Explanatory Notes: Ontario Lung Screening Program Reporting Template

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Ontario Health (Cancer Care Ontario) wishes to acknowledge the contributions of the Lung Cancer Screening Reporting Template Working Group members who shared their expertise to support the development of the first iteration of the Report Template and this document.

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Overview of Methods Used to Develop the LDCT Ontario Lung Screening Program Template

Organized cancer screening programs provide important benefits, such as ensuring that appropriate populations are screened with the right test, ensuring appropriate and timely follow-up of abnormal findings, and ongoing quality monitoring and management. In 2016, Ontario Health (Cancer Care Ontario) launched an initiative to pilot organized lung cancer screening, using low-dose computed tomography (LDCT), for people at high risk for lung cancer. The pilot ended in March 2021, the hospitals that participated in the pilot are now part of the Ontario Lung Screening Program (OLSP). Ontario Health plans to add more Ontario Lung Screening Program sites across the province in the future.

The utilization of a standardized reporting template for lung cancer screening LDCT examinations is thought to support more accurate communication of screening results to referring providers and other members of the patient's care team, as well as facilitate improved patient management and outcome monitoring. As such, creation of a *LDCT OLSP Reporting Template* was endorsed by consensus from the Synoptic Radiology Reporting Clinical Advisory Panel.

The OLSP Reporting Template is an evidence-based template, informed by:

- American College of Radiology – Lung-RADS®
- Systematic Reviews on lung cancer screening, radiology terminology, and reporting schemas
- Expertise & consensus from key stakeholders, including Radiologists, Primary Care Providers and Ontario Lung Cancer Screening Program (OLSP) facilities

This template should be used for LDCT examinations performed as part of the OLSP. Note, Ontario Health (Cancer Care Ontario) advises against LDCT screening of asymptomatic people on an opportunistic or ad hoc basis due to the considerable risks posed to patients outside of an organized program. Providers are advised to follow the PEBC guidelines for referral of suspected lung cancer and Ontario Health (Cancer Care Ontario)'s lung cancer diagnosis pathway map for patients exhibiting symptoms of lung cancer (2) (3).

Lung-RADS®

During the initial creation of the reporting template, the working group reviewed existing Reporting and Data Systems, and came to a decision to adapt the use of the American College of Radiology Lung Imaging Reporting and Data System (Lung-RADS®) for the OLSP (**Table 1**) (4). Lung-RADS® standardizes the classification and follow-

up of lung nodules found during a screening program. Note, version 1.1 of Lung-RADS® informed the first iteration of the OLSP Reporting Template and will be updated periodically to reflect changes released with Lung-RADS®, evidence in the literature and feedback from template users. The current version incorporates updates released with Lung-RADS® 2022.

Table 1. The Lung-RADS® tool categorizes nodules based on probability of malignancy which then determines a set management decision. For normal or near certainly benign nodules (Lung-RADS® category 1 and 2), continued annual screening is recommended. Suspicious nodules (category 4) warrant close follow up or further diagnostic evaluation. The complete table is included in Appendix A.

<table>
<tr><th>Lung-RADS</th><th colspan="2">Category Descriptor</th><th>Management</th></tr>
<tr><td rowspan="3">0</td><td rowspan="3">Incomplete</td><td>Prior chest CT examination being located for comparison</td><td>Comparison to prior chest CT</td></tr>
<tr><td>Part or all of lungs cannot be evaluated</td><td>Additional lung cancer screening CT imaging needed</td></tr>
<tr><td>Findings suggestive of an inflammatory or infectious process (see note 10)</td><td>1-3-month LDCT</td></tr>
<tr><td>1</td><td colspan="2">Negative
No nodules and nodule with benign features</td><td rowspan="2">12-month screening LDCT</td></tr>
<tr><td>2</td><td colspan="2">Benign
Based on imaging features or indolent behavior</td></tr>
<tr><td>3</td><td colspan="2">Probably Benign
Based on imaging features or behavior</td><td>6-month LDCT</td></tr>
<tr><td>4A</td><td colspan="2">Suspicious</td><td>3-month LDCT</td></tr>
<tr><td>4B</td><td colspan="2">Very Suspicious</td><td rowspan="2">Referral for further diagnostic assessment (3)</td></tr>
<tr><td>4X</td><td colspan="2">Very Suspicious</td></tr>
<tr><td>S</td><td colspan="2">Significant or Potentially Significant</td><td>As appropriate to the specific finding</td></tr>
</table>

Clinical Information

The radiologist does not need to narrate the clinical history received from the "Ontario Lung Screening Program" into this section. They should indicate that the reason for exam is a baseline, annual recall, or follow-up study.

Comparison Study

A comparison of the nodule should be made to the most recent prior (usually the last annual screen or occasionally a more recent 1-, 3- or 6-month follow-up). The most recent prior used for comparison should be recorded here. Readers are reminded that comparison to the baseline examination may be of clinical relevance to evaluate for slow growth.

Imaging Procedure Description

Overall image quality is determined by radiologist discretion. If a study is non-diagnostic (e.g. due to respiratory motion or inadequate coverage) then the patient should be recalled to complete the examination. When the patient has had a prior examination that is not immediately available to the reader then the examination may be coded as Lung-RADS® category 0 until the prior is retrieved for comparison (4).

The LDCT Lung Screening Protocol should meet the standards as specified by the American Association for Physicists in Medicine (**Table 2**) (5). The series number on which the nodules are being reported should be recorded.

Table 2. Select LDCT scan parameters adapted from the American Association for Physicists in Medicine's protocol for lung cancer screening CT. CTDIvol – volume computed tomography dose index.

Scan Parameter	Parameter Specification
Scanner type	Multidetector helical (spiral) detector rows ≥ 16
Contrast	Performed without any contrast. No oral or injected contrast should be used
Patient Positioning	Center the patient within the gantry; and Supine, optimally with arms above head
Scan Range	From top of lungs through the bottom of lungs
Respiration	Single breath-hold full inspiration
Reconstructed image width	Thin images (≤3mm thick) are preferred for reading; ≤ 1.5 mm should be made available for assessment of small nodules. Soft tissue and lung reconstruction should be provided
Reformats	Coronal and sagittal planar MPRs as well as axial or coronal MIPs may be helpful and are encouraged
CTDIvol	≤3 mGy for standard size patient

Findings

A. Nodules

Variability exists in research trials on how many nodules should be described. The ACRIN trial described 14 nodules, the NLST trial described 6, and the PanCan approach was to describe all nodules. A distribution of number of nodules in the NLST showed that a very small number of individuals had more than 10 nodules and the mean nodule count was only 1.9 (6).

Based on the preference of radiologists, the average number observed in NLST, and on the rarity of cases with more than 10 nodules, the working group decided on describing the 5 most dominant nodules that met the size criteria of ≥ 4mm. The size criteria was based on ACR Lung-RADS® criteria, as nodules <4 mm do not impact management using Lung-RADS®.

Although most studies will only have approximately 2 nodules to describe, a rare study may have >10. In this unusual circumstance, it is at the discretion of the radiologist which nodules to describe recognizing that dominant nodules of a Lung-RADS® 3 or greater category must not be excluded.

