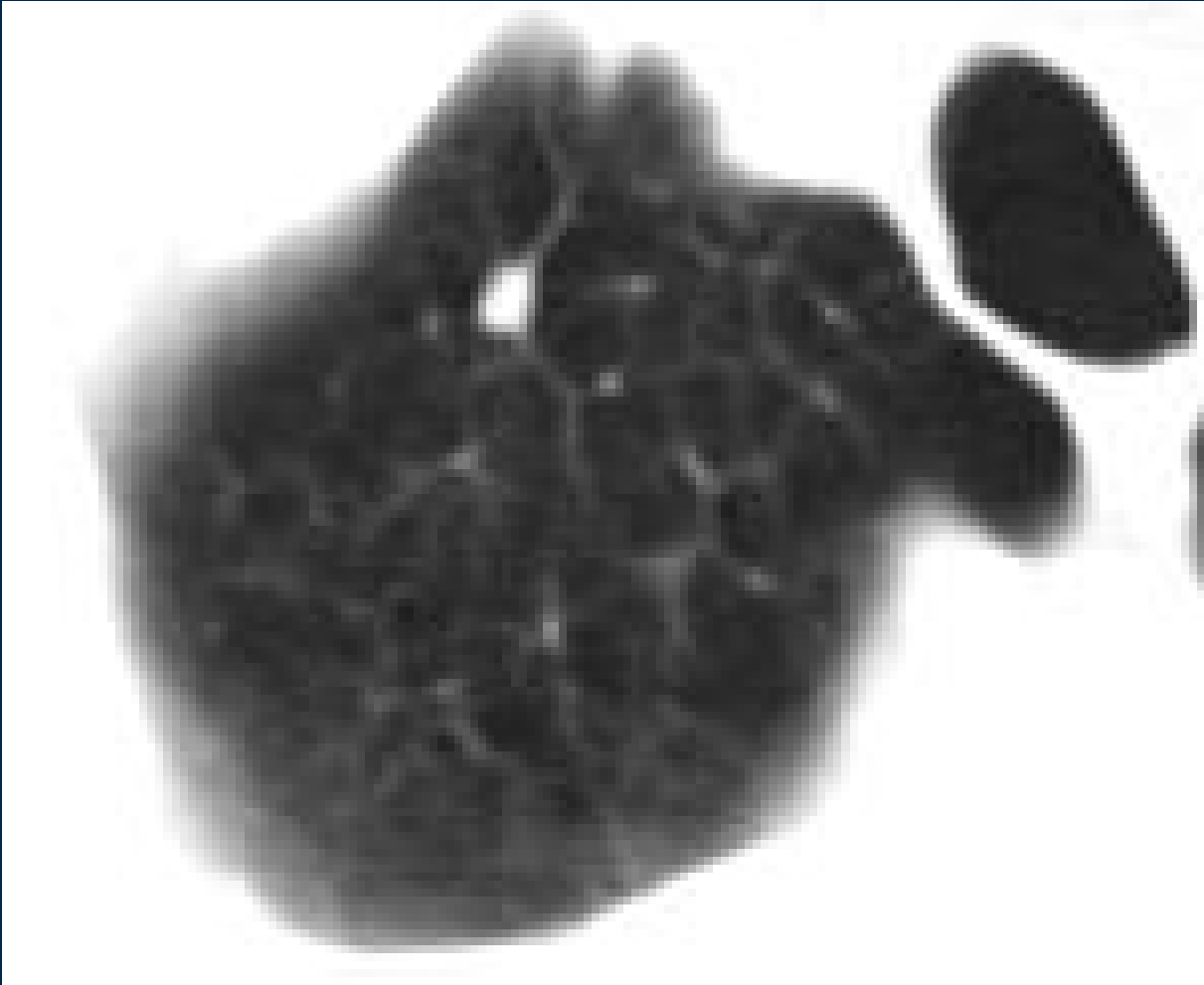# Lung Cancer Screening: LungRADS™ Update

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ellakaz

Lung Cancer

early stage

late stage

Lung Cancer Screening Essentials

- Shared decision making

- Smoking cessation

- Who to screen & Why

- What to screen with & how to do it

- LungRADS – schema to interpret screening exams & manage screening results

- Multidisciplinary team

Lung Cancer Screening Essentials

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- LungRADS – schema to interpret screening exams & manage screening results

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CMS - Lung Cancer CT Screening Coverage

Radiology Imaging Facility Eligibility Criteria:

- Performs LDCT with volumetric CT dose index (CTDIvol) of ≤ 3.0 mGy for standard size patients (defined to be 5′ 7″ and approximately 155 pounds) with appropriate reductions in CTDIvol for smaller patients and appropriate increases in CTDIvol for larger patients;

- Utilizes a standardized lung nodule identification, classification and reporting system;

- Makes available smoking cessation interventions for current smokers; and

- Collects and submits data to a CMS-approved registry for each LDCT lung cancer screening performed.

RADIOLOGY

ACR LungRADS™

- To provides a common lexicon & definitions
- To standardizes practice among radiologists for communicating with ordering providers
- To define a positive screen
- To address uncertainty in positive screen management
- To facilitate quality assurance & improvement
- *To be updated as knowledge evolves*

ACR RADS

newly formed RADS steering committee

Breast Imaging Reporting and Data System (BI-RADS®) Atlas

The BI-RADS Atlas provides standardized breast imaging findings terminology, report organization, assessment structure and a classification system for mammography, ultrasound and MRI of the breast.

CT Colonography Reporting and Data System (C-RADS)

C-RADS is a standardized reporting, risk assessment and management tool for colorectal and extra-colonic findings which allows monitoring of quality metrics and patient outcomes.
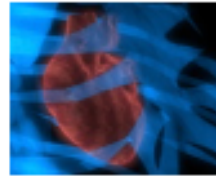
Coronary Artery Disease Reporting and Data System (CAD-RADS™)

CAD-RADS™ is a standardized system to classify and report patient data for CT angiography (CTA).

Head Injury Imaging Reporting and Data System (HI-RADS)

HI-RADS is being developed to standardize the reporting and data collection of imaging in patients with traumatic brain injury.
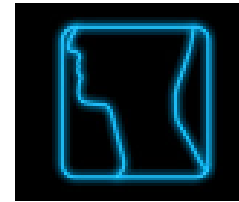
Liver Imaging Reporting and Data System (LI-RADS)

LI-RADS was created to standardize the reporting and data collection of CT and MR imaging for hepatocellular carcinoma (HCC) to classify observations as either definite HCC or definitely benign.
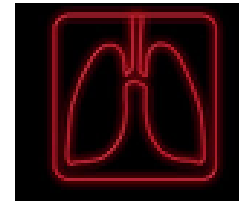
Lung CT Screening Reporting and Data System (Lung-RADS™)

Lung-RADS is a quality assurance tool designed to standardize lung cancer screening CT reporting and management recommendations, reduce confusion in lung cancer screening CT interpretations, and facilitate outcome monitoring.

