Ontario Health
Cancer Care Ontario

Recommendations for the Management of Actionable Incidental Findings in the Ontario Lung Screening Program

Dr. Micheal McInnis, Lead, Radiology Quality Assurance, University Health Network
Dr. Heidi Schmidt, Clinical Radiology Lead, Lung Cancer Screening Pilot for People at High Risk
Michelle Ang, Lead, Radiology Quality Assurance Program, Cancer Imaging Program

525 University Avenue, 5th Floor, Toronto ON, M5G 2L3

Resulting Recommendations

Summary Table: Actionable Incidental Findings Recommendations in the context of the Ontario Lung Screening Program.

Incidental Finding	Sources Consulted	Not Actionable	Actionable
Coronary artery calcification (CAC)	(7, 9, 10)	Using overall visual classification 1. Mild CAC **RECOMMENDATION:** No further evaluation. Comment in the body of the report	Using overall visual classification 1. Moderate and Heavy CAC **RECOMMENDATION:** Two stage approach: **1.** Statement: "Moderate/severe coronary calcification has been shown to correlate with a higher degree of cardiovascular risk" **2.** Formal assessment of cardiovascular risk factors is suggested, with or without cardiology consultation
Emphysema	(6,7,8)	1. Emphysema is not an actionable incidental finding. **RECOMMENDATION:** Grade emphysema in the body of the report as per Fleischner Society definitions: none, trace, mild, moderate, confluent, and advanced destructive.	1. Emphysema, even advanced, is generally not an actionable incidental finding in the lung screening population.
Indeterminate renal nodule or mass	(4)	1. Simple renal cysts (-10 - 20 HU), cysts >70 HU, and nodules too small to characterize. Fatty nodules without calcification (angiomyolipomas) **RECOMMENDATION**: No further evaluation	1. All other lesions: Defer to judgement of reading radiologist. **RECOMMENDATION**: Ultrasound or additional imaging as per institutional practice
Indeterminate hepatic nodule(s) or mass	(5)	1. Too small to characterize or with benign features (sharply marginated, homogeneous, ≤20 HU). **RECOMMENDATION:** No further evaluation	1. Suspicious features (ill-defined margins, heterogeneous density, mural thickening or nodularity, thick septa) or with cirrhosis **RECOMMENDATION:** Ultrasound or additional imaging as per institutional practice
Ascending aorta dilatation	(14)	Using mean ascending aorta diameter 1. 4.0 – 4.5 cm **RECOMMENDATION:** Report measure in body of text and re-measure on annual screening CT.	Using mean ascending aorta diameter 1. >4.5 – 4.9 cm **RECOMMENDATION:** Echocardiogram and consider referral to cardiology or cardiac surgery.

			2. ≥5.0 cm **RECOMMENDATION:** Echocardiogram and refer to cardiac surgery.
Thyroid	(11)	1. <1.5cm and lack suspicious features **RECOMMENDATION:** No further evaluation (11)	1. ≥1.5 cm and/or suspicious findings (Abnormal LN (calcifications, cystic components) and/or invasion of local tissues by thyroid nodule) **RECOMMENDATION**: Thyroid Ultrasound
Breast nodule or asymmetry		1. Definitely benign nodules (e.g. lipoma, densely calcified nodules, etc.). **RECOMMENDATION:** No further evaluation	1. Indeterminate breast lfs (e.g. non-calcified nodules, asymmetries, etc.) **RECOMMENDATION:** Mammogram

Background

In 2017, Ontario Health (Cancer Care Ontario) launched the Lung Cancer Screening Pilot for People at High Risk (HRLCSP) with the aim of assessing the implementation of organized lung cancer screening for individuals at high risk for lung cancer, due to cigarette smoking history. Initial data from the pilot program are currently being analyzed to determine the best way to implement findings into a provincial lung cancer screening program.

For the initial rollout of the pilot, three hospital sites representing different care delivery models, were selected to recruit and screen participants (Figure 1). The pilot sites include:

- The Ottawa Hospital (Ottawa), (together with Renfrew Victoria Hospital)
- Lakeridge Health (Oshawa)
- Health Sciences North (Sudbury)

Effective April 1st 2021, pilot sites have transitioned to operations as the Ontario Lung Screening Program (OLSP).

Screening Process

Once deemed eligible (2), participants were recruited into the HRLCSP, participants received a low-dose computed tomography (LDCT) scan. Nodules detected in the LDCT were assessed using a standardized scoring schema (Lung-RADS) developed by the American College of Radiology (3). According to the nodule scoring, participants are sent for follow-up, and results are communicated using a standardized radiology reporting template.