Image, Lobe, Location

Reporting of the image number, lobe, and location within the lung is critical for efficient identification and reporting of nodules on follow-up examinations. Furthermore, the lobe and location of the nodule conveys the probability of nodule malignancy. According to the Pulmonary Nodule Malignancy Probability Model upper lobe nodules are more likely to be malignant compared to nodules located in the middle or lower lobes (7).

New research indicates that the size and composition criteria applied to perifissural nodules in Lung-RADS® v1.1 can also be applied to all juxtapleural nodules (perifissural, costal pleural, peri-mediastinal, and peri-diaphragmatic). Lung-RADS® 2022 recommends that juxtapleural solid nodules ≤ 10 mm in mean diameter; smoothly marginated; and triangular, lentiform, or ovoid in shape be classified as category 2. For nodules 10 mm or larger, they will continue to be managed based on the size criteria (9) (10).

In Lung-RADS® 2022:

- Category 2 non-solid nodule(s) (GGN):
    - < 30 mm at baseline, new, or growing OR
    - ≥ 30 mm stable or slow-growing. For more extensive growth or size, may be up coded to 4X for a management referral
- Category 3 non-solid nodule(s):
    - (GGN) ≥ 30 mm on baseline CT or new

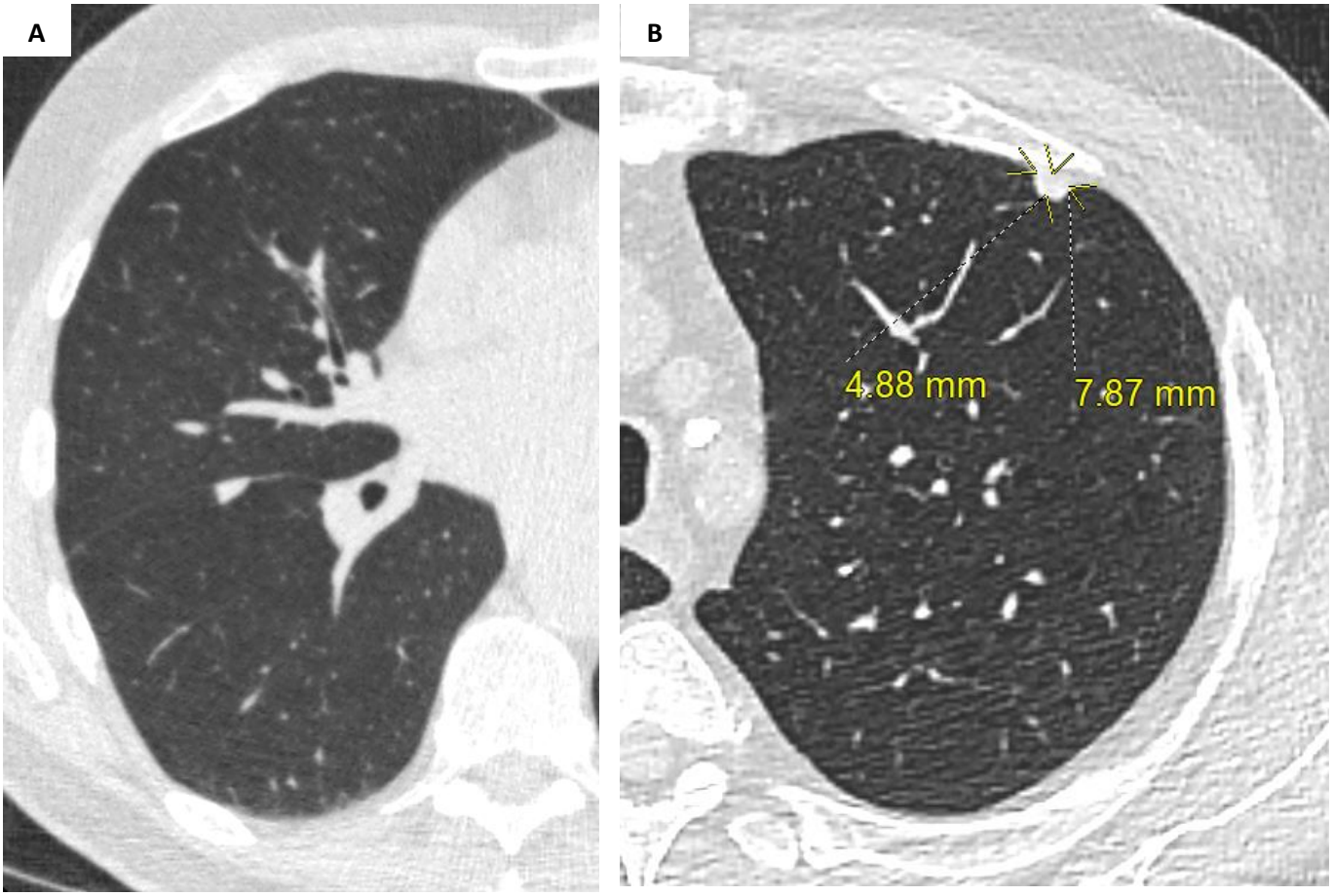

Figure 1. Examples of a juxtapleural nodule. A. This CT image demonstrates a perifissural nodule with a 7 mm mean diameter (9 x 5 mm). **B**. This CT image demonstrates a costal nodule measuring 6.4 mm (7.9 x 4.9 mm). Juxtapleural nodules measuring <10 mm receive a score of 2 in Lung-RADS® 2022.

Images provided by Dr. Micheal McInnis, University Health Network, Toronto and Dr. Carole Dennie, The Ottawa Hospital, Ottawa.