Neck Imaging Reporting and Data Systems (NI-RADS)

The goal of NI-RADS is to provide practitioners with a widely applicable, understandable, and validated template for the management of neck masses on the basis of CT, PET, and MRI features.

Prostate Imaging Reporting and Data System (PI-RADS)

The goal of PI-RADS is to expedite the transfer of high-quality MRI from laboratories to patients to address the major need in prostate cancer care — reducing unnecessary biopsies and treatment.

## Thyroid Imaging Reporting and Data System (TI-RADS)

The goal of TI-RADS is to provide practitioners with evidence-based recommendations for the management of thyroid nodules on the basis a set of well-defined sonographic features or terms that can be applied to every lesion.

RADIOLOGY

ACR LungRADS 1.0 Released April 2014

- Structured reporting and management tool for lung cancer screening CT interpretation; it will iterate with the evidence
  - Definition of (+) screen, management recommendations
  - How nodules are measured (diameter vs. volume)

- Modeled after the ACR's 20 year experience with BIRADS, now it's fifth edition

- http://www.acr.org/Quality-Safety/Resources/LungRADS

Why LungRADS for Lung Cancer CT Screening?

- High false positive rate & lack of clarity about how to manage positive screens

- Concerns about over testing, radiation exposure, patient anxiety, invasive procedures & cost

- Overdiagnosis: cancer you can live with vs. die of

- Provide standardize reporting & management; facilitate outcomes tracking
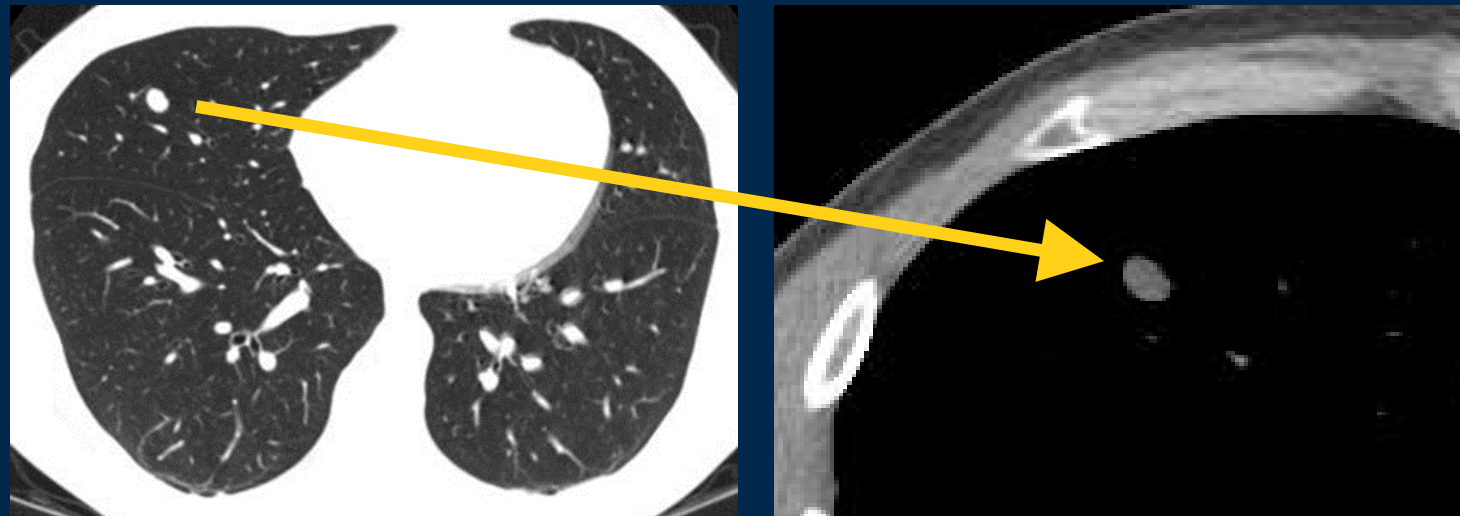
Fundamental question: What is a positive screen?

National Lung Screening Trial

- Positive screen: nodule ≥ 4 mm

  – Independent of nodule consistency (solid vs ground glass)

- Positive screen rates:
  - 27.3% baseline
  - 27.9% T1 screen
  - 16.8% T2 screen

- 20% reduction in lung cancer mortality

- LDCT screened group
  - lung cancer diagnosed in 1.1%
  - 90.4% at least 1 one f/u diagnostic procedure

Size Threshold for a Positive Lung Cancer Screening CT

I-ELCAP

ORIGINAL RESEARCH | Annals of Internal Medicine

Definition of a Positive Test Result in Computed Tomography Screening for Lung Cancer

A Cohort Study

Claudia I. Henschke, PhD, MD; Rowena Yip, MPH; David F. Yankelevitz, MD; and James P. Smith, MD, for the International Early Lung Cancer Action Program Investigators*

Ann Intern Med. 2013;158:246-252.

effect of alternative thresholds for defining a positive result on the rates of positive results and cancer diagnoses

M
RADIOLOGY

Size Threshold for a Positive Lung Cancer Screening CT

I-ELCAP

21,136 individuals with baseline CT performed between 2006 and 2010

Size	(+) Screen Rate	Work Up Reduction
≥ 5 mm	16.0%	
≥ 6 mm	10.2%	36%
≥ 7 mm	7.1%	56%
≥ 8 mm	5.1%	68%
≥ 9 mm	4.0%	75%

9 month delay in cancer dx 0%, 5%, 5.9%, 6.7%

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RADIOLOGY

NLST: Size Threshold for a Positive Lung Cancer Screening CT

- Examined impact of nodule size > 4 mm NLST (+) screen
- 64% of (+) screens (11,598/18141) were ≤ 7 mm nodules
- Going from 5 to 8 mm...
  - Missed or delayed cancer increased: 1.0% to 15.8%
  - False positives reduced: 65.8% to 10.5%