Also included in the radiology reports are incidental findings (IFs) deemed "actionable" by the reading radiologist, i.e. findings detected on the LDCT that are not related to lung cancer nodule detection that require action, such as follow up or further clinical investigation. Reporting an Actionable IF would trigger an additional communication to be sent to the referring provider to ensure proper investigation of the actionable IF would occur.

For more information on the Lung Cancer screening pathway, please visit the following website: https://www.cancercareontario.ca/sites/ccocancercare/files/assets/Lung_Cancer_Screening_Pathway_Map.pdf

Actionable Incidental Findings

Prior to the pilot launch, reading radiologists were trained in the use of the reporting template, scoring of nodules, and follow up recommendations. However, definitions of "actionability" with respect to IFs were left to the clinical discretion of the reading radiologist. Throughout the first year of the pilot, several radiologists requested additional support in determining the actionability of certain IFs. Additionally, first year pilot data analysis demonstrated variation in actionable IF rate and reporting between pilot sites (Table 1).

Year 1 HRLCSP	Site 1 n	Site 1 %	Site 2 n	Site 2 %	Site 3 n	Site 3 %	All Sites n	All Sites %
Total baseline LDCT scans	350	N/A	478	N/A	796	N/A	1,624	N/A
Actionable IFs detected	104	29.7	174	36.4	119	14.9	389	24.0

Table 1: Actionable IF rate from June 1st, 2017 to May 31st, 2018, HRLCSP program

Further analysis demonstrated that the most frequently identified actionable IFs were common amongst all sites. Frequently identified actionable IFs were:

- 17.7% (n=96) coronary artery calcifications
- 7.2% (n=39) emphysema
- 7.0% (n=38) interstitial lung abnormality
- 4.4% (n=24) indeterminate renal nodule or mass
- 4.4% (n=24) indeterminate hepatic nodule(s) or mass
- 3.1% (n=17) ascending aorta dilatation
- 2.9% (n=16) thyroid nodule
- 2.7% (n=15) breast lesion

Methods

A working group was developed to develop recommendations surrounding frequently identified actionable IFs reported in the first year of the pilot.
The working group consisted of:

- Dr. Heidi Schmidt – Radiology Clinical Lead, Ontario Health (Cancer Care Ontario)
- Dr. Micheal McInnis – Radiology Lead, University Health Network
- Michelle Ang – Lead, Radiology Quality Assurance Workstream, Cancer Imaging Lead, Ontario Health (Cancer Care Ontario)

Data pulled from the first year of the HRLCSP program was analyzed and the most frequent actionable IFs were determined. A literature search was conducted for each actionable IF to determine if recommendations for management of these actionable IFs could be adopted into the HRLCSP.

Clinical Input

Clinical consultation with experts in the field occurred for each IF. Experts provided input into recommendation summaries from literature, as well as adaptation suggestions for a local Ontario

context. Experts also provided feedback on the proposed impacts, including implementation strategies and educational considerations

Actionability

After consulting the literature, the working group examined clinical evidence to determine which clinical scenarios would be considered "actionable" for each IF in a lung cancer screening population. Actionability was also discussed with relevant clinical experts.

For the purposes of this project, actionability will be defined as follows:

- **Actionability** – Whether an identified IF would be considered "actionable" within a lung cancer screening context was developed.
    - **Non-Actionable Incidental Finding** – an IF that does not require clinical follow up. The reporting template S-modifier should not be utilized. Observations can be described within the body of the template but should not be repeated in the Impressions section
    - **Actionable Incidental Finding** – IFs that require follow up to confirm their benign and incidental nature(s). Recommendations and relevant clinical information will be reported in the Impressions section of the reporting template, and the S-Modifier should be utilized

For each IF, follow up recommendations were developed for actionable scenarios and are described in the summary table.

References

1. *CT-Definable Subtypes of Chronic Obstructive Pulmonary Disease: A Statement of the Fleischner Society.* **Lynch, David A. et al.** 1, Octover 2015, Radiology, Vol. 277.

2. *Selection criteria for lung-cancer screening.* **Tammemägi MC, Katki HA, Hocking WG, Church TR, Caporaso N, Kvale PA, et al.** 8, Feb 21, 2013, New England Journal of Medicine, Vol. 368, pp. 728-36.

3. *Performance of ACR Lung-RADS in a Clinical CT Lung Screening Program.* **McKee, Brady J. et al.** 3, 2015, Journal of the American College of Radiology, