Updates in Lung CT Screening Reporting and Data System (Lung-RADS)

Al Shaimaa Fathi Elshetry[1], Hadeer Khaled Safwat[1], Hazem M. El Shahat Mousa[1], Ramadan Nafea[2], Rania M. Almolla[1]
1 Radiodiagnosis Department, Faculty of Medicine - Zagazig University, Egypt
2 Chest Diseases Department, Faculty of Medicine - Zagazig University, Egypt
Corresponding author: Hadeer Khaled Safwat
E-mail: Hadeerkhsafwat@gmail.com, h.khaled22@medicine.zu.edu.eg
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Abstract
Lung cancer is the principal cause of cancer-related mortality worldwide. There is global growing interest in lung cancer screening (LCS) using low-dose computed tomography (LDCT) to help early detection of lung cancer and decrease mortality rates. In 2014, the American College of Radiology (ACR) introduced Lung CT Screening Reporting and Data System (Lung-RADS) version 1.0, a standardized reporting system for managing lung nodules detected on LCS LDCT. The updated versions, Lung-RADS 1.1 and 2.0, were introduced in 2019 and 2022, respectively, to incorporate new knowledge about lung nodules' behavior and align with current LCS criteria. This review aims to provide a comprehensive overview of the changes made in these updated versions and highlight their implications for clinical practice.

Keywords: Lung Reporting and Data System; Lung cancer screening; low-dose CT.

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Introduction
Lung cancer is the principal cause of cancer-related mortality worldwide **(1,2)**. Therefore, there is global growing interest in lung cancer screening (LCS). Low-dose computed tomography (LDCT) has been used in several screening studies to help detect lung cancer at an early stage and reduce mortality rates **(3-5)**. Additionally, in 2014, the American College of Radiology (ACR) introduced version 1.0 of the Lung CT screening Reporting and Data System (Lung-RADS) **(6)**. This is a standardized tool for reporting and management of lung nodules detected on LCS LDCT **(7)**. Lung-RADS 1.0 includes six assessment categories based on the adequacy of the CT scan and the suspicion level for malignancy **(6)**. Category 0 represents an incomplete CT scan, categories 1 and 2 indicate a negative screen, and categories 3 and 4 (4A, 4B, and 4X) indicate a positive screen.
By implementing this standardized reporting system, radiologists can achieve the necessary specificity, reduce the false positive rate in LCS **(4,7)**, while ensuring consistent reporting, and improving communication with clinicians.

To incorporate new knowledge in the field about lung nodules' behavior and improve the system appropriateness for the current LCS criteria, the ACR subsequently introduced updated versions of Lung-RADS in 2019 (Lung-RADS 1.1), and 2022 (Lung-RADS 2.0) **(8,9)**. While maintaining certain similarities with the previous version, the updated versions underwent multiple changes and updates that will be discussed in this review. We will also highlight the impact of the updated Lung-RADS versions on clinical practice.

Lung-RADS versions 1.1 and 2.0

What's new?

Lung-RADS version 1.1 incorporated significant changes compared to its antecedent, Lung-RADS versions 1.0 **(5)**, with the goal of reducing the false positive rate. These updates have been retained in Lung-RADS version 2.0 along with additional modifications **(9)**. All these changes are summarized in **Table 1** and discussed in detail below.

Lung nodule measurements

The Lung-RADS 1.1 has introduced changes to the nodule measurement guidelines that were retained in Lung-RADS version 2.0. These changes aim to improve the accuracy and consistency of nodule measurement in order to facilitate better diagnosis and management of lung nodules. One notable change is the inclusion of volumetric measurements in addition to the traditional linear two-dimensional measurements **(8)**. Using volumetric measurements allows for a more comprehensive assessment of nodule size and growth. Additionally, the guidelines now recommend measuring to one decimal point and reporting the average diameter to one decimal point for two-dimensional measurements **(10, 8)**.

However, there is some debate about the accuracy of volumetric measurements, especially for nodules smaller than 3 mm **(11)**. Also, the Fleischner Society has expressed concerns about the accuracy of measuring to such decimal points and stated that linear measurements remain the standard method **(11,12)**. Further research is needed to determine the true value and utility of these new measurement guidelines **(10)**.