"Raising the nodule size threshold for a (+) screen would substantially reduce false-positive CT screenings and medical resource utilization with a variable impact on screening outcomes."
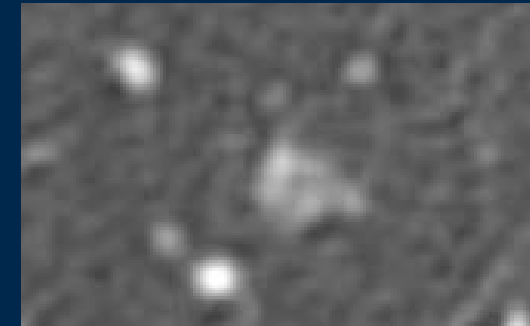
Gierada DS, Pinsky P, Nath H, Chiles C, Duan F, Aberle DR. Journal of the National Cancer Institute October 2014

2011 IASLC/ATS/ERS

International Multidisciplinary Classification of Lung Adenocarcinoma
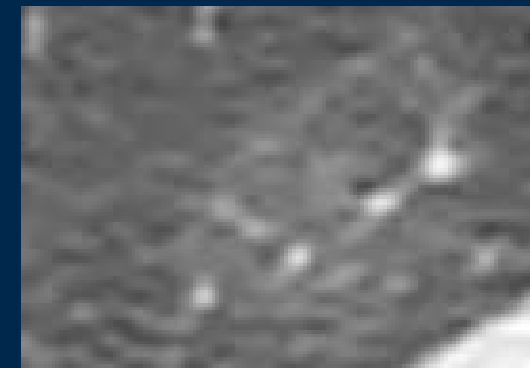
- Preinvasive Lesions:
  - Atypical adenomatous hyperplasia (AAH)
    - localized small proliferation of atypical Type II pneumocytes and/or Clara cells lining the alveolar walls and respiratory bronchioles
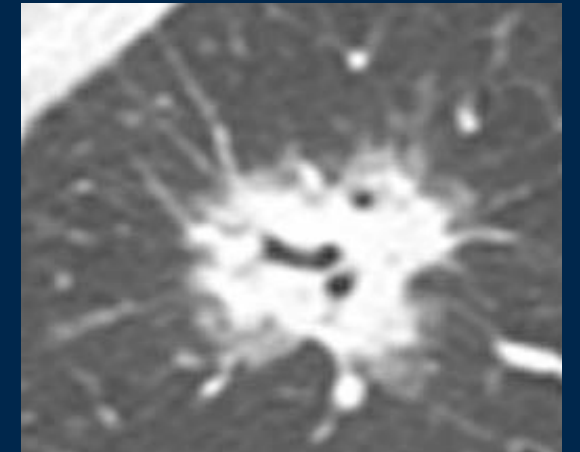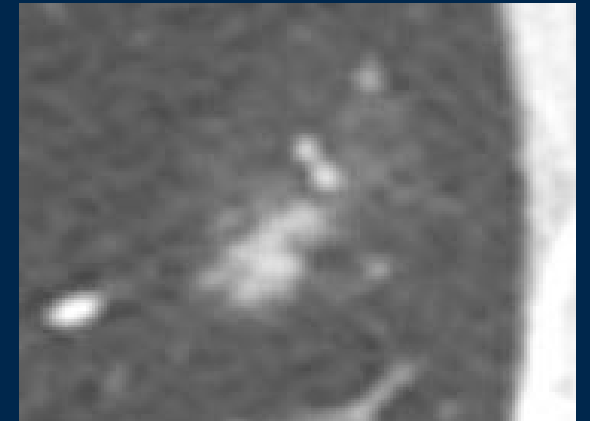 - Adenocarcinoma in situ (AIS)
    - ≤ 3 cm solitary adenocarcinoma with pure lepidic growth
    - complete resection achieves 100% disease-specific survival

2011 IASLC/ATS/ERS

International Multidisciplinary Classification of Lung Adenocarcinoma

- Minimally invasive adenocarcinoma (MIA)
  - ≤ 3 cm with predominantly lepidic pattern & ≤5 mm invasion at the largest dimension
  - Does not invade lymphatics, blood vessels or pleura
  - No necrosis
  - Complete resection achieves nearly 100% disease-specific survival

- Invasive adenocarcinoma

ACR LungRADS™

Category Descriptor	Category Descriptor	Primary Category
Incomplete	-	0
Negative	No nodules & definitely benign nodules	1
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A
		4B

ACR LungRADS™

Category Descriptor	Category Descriptor	Primary Category
Incomplete	-	0
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		4B

ACR LungRADS™

Category Descriptor	Category Descriptor	Primary Category	Expected Distribution	Probability of Malignancy
Incomplete	-	0		
Negative	No nodules & definitely benign nodules	1		
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	90%	< 1%
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	6%	1-2%
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	2%	5-15%
		4B	2%	> 15%

ACR LungRADS™

Category Descriptor	Category Descriptor	Primary Category	Management
Incomplete	-	0	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed
Negative	No nodules & definitely benign nodules	1	Continue annual screening with LDCT in 12 months
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	Continue annual screening with LDCT in 12 months
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	6 month LDCT
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4B	chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component.

ACR LungRADS™ 4X: Subsolid Nodules

Category Descriptor	Category Descriptor	Primary Category	Expected Distribution	Probability of Malignancy
Suspicious	Radiologist discretion to upcode categories based on additional findings and nodule features	4X		?
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4B	2%	> 15%

Malignancy Rates for Lesions Upgraded to Category 4X

| Observer	Total Upgraded to Category 4X	Upgraded from Lung-RADS 3	Upgraded from Lung-RADS 4A	Upgraded from Lung-RADS 4B
1	30/58 (52)	8/18 (44)	2/3 (67)	20/37 (54)
2	42/74 (57)	14/28 (50)	8/12 (67)	20/34 (59)
3	35/64 (55)	10/19 (53)	6/10 (60)	19/35 (54)
4	29/55 (53)	9/19 (47)	4/8 (50)	16/28 (57)
5	42/91 (46)	11/30 (37)	8/12 (67)	23/49 (47)
6	35/66 (53)	8/19 (42)	7/9 (78)	20/38 (53)
Average (%)*	53 (49, 56)	46 (40, 52)	65 (55, 74)	54 (50, 58)

| Feature |
|---|
| Effect on surrounding tissue |
| Internal nodule structure |
| Border characteristics |

4X malignancy rate was 46-57% per observer & substantially higher than malignancy rates of categories 3, 4A& 4B SSNs; *Radiology 2016 Chung et al*