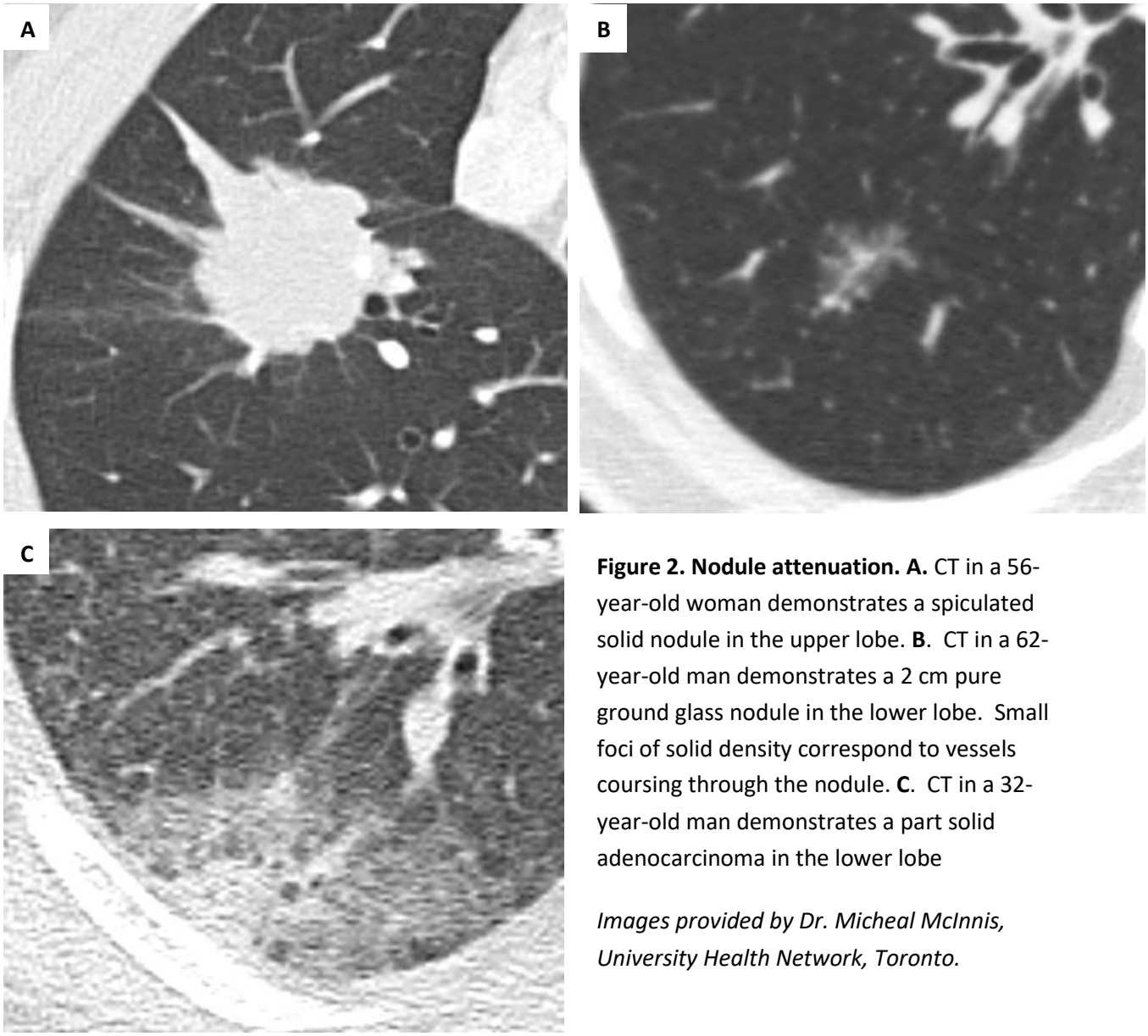

Figure 2. Nodule attenuation. A. CT in a 56-year-old woman demonstrates a spiculated solid nodule in the upper lobe. **B**. CT in a 62-year-old man demonstrates a 2 cm pure ground glass nodule in the lower lobe. Small foci of solid density correspond to vessels coursing through the nodule. **C**. CT in a 32-year-old man demonstrates a part solid adenocarcinoma in the lower lobe

Images provided by Dr. Micheal McInnis, University Health Network, Toronto.

Attenuation

Nodule attenuation correlates with risk of malignancy and is therefore important. Part-solid and persistent pure ground glass nodules are more likely to be malignant than solid nodules detected at lung cancer screening (11) (12) (13). Part-solid nodules are more likely to be malignant compared to solid nodules (**Figure 2**) (7).

Although pure ground glass nodules are more likely to be malignant than solid nodules, multiple studies have confirmed that small pure ground glass nodules usually correlate with non-invasive lesions such as atypical adenomatous hyperplasia or adenocarcinoma in situ. Therefore, most pure ground glass nodules can be safely followed in the context of a screening program (14) (15). Careful attention should be paid to pure ground glass nodules to evaluate for the presence of a solid component at baseline or follow-up which may warrant re-categorization and, in some cases, warrant intervention. Use of thin sections may be helpful in evaluating for sub-centimeter solid components (14).

Atypical Pulmonary Cysts

Lung cancers associated with cysts are rare but encountered in clinical practice, and many cases are not initially recognized as malignant. Most are adenocarcinomas. In the NELSON study, cancers associated with a cyst accounted for 22% of missed lung cancers (16). An atypical pulmonary cyst is defined as a thick-walled cyst (Figure 3A), a multilocular cyst (Figure 3B) or a cyst associated with a nodule (Figure 3D &E). A unilocular cyst has a wall thickness of ≥2 mm, that may be uniform, asymmetric, or nodular. A multilocular cyst is thin- or thick-walled with internal septations and a nodule associated with a cyst may be endophytic or exophytic. A thin-walled unilocular cyst with wall thickness <2 mm is not an atypical pulmonary cyst and is not classified or managed in Lung-RADS®. Appropriate classification of atypical pulmonary cysts is important to ensure standardized communication and appropriate management.

Calcification

Calcification is most frequently seen as the benign sequela of granulomatous disease (e.g. tuberculosis) and commonly coexists with calcified mediastinal or hilar lymphadenopathy. Importantly, calcification can be seen in some tumors, both benign and malignant, most commonly carcinoid tumors (17). Occasionally, a primary lung malignancy may engulf adjacent calcified granulomas. The presence of calcification is not necessarily regarded as benign. A small portion of primary malignant lung tumors show indeterminate calcification at baseline (18). Benign calcification patterns include central, diffuse solid, laminated, and popcorn.