It is worth mentioning that two-dimensional measurements have demonstrated inconsistency with significant intra- and inter-reader variability in assessing irregularly growing malignant nodules, as reported in literature **(13)**. Conversely, volumetric measurements offer advantages, such as 3D analysis of the nodule and improved reproducibility and sensitivity in detecting nodule growth **(14-16)**. These advantages promote using volumetric measurement as the preferred method of determining lung nodule size and growth in LCS studies. Notably, volumetric measurements were applied in the NELSON trial **(17)**.

Perifissural nodules

Perifissural nodules (PFNs) are believed to represent intrapulmonary lymph nodes **(18)**. Their benign potential has been demonstrated in several studies **(19-21)**. Two types of PFNs have been described: typical and atypical PFNs **(20,22)** **(Figure 1)**. Typical PFNs are small, solid nodules with smooth margins and three major characteristics including typical lentiform/oval/triangular shapes and located either attached to or within 10 mm of a fissure, with extending linear densities. Whereas atypical PFNs meet two out of the aforementioned three major characteristics of a PFN **(20,22)**.

One important change implemented in Lung-RADS version 1.1 is the modified approach to solid PFNs that have oval or lentiform shape and smooth margins, measuring < 10 mm in size **(8,9)**. In Lung-RADS version 1.1, these PFNs are now reclassified as Lung-RADS 2 category (benign), rather than being classified as Lung-RADS 3 (6-8 mm) and Lung-RADS 4A (8-10 mm) categories, as in Lung-RADS version 1.0 **(8,9)**. When this updated size threshold was applied to reclassify PFNs in the National Lung Screening Trial (NLST) using Lung-RADS 1.1, a statistically significant decrease in false positive results was demonstrated **(18)**.

Juxtapleural nodules

The juxtapleural nodules (JPNs) are also believed to have a benign potential, representing intrapulmonary lymph nodes **(18)**. The change in management of JPNs, resembling PFNs, was not specifically addressed until the latest update in 2022. In line with the modified approach for PFNs, Lung-RADS 2.0 now describes JPNs measuring <10 mm in size as benign nodules, reclassified as Lung-RADS 2 category **(9) (Figure 2)**. This change is expected to further decrease false positive results, similar to the impact observed with changing management of PFNs in Lung-RADS 1.1 **(23)**.

Ground-glass Nodules

Another change implemented in Lung-RADS 1.1 and maintained in Lung-RADS 2.0 was the update of the size threshold for classifying ground-glass nodules (GGNs) as Lung-RADS 3 category. In Lung-RADS 1.1, the size threshold for categorizing GGNs as Lung-RADS 3 category was updated from ≥20 to ≥30 mm **(8) (Figure 3)**.

In Lung-RADS 2.0, there was further clarification regarding slowly growing GGNs, stating that if a GGN demonstrates growth across multiple screenings without meeting the >1.5 mm size increase threshold in any 12-month interval, it can still be classified as Lung-RADS 2 category until it reaches the criteria of another category, such as developing a solid component. At that point, it can be assessed using the criteria for part-solid nodules **(9)**.

Slowly growing solid or part-solid nodules

In Lung-RADS 2.0, there was additional clarification regarding slowly growing solid or part-solid nodules, stating that if these nodules show growth across multiple screening exams without meeting the >1.5 mm size increase threshold in any 12-month interval, they are considered suspicious and classified as Lung-RADS 4B nodules **(9)**. Lung-RADS 2.0 recommends that biopsy, or surgical evaluation may be the most appropriate management recommendation for slowly growing solid or part-solid nodules with no increased metabolic activity on PET/CT **(9)**.

Infectious/Inflammatory Changes

Lung-RADS 1.1 introduces a management recommendation for new large nodules that are likely to be infectious or inflammatory, detected on LCS LDCT **(8)**. These nodules are classified as Lung-RADS 4B category with recommendation of a follow-up LDCT scan after 1-month to ensure their resolution **(8) (Table 1)**. However, the imaging characteristics and progression of these nodules can vary significantly, making the prescribed 1-month follow-up interval potentially unsuitable in certain cases **(23)**. To address this, Lung-RADS 2.0 provides more detailed guidance for these nodules, offering specific recommendations for different types of them **(9)**.