M RADIOLOGY

ACR LungRADS™

- What nodules or other findings get into what categories?
  - Nodule size
    - Baseline or new finding
    - Growth vs. Stability
  - Nodule consistency
    - Solid, part solid, non solid (aka ground glass nodule)
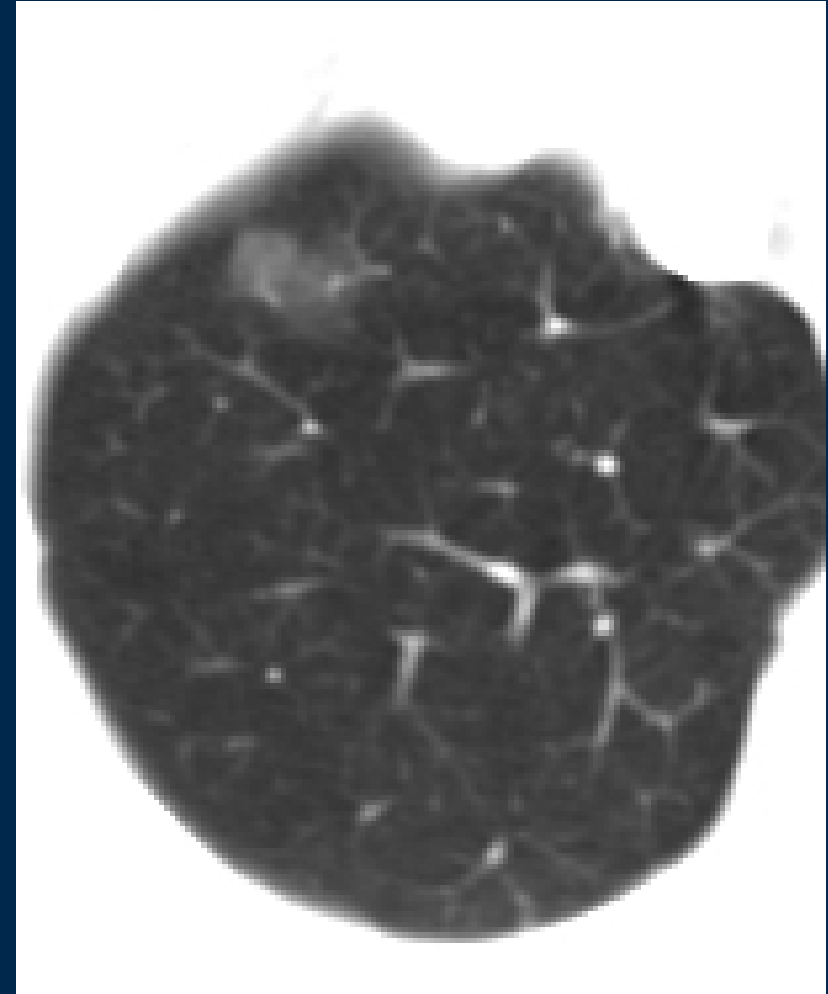   - Specific benign features (calcification, fat)

# Classifying Screen-Detected Lung Nodules
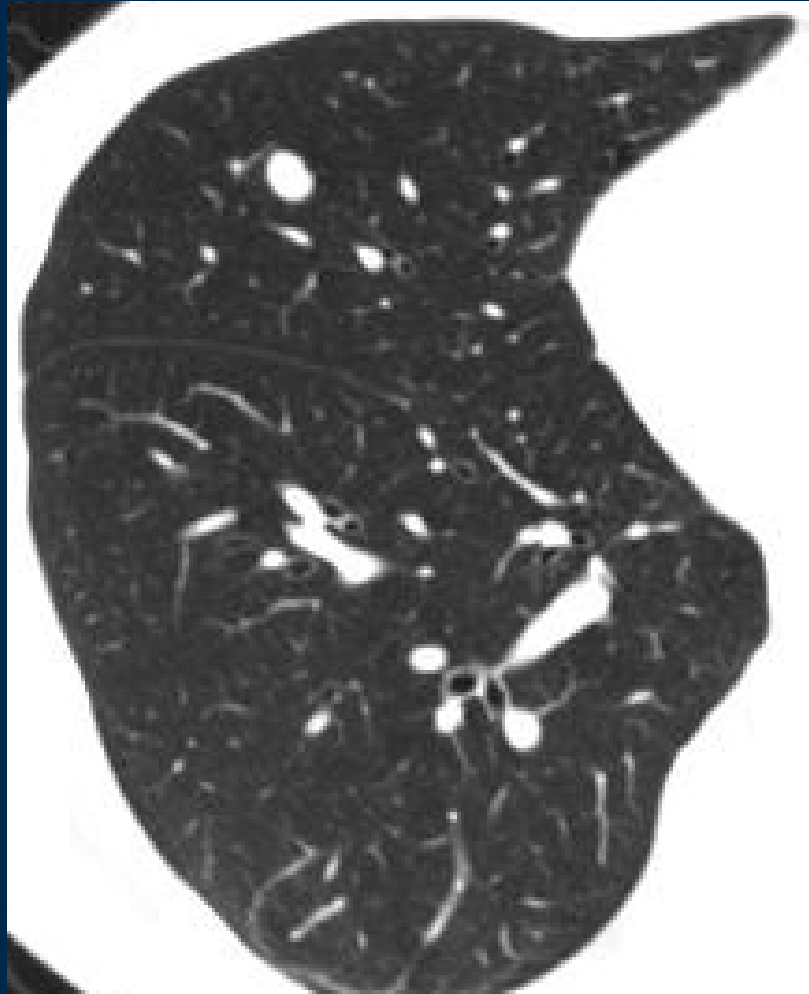

solid
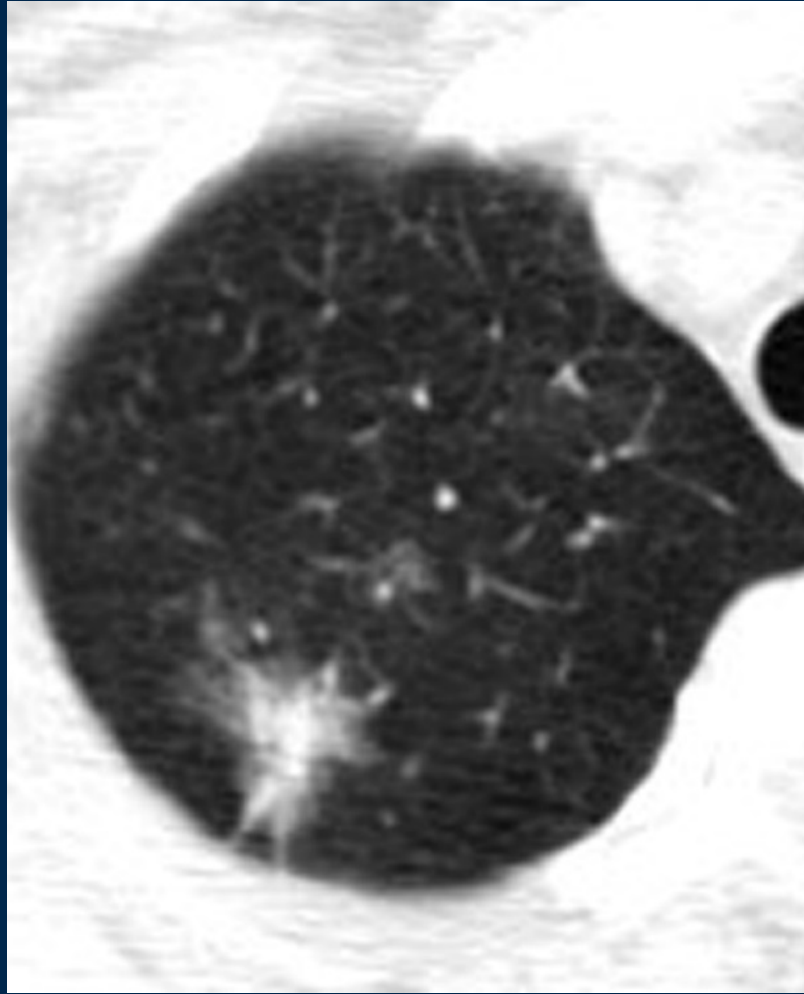
part solid

non solid
aka GGO or GGN

NEGATIVE SCREEN: ACR LungRADS™

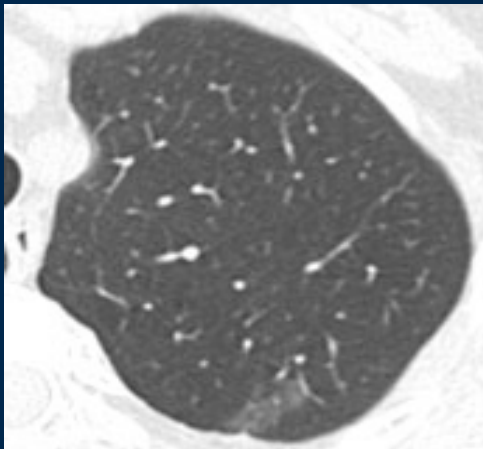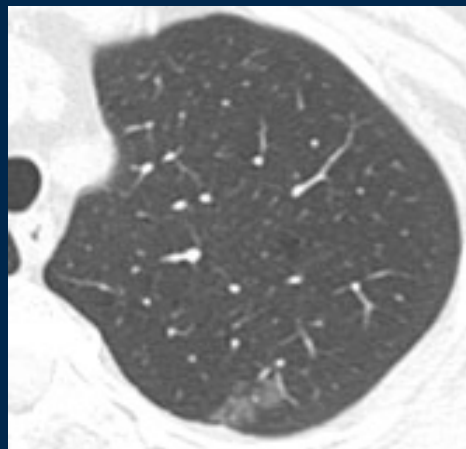| Category	Category Descriptor	Primary Category	Findings	Management
Negative	No nodules & definitely benign nodules	1	No lung nodules nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules	Continue annual screening with LDCT in 12 months
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	solid nodule(s): • < 6 mm • new < 4 mm part solid nodule(s): • < 6 mm total diameter on baseline screening non solid nodule(s) (GGN): • < 20 mm OR • ≥ 20 mm and unchanged or slowly growing Category 3 or 4 nodules unchanged for ≥ 3 months	

LungRADS™ 2: Non solid nodule < 2 cm
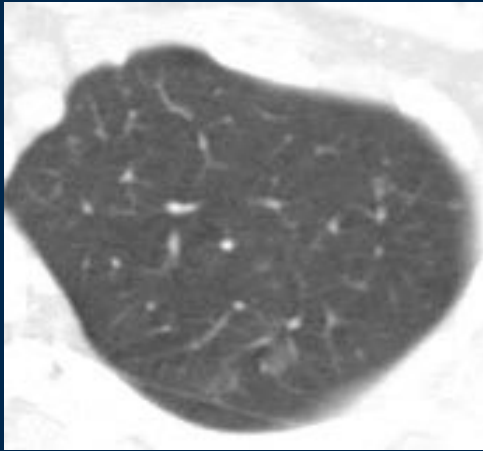
T0
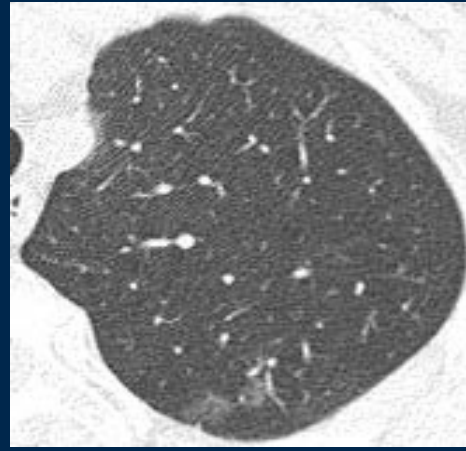
1 YR
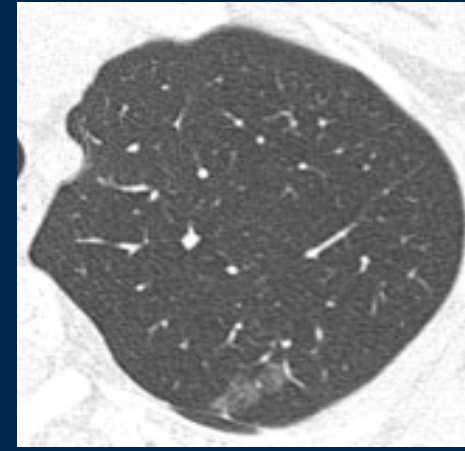
2 YR

3 YR

4 YR
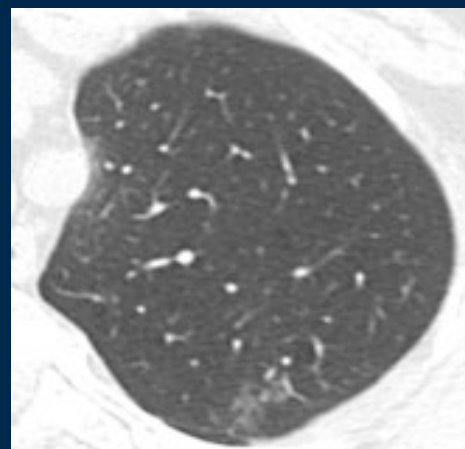
5 YR

POSITIVE SCREEN: ACR LungRADS™ 3

Category	Category Descriptor	Primary Category	Findings	Management
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	solid nodule(s): • ≥ 6 to < 8 mm at baseline OR • new 4 mm to < 6 mm part solid nodule(s): • ≥ 6 mm total diameter with • Solid component < 6 mm OR • New < 6 mm total diameter Non solid nodule(s) (GGN) ≥ 20 mm on baseline CT or new	6 month LDCT