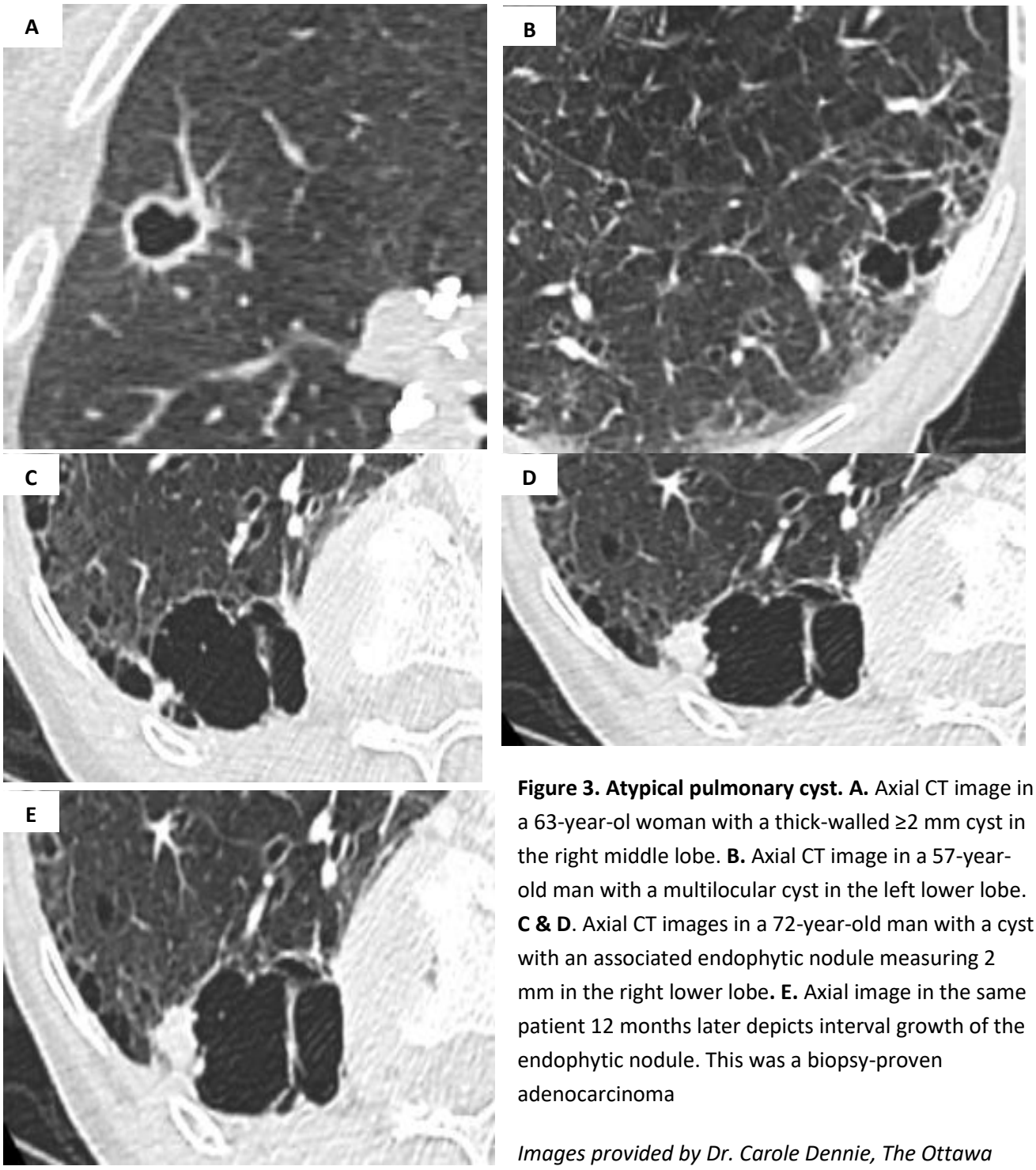

Figure 3. Atypical pulmonary cyst. A. Axial CT image in a 63-year-ol woman with a thick-walled ≥2 mm cyst in the right middle lobe. **B.** Axial CT image in a 57-year-old man with a multilocular cyst in the left lower lobe. **C & D**. Axial CT images in a 72-year-old man with a cyst with an associated endophytic nodule measuring 2 mm in the right lower lobe**. E.** Axial image in the same patient 12 months later depicts interval growth of the endophytic nodule. This was a biopsy-proven adenocarcinoma

Images provided by Dr. Carole Dennie, The Ottawa Hospital, Ottawa.

Size of Nodule

The main determinant of management in Lung-RADS® is nodule size which is usually measured in the axial plane on lung windows as the average of two dimensions (4). 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. Occasionally, the length and width will be significantly different, and calculation of the mean will have an impact on the Lung-RADS® categorization. The McWilliams Lung Cancer Risk Calculator uses maximum nodule length whereas Lung-RADS® utilizes mean size. Select examples of how to measure nodules for lung cancer screening are provided below (**Figure 4**). Nodules are conventionally measured in the axial plane and this is encouraged for consistency. It is at the discretion of the radiologist when to measure in orthogonal planes.

Solid & Pure Ground Glass Nodules

These nodules should be measured in two dimensions.

Part solid

The overall size of part solid nodules is the measure of the nodule including both the solid and ground glass component in two dimensions. The size of the solid component should be measured separately in two dimensions at the level where it is greatest in size. The measure of the solid component and the nodule as a whole will often be on two separate axial slices.

Comparison

During follow-up studies (1 month, 3 months, 6 months, and 1 year recall exams), a comparison of the nodule should be made to previous exams to examine changes in size.

Interval increases in the solid component drives changes to the Lung-RADS® score. The interval increase in the solid component applies to both solid and part-solid nodules.

Interval increase in ground glass component applies to both part-solid nodules and pure ground glass nodules.

As specified by Lung-RADS®, only increases in mean diameter size of > 1.5 mm (> 2 mm^3) within a 12-month interval should be regarded as significant as differences <1.5 mm are frequent and unreliable given variability between radiologists and technical error (4).

When a nodule crosses a new size threshold for another Lung-RADS category, even if not meeting the definition of growth, the nodule may be reclassified based on size and managed accordingly.