For instance, tree-in-bud nodules, which are highly likely to be infectious or aspiration-related, are classified as benign and assessed as Lung-RADS 2 category **(9) (Figure 4)**. However, specific follow-up recommendations beyond annual screening are not provided for tree-in bud nodules **(9,23)**. Additionally, the presence of multiple new nodules (more than 6 nodules) or large solid nodules measuring >8 mm in a short period indicates a high likelihood of infection. These nodules should also be classified as Lung-RADS 0 category, warranting a follow-up LDCT scan within 1 to 3 months **(9)**. This approach is also relevant for new nodules in immunocompromised individuals who are at a higher risk of infection **(9)**.

However, if any of the aforementioned scenarios involve a solid or part solid nodule displaying suspicious features for malignancy, such as spiculated margins, its categorization should be based on size and internal composition. At the assigned follow-up, any previously presumed infectious or inflammatory nodules that persist should also be evaluated based on size and composition **(9)**. Similarly, Lung-RADS 2.0 recommends assessment of segmental and lobar consolidation as Lung-RADS 0 category with a follow-up period of 1 to 3 months **(9) (Table 1)**.

Lung nodule reclassification

Lung-RADS 2.0 has introduced updated guidelines for reclassification of Lung-RADS 3, 4A and 4B nodules **(Table 1)**. For instance, a Lung-RADS 3 nodule that remains stable or shows a reduction in size at 6-month follow-up CT or a Lung-RADS 4B nodule proven to be benign through proper work-up, should be reclassified as benign nodules, Lung-RADS 2 nodules **(9)**. Whereas a Lung-RADS 4A nodule that remains stable or demonstrates a decreased size at 3-month follow-up CT, with the exception of airway nodule, should be reclassified as probably benign nodule, a Lung-RADS 3 nodule **(9) (Figure 5)**.

Atypical pulmonary cyst

Lung-RADS 2.0 offers updated guidelines for assessment of atypical pulmonary cysts, as illustrated in **Table 1**. Atypical pulmonary cysts include unilocular thick-walled cyst, with uniform, asymmetric, or nodular wall thickening measuring ≥2 mm and thin or thick-walled multilocular cysts **(9)**. Unilocular cysts with uniform thin wall measuring < 2 mm, fluid-containing cysts (likely infectious) or multiple cysts, such as in Langerhans cell histiocytosis or lymphangioleiomyomatosis do not require categorization in Lung-RADS due to their benign nature **(9)**.

Lung-RADS 2.0 also states that when a cyst is accompanied by an adjacent internal or external nodule, the assessment of the lesion is determined using Lung-RADS criteria for the most concerning feature according to Lung-RADS criteria **(9) (Figure 6)**.

Endobronchial Nodules

Lung-RADS 2.0 offers more comprehensive guidance for managing endobronchial nodules compared to previous versions **(9) (Table 1)**. Prior to Lung-RADS 2.0, endobronchial nodules were classified as Lung-RADS 4A category without specific follow-up guidelines, apart from the recommended 3-month LDCT follow-up for Lung-RADS 4A nodules **(6,8)**.

Lung-RADS 2.0 now states that nodules in subsegmental or more proximal airways lacking concerning features, like a soft tissue component, can be categorized as Lung-RADS 2 category **(9)**. Whereas

nodules in segmental or more proximal airways that have concerning features would still be designated as Lung-RADS 4A category, requiring a 3-month LDCT follow-up. Additionally, persistent endobronchial nodules warrant upgrading to category 4B, and patients should undergo further diagnostic workup, such as bronchoscopy **(9)**.

In addition, the presence of multiple tubular or subsegmental endobronchial abnormalities indicates a likely infectious process. If there is no obstructive nodule observed, these lesions can be classified as Lung-RADS 0 or Lung-RADS 2 **(9)**.

Clinical Impact

The updates to the Lung-RADS have significant implications in clinical practice, offering substantial improvements in nodules risk stratification and patient management in the field of LCS. These updates have improved the reporting categories, providing more comprehensive risk assessment of the lung nodules. Consequently, these Lung-RADS updates can facilitate decision-making and enhance patient management. Furthermore, these updates incorporate tailored management recommendations for specific nodule types, such as inflammatory/infectious nodules. As a result, clinicians can make well-informed decisions about further diagnostic evaluations and follow-up imaging.

Conclusions

Lung-RADS versions 1.1 and 2.0 represent significant updates to the standardized reporting system for lung nodules. The implementation of Lung-RADS updates is anticipated to have a positive impact on risk assessment and management of patients with lung nodules.

Table 1: Changes in the assessment category findings and recommended management for Lung-RADS versions 1.1 and 2.0.

	Changes		
Lung-RADS assessment category	**Lung-RADS 1.1**	**Lung-RADS 2.0**	**Recommended management**
Lung-RADS 0 (incomplete)	No changes	CT findings suggestive of an inflammatory or infectious disease, such as segmental or lobar consolidations, and appearance of multiple new nodules (more than 6 nodules), large solid nodules (≥ 8 mm) in a short interval, or new nodules in certain clinical scenarios, as in immunocompromised patients	Lung-RADS 2.0 recommends 1 to 3-month follow-up LDCT for CT findings suggestive of an inflammatory or infectious disease
Lung-RADS 1 (negative)	No changes	No changes	No changes
Lung-RADS 2 (benign)	-Perifissural nodule(s): solid nodule with smooth margins and an oval, lentiform, or triangular shape, measuring less than 10 mm in size* -Ground glass nodule(s) (GGN): <30 mm	-Juxtapleural nodule: solid nodule with smooth margins and an oval, lentiform, or triangular shape, measuring less than 10 mm in size at baseline CT or when newly detected.	No changes

	or ≥ 30 mm and remains stable or slowly growing*	-A subsegmental airway nodule: observed at baseline, newly detected, or remains stable. -Category 3 nodule: stable or decreased in size at 6-month follow-up CT -Category 4B nodule: proved to be benign in nature based on proper diagnostic workup	
Lung-RADS 3 (probably benign)	GGN: ≥ 30 mm at baseline CT or when newly detected*	-Atypical pulmonary cyst: growing cystic component of a thick-walled pulmonary cyst -Category 4A nodule: stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	No changes
Lung-RADS 4A (suspicious)	4A category became a separate category from 4B/4X, described as "suspicious"*	- Segmental or more proximal airway nodule: at baseline CT -Atypical pulmonary cyst: Thick-walled cyst or multilocular cyst at baseline CT, or thin- or thick-walled cyst that change to multilocular cyst	No changes
Lung-RADS 4B (very suspicious)	No changes	- Segmental or more proximal airway nodule: stable or growing -Atypical pulmonary cyst: thick-walled cyst with increasing wall thickness/nodularity or growing multilocular cyst, or multilocular cyst with increased loculation or new/increased opacity (nodular, ground glass, or consolidation) -Slow growing solid or part solid nodule that demonstrates growth over multiple screening CT scans	-Lung-RADS 1.1 recommends 1-month LDCT for new large nodules developing on annual LDCT to address infectious or inflammatory nodules -Lung-RADS 2.0 recommends clinical referral for further evaluation of airway nodules -Lung-RADS 2.0 recommends management depends on clinical evaluation, patient preference, and the probability of malignancy for other lesions
Lung-RADS 4X	No changes	No changes	No changes
Exam modifier S	No changes	No changes	No changes
Exam modifier C	Removed	Removed	------

*These changes in Lung-RADS 1.1 have been retained in Lung-RADS 2.0.

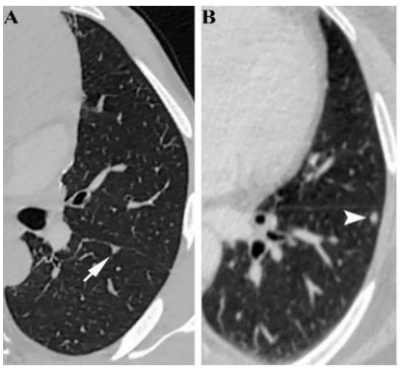

Figure 1: Axial CT images lung window showing **A,** typical perifissural nodule (arrow) and **B,** atypical (arrowhead) perifissural nodule.