LungRADS™ 2 to 3: Non solid nodule < 2 cm
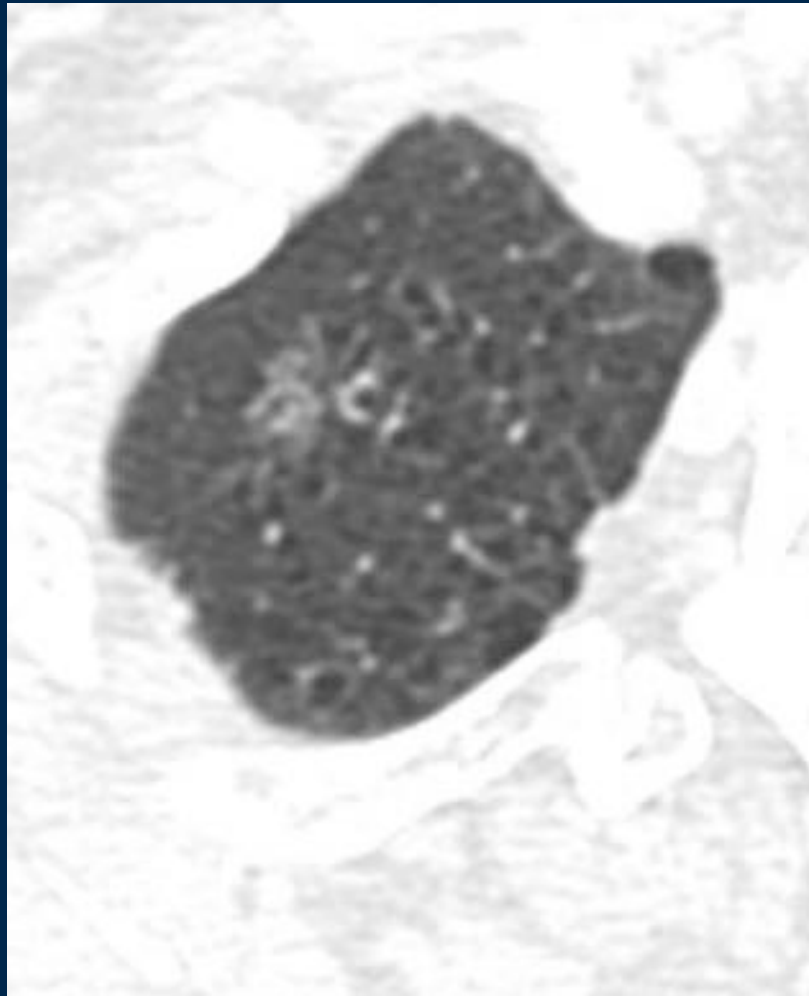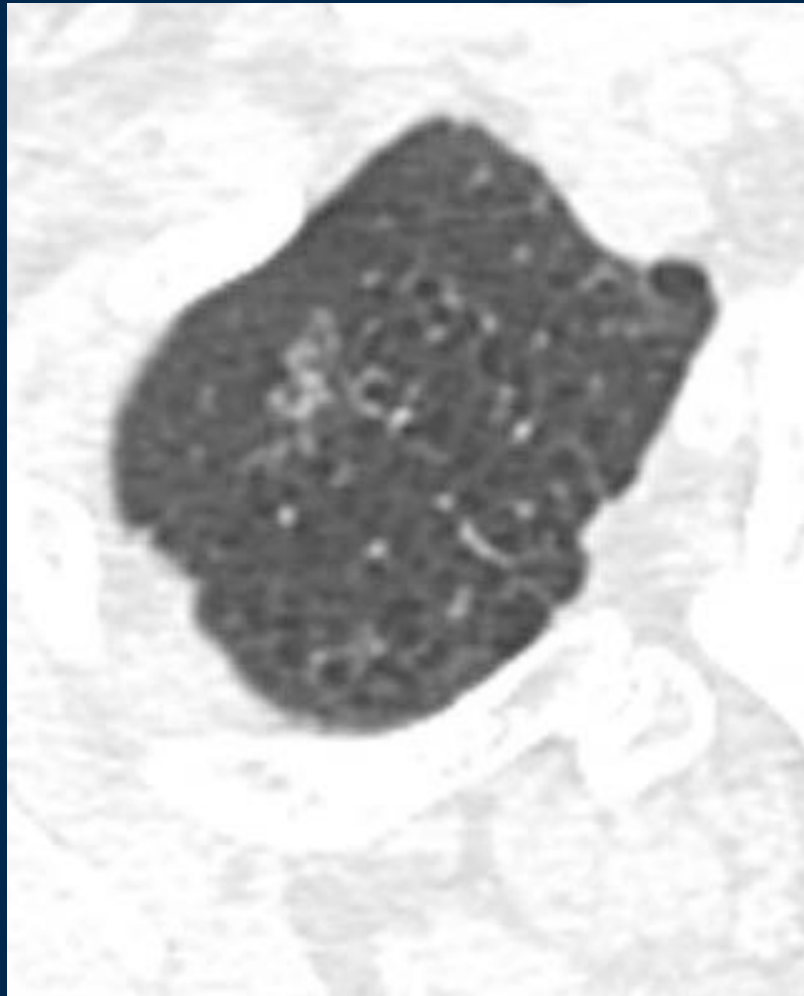
T0   1 YR   2.5 YR

Stage 1A adenocarcinoma

Courtesy of Ann Leung

RADIOLOGY

Nonsolid Nodule Becomes Part Solid Nodule

Baseline 17 x 13 mm

2 years

9 years part solid

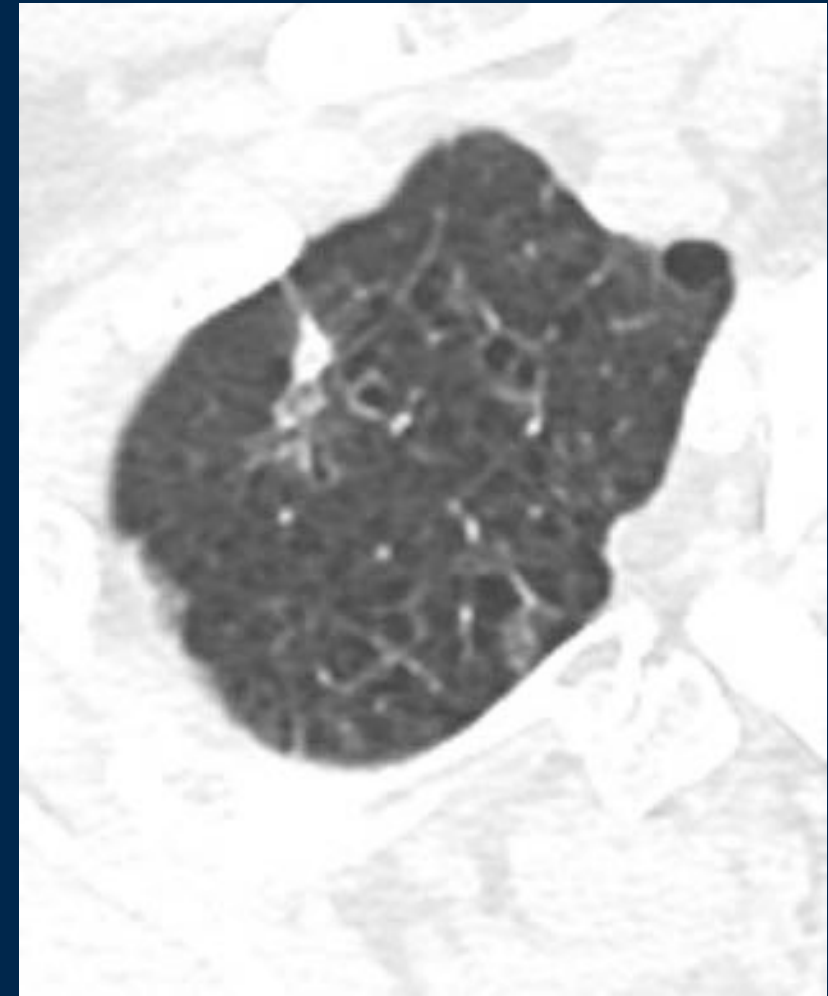# POSITIVE SCREEN ACR LungRADS™ 4

Category	Category Descriptor	Primary Category	Findings	Management
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	solid nodule(s): • ≥ 8 to < 15 mm at baseline OR • Growing < 8 mm OR • New 6 to < 8 mm part solid nodule(s): • ≥ 6 mm with solid component ≥ 6 mm to < 8 mm OR • With a new or growing < 4 mm solid component Endobronchial nodule	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component
		4B	solid nodule(s): • ≥ 15 mm OR • new or growing and ≥ 8 mm part solid nodule(s) with: • a solid component ≥ 8 mm OR • a new or growing ≥ 4 mm solid component	chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component
		4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy	

ACR LungRADS™

Performance of Lung-RADS in the National Lung Screening Trial: A Retrospective Assessment

- Reclassified NLST CT screening exams using LungRADS

- 26,722 LDCT arm subjects (26,309 baseline; 48,671 post-baseline)

	BASELINE Lung RADS (NLST)	POST BASELINE LungRADS (NLST)
FPR (1-Specificity)	12.9% (26.6%)	5.3% (27.4%)
Sensitivity	86.1% (93.8%)	78.6% (94.4%)
PPV	6.9% (3.8%)	10.9% (2.4%)

Paul F. Pinsky, PhD; David S. Gierada, MD; William Black, MD; Reginald Munden, MD; Hrudaya Nath, MD; Denise Aberle, MD; and Ella Kazerooni, MD Annals of Internal Medicine February 2015

M
RADIOLOGY

LungRADS™ Category S

- Incidental clinically significant findings in 7.5% of screening CTs
  - Reported to be as high as 14% in a systematic review; varying definition of "clinically significant"
  - Some findings lead to health benefit
  - Sone findings require additional testing with no health benefit
  - Types of findings:
    - cardiac
    - COPD
    - vascular (aneurysms)
    - masses (upper abdomen, neck, mediastinal)
- ACR incidental findings guidelines on managing incidental findings (abdomen, thyroid; thoracic in progress); included in ACRSelect™ decision support tool

ACR LungRADS™

- To provides a common lexicon & definitions
- To standardizes practice among radiologists for communicating with ordering providers
- To define a positive screen
- To address uncertainty in positive screen management
- To facilitate quality assurance & improvement
- *To be updated as knowledge evolves*

ACR LungRADS™ - Update

Lung-RADS: Pushing the Limits[1]

Maria D. Martin, MD
Jeffrey P. Kanne, MD
Lynn S. Broderick, MD
Ella A. Kazerooni, MD, MS
Cristopher A. Meyer, MD

In response to the recommendation of the U.S. Preventive Services Task Force and the coverage decision by the Centers for Medicare and Medicaid Services for lung cancer screening (LCS) computed tomography (CT), the American College of Radiology introduced the Lung CT Screening Reporting and Data System (Lung-RADS) in 2014 to standardize the reporting and management of screening-detected lung nodules. As with many first-edition guidelines, questions arise when such reporting systems are used in daily practice. In this article, a collection of 15 LCS-related scenarios are presented that address situations in which the Lung-RADS guidelines are unclear or situations that are not currently addressed in the Lung-RADS guidelines. For these 15 scenarios, the authors of this article provide the reader with recommendations that are based on their collective experiences, with the hope that future versions of Lung-RADS will provide additional guidance, particularly as more data from widespread LCS are collected and analyzed.

ACR LungRADS™ - Update

Lung-RADS: Pushing the Limits[1]

Scenario 1: New LungRADS category 3 solid lung nodule in a patient who is aging out of the screening program.
Scenario 2: Lung mass in a patient with vague symptoms.
Scenario 3: Solid suspicious (Lung-RADS category 4B) nodule with very slow growth rate.
Scenario 4: Ground-glass nodule that increases in density but remains stable in size.
Scenario 5: Ground-glass nodule with slow growth rate.
Scenario 6: How to measure and classify a part-solid nodule.
Scenario 7: Nodule that decreases in size but increases in attenuation.
Scenario 8: Nodule with characteristic features of an intrapulmonary lymph node.
Scenario 9: Airway (endotracheal or endobronchial) nodule.
Scenario 10: Incidental potentially important finding other than lung cancer detected at low-dose LCS CT.
Scenario 11: Reenrolling patients in the LCS CT program after a stable abnormality.
Scenario 12: Low-dose LCS CT of a patient with a recent respiratory infection.
Scenario 13: Categorization of a cavitary lung nodule or nodules.
Scenario 14: Low-dose LCS CT of a patient with a history of a treated lung malignancy.
Scenario 15: Low-dose LCS CT of a patient with a treated low-risk non lung malignancy.

RADIOLOGY

ACR LungRADS™ - Update

The American College of Radiology Lung Imaging Reporting and Data System
Potential Drawbacks and Need for Revision

Hiren J. Mehta, MD; Tan-Lucien Mohammed, MD; and Michael A. Jantz, MD

Lung cancer screening using low-dose CT scanning reduces lung-cancer-specific and overall mortality in high-risk patients. A significant limitation of lung cancer screening is the false-positive rate. The American College of Radiology Lung Imaging Reporting and Data System (Lung-RADS) was designed to standardize reporting of low-dose lung cancer screening results and to decrease the false-positive rate without significantly compromising sensitivity. Implementing Lung-RADS can also improve cost-effectiveness. However, Lung-RADS has never been studied in a prospective fashion. It also does not have a specific reporting category for patients with isolated hilar and mediastinal adenopathy or pleural effusion in the absence of lung nodules. We report four such cases from our lung cancer screening program. We believe that this is a significant limitation of Lung-RADS and should be revised in its new version.

CHEST 2017; 151(3):539-543

does not have a specific reporting category for patients with isolated hilar and mediastinal adenopathy or pleural effusion in the absence of lung nodules

ACR LungRADS™ Update 1.1 2019

LungRADS Update #1 – '19 – Perifissural Nodules

- Define perifissural nodules
- Current:
  - Nodules with features of an intrapulmonary lymph node should be managed by mean diameter and the 0-4 numerical category classification
- *Future:*
  - *Solid nodules with smooth margins, an oval, lentiform or triangular shape, and maximum diameter less than 10 mm (perifissural nodules) should be classified as category 2*

LungRADS Update #1 – '19 – Perifissural Nodules

- A perifissural nodule is a fissure-attached, homogeneous, solid nodule that had smooth margins and an oval, lentiform, or triangular shape [1]. They represent about 20% of nodules detected in lung cancer screening, are invariably benign, and do not require follow-up [1,2,3].

- More broadly, smooth or attached NCNs comprised 83% of all indeterminate solid pulmonary nodules detected in the NELSON trial [4]. At 1 year follow-up, no cancer was found in smooth (0/654) or attached (0/503) 5-10 mm nodules. Xu et al concluded that 1 year follow-up is sufficient.

- PANCAN & BCCA pooled: probability of lung cancer in perifissural nodules was zero (0 of 571 nodules; one-sided 97.5% CI, 0 to 0.006) [5]

1. Collins J, Sterns EJ. Solitary and multiple pulmonary nodules. 3 ed. Collins J, Sterns EJ, editors. Philadelphia: Wolters Kluwer; 2015. 123-45 p.
2. de Hoop B et al. Pulmonary perifissural nodules on CT scans: rapid growth is not a predictor of malignancy. Radiology. 2012;265(2):611-6
3. Fleischner revision
4. Xu DM et al. Smooth or attached solid indeterminate nodules detected at baseline CT screening in the NELSON study: cancer risk during 1 year of follow-up. Radiology. 2009;250(1):264-72
5. McWilliams A et al. Probability of Cancer in Pulmonary Nodules Detected on First Screening CT. NEJM2013;369;910-919

RADIOLOGY

LungRADS Update #2 – '19 – Non Solid Nodules

- Raise the size threshold for pure non solid nodules from 20 mm to 30 mm

- Current: Category 2
  - non solid nodule(s) (GGN):
    - < 20 mm OR
    - ≥ 20 mm and unchanged or slowly growing

- *Future: Category 2*
  - *non solid nodule(s) (GGN):*
    - *< 30 mm OR*
    - *≥ 30 mm and unchanged or slowly growing*

LungRADS Update #2 – '19 – Non Solid Nodules

- Slow-growing & longer volume doubling time than solid nodules
- Mean volume doubling time for growing NSNs
  - 769 &1041 days de Hoop B, et al Radiology. 2010;255:199-206 & Veronesi G et al. Eur Respir J. 2015;45:501-10
- No growth:
  - 90% did not grow @ long-term follow-up (median 59 mths) Chang et al. Chest 2013;143:172
- Indolent course:
  - Especially in screening settings Gulati CM et al. Outcomes of unresected ground-glass nodules with cytology suspicious for adenocarcinoma. J Thorac Oncol 2014;9:685-91
- Management evolved to selective surgery & longer annual follow-up
  - 2017 Fleischner Guideline solitary GGO > 8 mm: CT in 6-12 months to confirm persistence, then every 2 yrs until 5 yrs; if grows or new solid component, consider resection

M RADIOLOGY

LungRADS Update #3 – '19 – 4B Management

- Address management for <u>new</u> large nodules

- Current: Category 4B Management
  - Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component. For new large nodules that develop on an annual repeat screening CT

- *Future: Category 4B Management*
  - Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component. *For new large nodules that develop on an annual repeat screening CT, a 1 month LDCT may be considered*

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RADIOLOGY

LungRADS Update #4 – '19 – Nodule Measurement

- Change in how nodule diameter is measured & recorded
- Current:
  - Report average diameter (of long and short axis diameters) rounded to the nearest whole number
- *Future:*
  - To calculate nodule mean diameter, measure both the long and short axis to one decimal point, and report mean nodule diameter to one decimal point

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LungRADS Update #4 – '19 – Nodule Measurement

- Change in how diameter is measured & recorded

- Change in nodule size represents a combination of true change plus measurement error.

- Using average diameter measurements, in order to overcome measurement error and confirm true change, growth of at least 1.5 mm is required. If using volumetric techniques, true change can be determined using the QIBA Lung Nodule Profile Calculator (v0.1) http://services.accumetra.com/NoduleCalculator.html

LungRADS Update #5 – '19 – Volumetry

- Will add volume measurements next to diameter measurements

- Facilitates future movement to more accurate and comparable 3D volume measurements over time

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LungRADS Update - Futures

Size & growth defined in mm to volume

- Current: Mean diameter

- Future: Volumetric; new QIBA small nodule profile and growth profile to aid in measuring system performance and the variance around size measurements

- Obstacles:
  - Availability of accurate, robust software tools
  - Fully integrated into radiologist workflow
  - Reimbursement for lung nodule CAD/CAD-like tools which require facility investment & radiologist time to translate

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Lung Cancer Screening: LungRADS™ Update

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