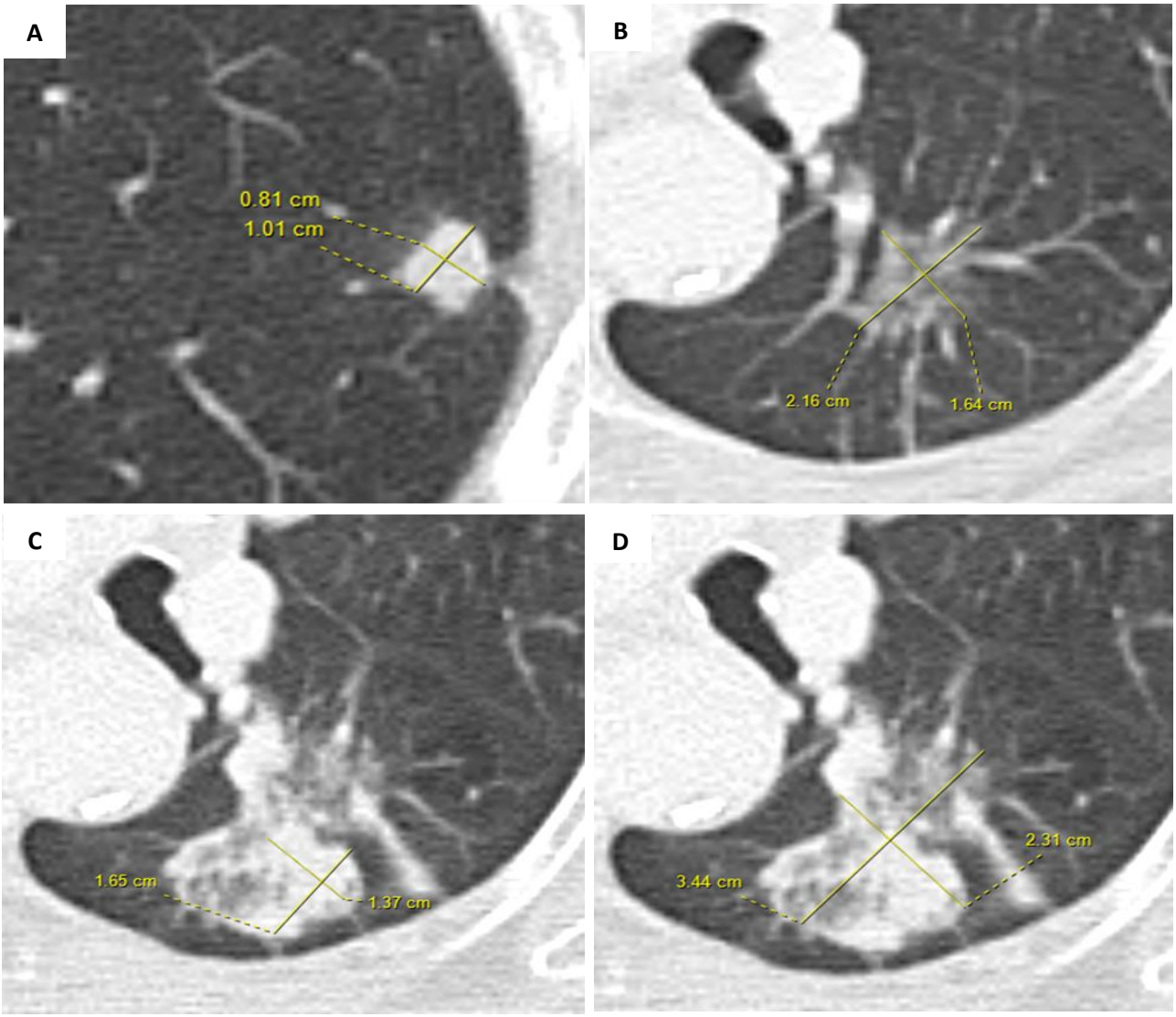

Figure 4. **Measurement of nodules. A**. CT in a 64-year-old woman. Solid nodules are measured in two dimensions in the transverse plane. This 10 x 8 mm nodule is categorized in Lung-RADS® by its mean diameter of 9 mm. Biopsy revealed adenocarcinoma. **B**. CT in a 73-year-old woman. Pure ground glass nodules are measured in two dimensions in the transverse plane. This 22 x 16 mm nodule is managed by its mean diameter of 19 mm. Pure ground glass nodules < 30 mm on baseline are Category 2 whereas those ≥ 30 mm at baseline or new are Category 3. **C** and **D**. Follow-up in the same patient in image B, 6 years later. The pure ground glass nodule developed a solid component consistent with invasive adenocarcinoma. Both the solid (**C**) and total nodule diameter (**D**) are reported.

Images provided by Dr. Micheal McInnis, University Health Network, Toronto.

Margins

A number of studies have linked margin types to survival (19) and the probability of malignancy (13). Spiculated margins have been associated with a shorter survival and greater chance of malignancy compared to smooth margins (**Figure 5**) (19) . Spiculation in nodules categorized as a Lung-RADS® 3 or 4 may be regarded as suspicious and can be re-classified as Lung-RADS® 4X when applicable.

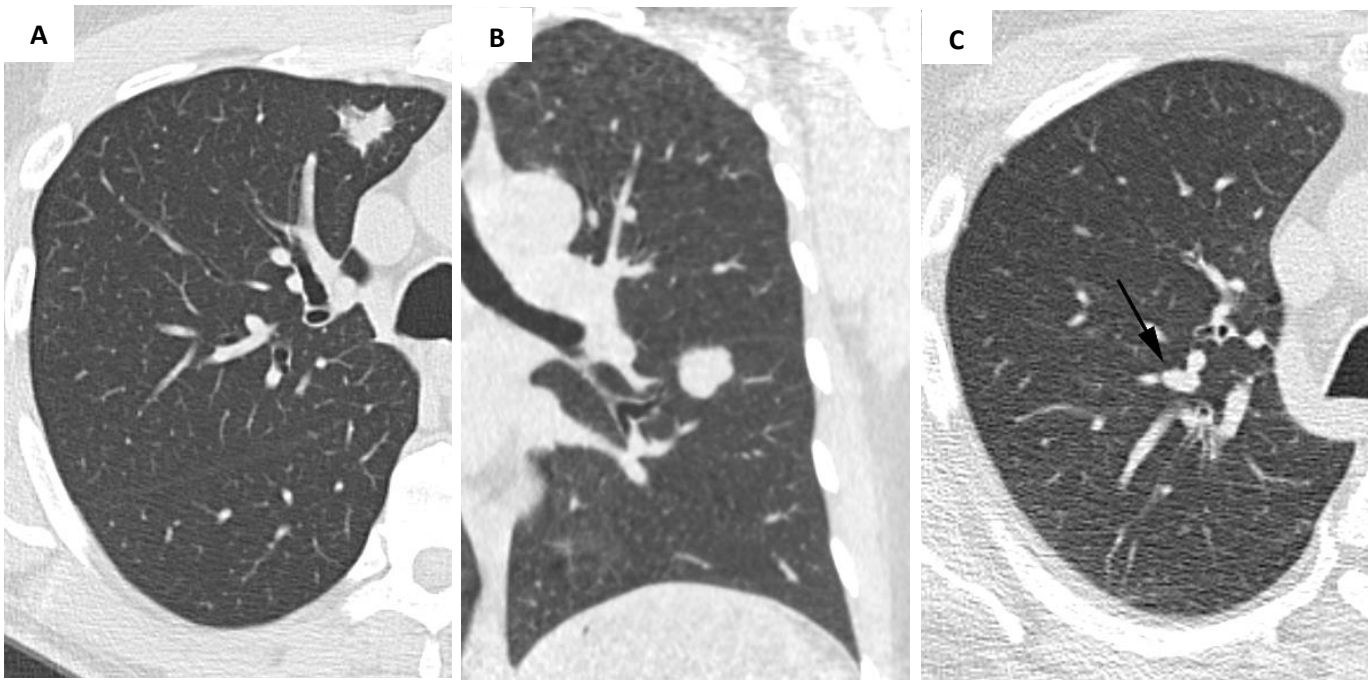

Figure 5. Nodule Margins. A. CT in a 50-year-old man demonstrates a spiculated upper lobe nodule. **B.** Coronal reformat CT in a 40 year-old woman demonstrates a lobulated lower lobe nodule adjacent the major fissure. Biopsy yielded adenocarcinoma. **C.** CT in a 63-year-old man demonstrates a growing nodule in the right upper lobe (arrow). Smooth margins and central location render this nodule easy to miss.

Images provided by Dr. Micheal McInnis, University Health Network, Toronto.

Inflammatory or Infectious Findings

Findings of lobar or segmental consolidation as well as multiple (>6) new nodules and solid nodules ≥8 mm developing over a brief time period are often inflammatory or infectious in nature. They may also obscure the underlying lung. New nodules appearing in immunocompromised hosts may also be indeterminate. These should be classified as Lung-RADS® 0 with a follow-up LDCT recommended in 1-3 months to ensure resolution. These were previously classified as Lung-RADS® 4B in Lung-RADS v. 1.1. Tree-in-bud opacities should be classified as Lung-RADS® 2 as they are most likely infectious or inflammatory.

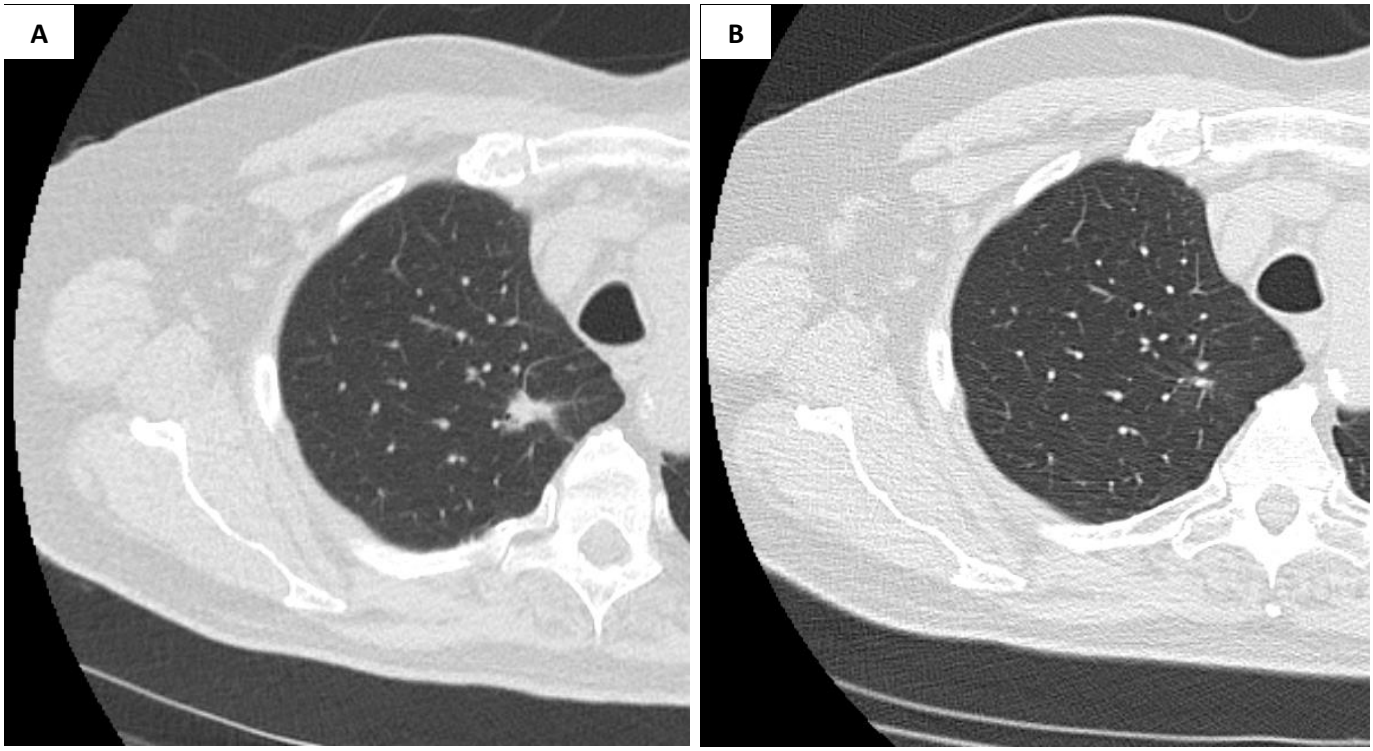

Figure 6. Example of a Category 0 nodule with inflammatory features. **A.** A new part solid nodule identified on a CT measuring 22.2 x 10.1 mm with an overall mean diameter of 16.2 mm and spiculated margins. It appeared on a 3-month follow-up LDCT done for another nodule. This would be most consistent with an inflammatory lesion. **B.** A follow-up LDCT 3 months later demonstrates two adjacent residual <4 mm nodules reclassified as Lung-RADS® 2.

Images provided by Dr. Carole Dennie, The Ottawa Hospital, Ottawa.

B. Incidental Findings

In this section of the report, radiologists are asked to comment on an incidental finding by anatomical region. For further details, see *Recommendations for the Management of Actionable Incidental Findings in the Lung Cancer Screening Pilot for People at High Risk.*

Lung or Pleura

Interstitial lung abnormalities (ILA) are common in the lung cancer screening population seen in near 10% in one study of NLST subjects. Interstitial lung abnormalities will progress in a small but significant number of patients and therefore the presence of fibrotic or non-fibrotic ILA may be clinically important (20).

The presence of pleural abnormalities such as evidence of prior asbestos exposure should be commented on when present. Occasionally, a new pleural abnormality such as a new pleural effusion would be a clinically significant finding that warrants use of the Lung-RADS® S modifier.

Emphysema

Emphysema should be visually quantified. The Fleischner Society provides guidance on the classification and quantification of emphysema that may be helpful to the reader (21). Emphysema is an independent risk factor for lung cancer and increases the odds of lung cancer (7). Severity of emphysema as visually assessed on CT is also associated with increased mortality risk (22).

Mediastinum or Hilum

Cardiovascular illness remained the most common cause of death in the NLST cohort despite their high risk for lung cancer (1). Furthermore, coronary artery calcification (CAC) was found to correlate with coronary heart disease death and all-cause mortality in lung cancer screening patients. A simple visual assessment on LDCT as described by Chiles et al is comparable to the Agatston score and therefore use is encouraged (**Figure 6**). In this scheme, CAC may be classified globally as none, mild, moderate, or heavy. The burden of CAC in each vascular territory need not be provided (23).

The International Association for the Study of Lung Cancer (IASLC) regional lymph node map should be used in the classification of lymphadenopathy at lung cancer screening (24). Generally, lymph nodes should be reported in short axis diameter with those ≥10 mm being regarded as suspicious.

However, LDCT lung cancer screening does not constitute a staging CT even when there is a suspicious mass (e.g. Lung-RADS® 4B). The reader will find that some lymph node stations may be difficult to assess by LDCT,

particularly in those with little mediastinal fat or a large body habitus. Therefore, a regular dose contrast-enhanced CT may be performed for staging in suspected lung cancers at which time the lymph node stations may be more accurately staged (1).

The presence of lymphadenopathy may warrant categorization of a lung nodule as Lung-RADS® 4X or may warrant use of the S modifier in the absence of a concerning nodule.

Chest Wall and Axillae, Bones, Upper Abdomen, and Other

Incidental findings outside of those described above are common at lung cancer screening and the majority are likely to be benign. The American College of Radiology provides guidance on the management of incidental thyroid nodules and abdominal findings (25) (26).

For definitions of actionability, see *Recommendations for the Management of Actionable Incidental Findings in the Lung Cancer Screening Pilot for People at High Risk.*

Impression

The most suspicious nodule drives the Lung-RADS® category. It should be described again in the impression section, along with the image number where it can be seen.

The most suspicious nodule is assigned a Lung-RADS® category (0, 1, 2, 3, 4A, 4B, 4X).

An S modifier is added if there are any clinically significant, or potentially clinically significant actionable incidental findings discovered on the LDCT images. Actionable incidental findings should be restated, and a follow-up recommendation should be provided.

For definitions of actionability, see *Recommendations for the Management of Actionable Incidental Findings in the Lung Cancer Screening Pilot for People at High Risk.*

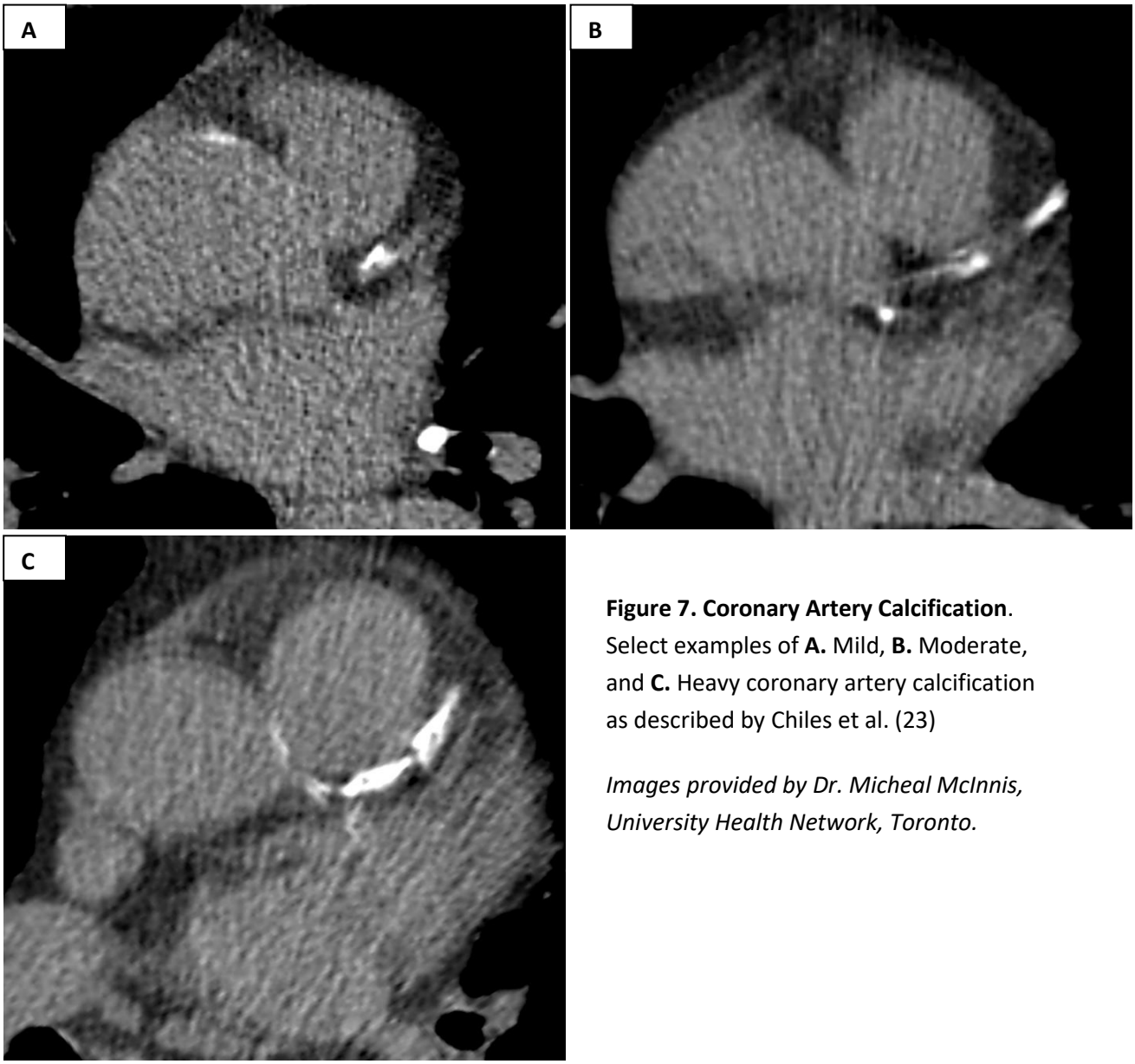

Figure 7. Coronary Artery Calcification. Select examples of **A.** Mild, **B.** Moderate, and **C.** Heavy coronary artery calcification as described by Chiles et al. (23)

Images provided by Dr. Micheal McInnis, University Health Network, Toronto.

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Appendix A – Lung-RADS® 2022

Lung-RADS	Category Descriptor	Findings	Management
0	**Incomplete** Estimated Population Prevalence: ~ 1%	Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT;
		Part or all of lungs cannot be evaluated	Additional lung cancer screening CT imaging needed;
		Findings suggestive of an inflammatory or infectious process (see note 10)	1-3 month LDCT
1	**Negative** Estimated Population Prevalence: 39%	**No lung nodules OR**	12-month screening LDCT
		Nodule with benign features: • Complete, central, popcorn, or concentric ring calcifications **OR** • Fat-containing	
2	**Benign** Based on imaging features or indolent behavior Estimated Population Prevalence: 45%	**Juxtapleural nodule:** • < 10 mm (524 mm^3) mean diameter at baseline or new **AND** • Solid; smooth margins; and oval, lentiform, or triangular shape	
		Solid nodule: • < 6 mm (< 113 mm^3) at baseline **OR** • New < 4 mm (< 34 mm^3)	
		Part-solid nodule: • < 6 mm total mean diameter (< 113 mm^3) at baseline	
		Non-solid nodule (GGN): • < 30 mm (< 14,137 mm^3) at baseline, new, or growing **OR** • ≥ 30 mm (≥ 14,137 mm^3) stable or slow-growing (see note 7)	
		Airway nodule, subsegmental at baseline, new, or stable (see note 11)	
		Category 3 nodule that is stable or decreased in size at 6-month follow-up CT, **OR** Category 3 or 4A nodules that resolve on follow-up, **OR** Category 4B findings proven to be benign in etiology following appropriate diagnostic workup	
3	**Probably Benign** Based on imaging features or behavior Estimated Population Prevalence: 9%	**Solid nodule:** • ≥ 6 to < 8 mm (≥ 113 to < 268 mm^3) at baseline **OR** • New 4 mm to < 6 mm (34 to < 113 mm^3)	6-month LDCT
		Part-solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm^3) with solid component < 6 mm (< 113 mm^3) at baseline **OR** • New < 6 mm total mean diameter (< 113 mm^3)	
		Non-solid nodule (GGN): • ≥ 30 mm (≥ 14,137 mm^3) at baseline or new	
		Atypical pulmonary cyst: (see note 12) • Growing cystic component (mean diameter) of a thick-walled cyst	
		Category 4A nodule that is stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	

4A	**Suspicious** Estimated Population Prevalence: 4%	**Solid nodule:** • ≥ 8 to < 15 mm (≥ 268 to < 1,767 mm³) at baseline **OR** • Growing < 8 mm (< 268 mm³) **OR** • New 6 to < 8 mm (113 to < 268 mm³)	3-month LDCT; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm³) solid nodule or solid component
		Part-solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm³) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm³) at baseline **OR** • New or growing < 4 mm (< 34 mm³) solid component	
		Airway nodule, segmental or more proximal at baseline or new (see note 11)	
		Atypical pulmonary cyst: (see note 12) • Thick-walled cyst **OR** • Multilocular cyst at baseline **OR** • Thin- or thick-walled cyst that becomes multilocular	
4B	**Very Suspicious** Estimated Population Prevalence: 2%	**Airway nodule,** segmental or more proximal, and stable or growing (see note 11)	Referral for further clinical evaluation
		Solid nodule: • ≥ 15 mm (≥ 1767 mm³) at baseline **OR** • New or growing ≥ 8 mm (≥ 268 mm³)	Diagnostic chest CT with or without contrast; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm³) solid nodule or solid component; tissue sampling; and/or referral for further clinical evaluation Management depends on clinical evaluation, patient preference, and the probability of malignancy (see note 13)
		Part-solid nodule: • Solid component ≥ 8 mm (≥ 268 mm³) at baseline **OR** • New or growing ≥ 4 mm (≥ 34 mm³) solid component	
		Atypical pulmonary cyst: (see note 12) • Thick-walled cyst with growing wall thickness/nodularity **OR** • Growing multilocular cyst (mean diameter) **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 exams (see note 8)	
4X	Estimated Population Prevalence: < 1%	Category 3 or 4 nodules with additional features or imaging findings that increase suspicion for lung cancer (see note 14)	
S	**Significant or Potentially Significant** Estimated Population Prevalence: 10%	**Modifier:** May add to category 0-4 for clinically significant or potentially clinically significant findings unrelated to lung cancer (see note 15)	As appropriate to the specific finding

IMPORTANT NOTES FOR USE:

1) **Lung-RADS Category:** Each exam should be coded 0-4 based on the nodule with the highest degree of suspicion.