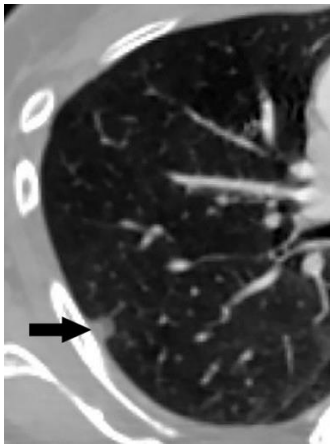

Figure 2: Axial CT image lung window showing solid juxtapleural nodule, measuring 9 mm with smooth margin and oval shape (arrow). In Lung-RADS versions 1.0 and 1.1, this nodule would have been classified as a Lung-RADS 4A category, while in Lung-RADS 2.0, it would be categorized as a Lung-RADS 2 nodule.

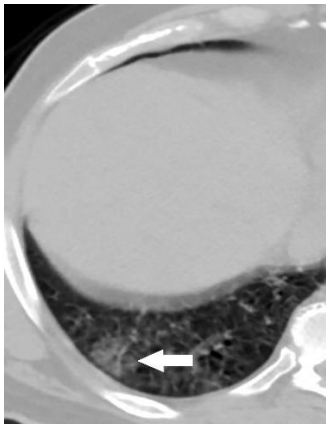

Figure 3: Axial CT image lung window showing a 22 mm ground-glass nodule (arrow) at baseline CT. This nodule would have been classified as a Lung-RADS 3 category in Lung-RADS 1.0, while in Lung-RADS 1.1 and 2.0 it would be classified as a Lung-RADS 2 category

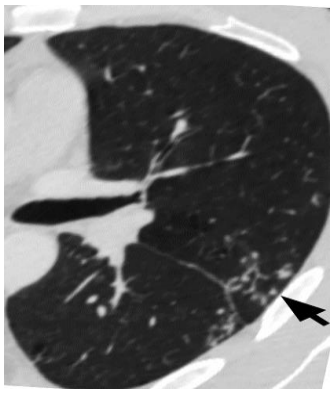

Figure 4: Axial CT image lung window showing tree in bud nodules (arrow) at baseline CT. These nodules would be classified as a Lung-RADS 0 category in Lung-RADS 2.0.

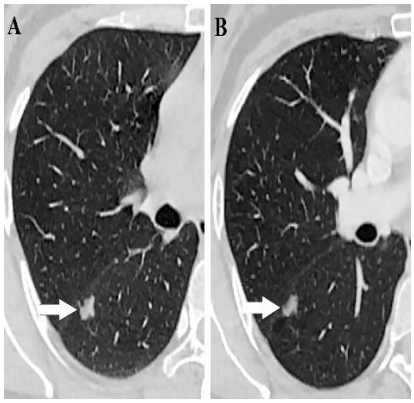

Figure 5: Axial CT images lung window showing **A,** a12 mm solid lung nodule (arrow) at baseline CT (Lung-RADS 4A nodule) that demonstrates a 2 mm reduction in size at **B,** >3-month follow-up CT. This nodule would be reclassified as a Lung-RADS 3 nodule in Lung-RADS 2.0.

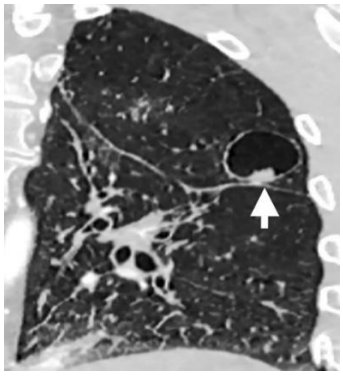

Figure 6: Axial CT image lung window showing atypical pulmonary cyst. This lesion appears as unilocular cyst with internal eccentric solid nodule that measures <15 mm (arrow). The size and composition of the associated nodule, which is the most concerning feature, warrant classifying this lesion as Lung-RADS 4A in Lung-RADS 2.0.

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