2) **Lung-RADS Management:** The timing of follow-up imaging is from the date of the exam being interpreted. For example, 12-month screening LDCT for Lung-RADS 2 is from the date of the current exam. Also note that management of category 3 and 4A nodules follows a stepped approach based on follow-up stability or decrease in size. If nodules resolve on follow-up, reclassify according to the most concerning finding.

3) **Practice Audit Definitions:** A negative screen is defined as categories 1 and 2; a positive screen is defined as categories 3 and 4. A negative screen does not mean that an individual does not have lung cancer.

4) **Nodule Measurement:** To calculate nodule mean diameter, measure both the long and short axis to one decimal point in mm, and report mean nodule diameter to one decimal point. The long and short axis

measurements may be in any plane to reflect the true size of the nodule. Volumes, if obtained, should be reported to the nearest whole number in mm^3.

5) **Size Thresholds:** Apply to nodules at first detection and that enlarge, reaching a higher size category. When a nodule crosses a new size threshold for other Lung-RADS categories, even if not meeting the definition of growth, the nodule should be reclassified based on size and managed accordingly.

6) **Growth:** An increase in mean diameter size of > 1.5 mm (> 2 mm^3) within a 12-month interval.

7) **Slow-Growing–Non-Solid (Ground-Glass) Nodules:** A ground-glass nodule (GGN) that demonstrates growth over multiple screening exams but does not meet the > 1.5 mm threshold increase in size for any 12-month interval may be classified as LungRADS 2 until the nodule meets findings criteria of another category, such as developing a solid component (then manage per partsolid nodule criteria).

8) **Slow-Growing-Solid or Part-Solid Nodules:** A solid or part-solid nodule that demonstrates growth over multiple screening exams but does not meet the > 1.5 mm threshold increase in size for any 12-month interval is suspicious and may be classified as a LungRADS 4B. Slow-growing nodules may not have increased metabolic activity on PET/CT; therefore, biopsy, if feasible, or surgical evaluation may be the most appropriate management recommendation.

9) **Prior Exams:** If waiting on prior exams (either a prior screening or diagnostic CT), the Lung-RADS 0 category is temporary until the comparison study is available and a new Lung-RADS category is assigned.

10) Suspected Infectious or Inflammatory Findings:

a. Lung-RADS 0 with 1-3 month follow-up LDCT may be recommended for pulmonary findings suggesting an indeterminate infectious or inflammatory process. Such findings may include segmental or lobar consolidation, multiple new nodules (more than six), large solid nodules (≥ 8 mm) appearing in a short interval, and new nodules in certain clinical contexts (eg, immunocompromised patient). At 1-3 month follow-up, a new Lung-RADS classification and management recommendation should be provided based on the most suspicious nodule.
b. New solid or part-solid nodules with imaging features more concerning for malignancy than an infectious or inflammatory process meeting Lung-RADS 4B size criteria may be classified as such with appropriate diagnostic and/or clinical evaluation.
c. Some findings indicative of an infectious or infectious process may not warrant short-term follow-up (eg, tree-in-bud nodules or new < 3 cm ground glass nodules). These nodules may be evaluated using existing size criteria with a Lung-RADS classification and management recommendation based on the most suspicious finding.

11) Airway Nodules:

a. Endotracheal or endobronchial abnormalities that are segmental or more proximal are classified as Lung-RADS 4A.

b. Subsegmental and/or multiple tubular endobronchial abnormalities favor an infectious process; if no underlying obstructive nodule is identified, these findings may be classified as Lung-RADS 0 (likely infectious or inflammatory) or 2 (benign).
c. The presence of air in segmental or more proximal airway abnormalities often favors secretions; if no underlying soft tissue nodule is identified, these findings may be classified as Lung-RADS 2.
d. Segmental or more proximal airway nodules that are stable or growing on 3-month follow-up CT are upgraded to Lung-RADS 4B with management recommendation for further clinical evaluation (typically bronchoscopy).

12) **Atypical Pulmonary Cysts:**
a. Thin-walled Cyst: Unilocular with uniform wall thickness < 2 mm. Thin-walled cysts are considered benign and are not classified or managed in Lung-RADS.
b. Thick-walled Cyst: Unilocular with uniform wall thickness, asymmetric wall thickening, or nodular wall thickening ≥ 2 mm (cystic component is the dominant feature); manage as an atypical pulmonary cyst.
c. Multilocular Cyst: Thick- or thin-walled cyst with internal septations. Manage as an atypical pulmonary cyst.
d. Cavitary Nodule: Wall thickening is the dominant feature; manage as a solid nodule (total mean diameter).
e. Cyst with an Associated Nodule: Any cyst with adjacent internal (endophytic) or external (exophytic) nodule (solid, part-solid, or ground-glass). Management is based upon Lung-RADS criteria for the most concerning feature.
f. Growth: > 1.5 mm increase in nodule size (mean diameter), wall thickness, and/or size of the cystic component (mean diameter) occurring within a 12-month interval.
g. Fluid-containing cysts may represent an infectious process and are not classified in Lung-RADS unless other concerning features are identified.
h. Multiple cysts may indicate an alternative diagnosis such as Langerhans cell histiocytosis (LCH) or lymphangioleiomyomatosis (LAM) and are not classified in Lung-RADS unless other concerning features are identified. (Reference: Seaman DM, Meyer CA, Gilman MD, McCormack FX. Diffuse Cystic Lung Disease at High-Resolution CT. AJR 2011;196: 1305-1311)

13) **Category 4B:** Management is predicated on clinical evaluation (comorbidities), patient preference, and risk of malignancy. Radiologists are encouraged to use the McWilliams, et al Assessment Tool when making recommendations (https://brocku.ca/lungcancer-screening-and-risk-prediction/risk-calculators/).

14) **Category 4X:** Category 3 or 4 nodules with additional imaging findings that increase the suspicion of lung cancer, such as
spiculation, lymphadenopathy, frank metastatic disease, a GGN that doubles in size in 1 year, etc. 4X is a distinct Lung-RADS
category; X should not be used as a modifier.

15) **Exam Modifier:** An S modifier may be added to Lung-RADS categories 0-4 for clinically significant or potentially clinically significant findings unrelated to lung cancer.

a. Management should adhere to available ACR Incidental Findings management recommendations (https://www.acr.org/ClinicalResources/Incidental-Findings). The ACR Lung Cancer Screening CT Incidental Findings Quick Reference Guide summarizes common findings and management (https://www.acr.org/-/media/ACR/Files/Lung-Cancer-Screening-Resources/LCS-IncidentalFindings-Quick-Guide.pdf).
b. Findings that are already known, and have been or are in the process of clinical evaluation DO NOT require an S modifier. Any evidence of a concerning change in a known significant or potentially significant finding that is unexpected warrants renewed use of the S modifier.

16) **Lung Cancer Diagnosis:** Once a patient is diagnosed with lung cancer, further management (including additional imaging, such as PET/CT) may be performed for purposes of lung cancer staging; this is no longer considered screening.

Abbreviations: LDCT: low-dose chest CT; GGN: ground-glass nodule

*Additional resources available at - https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads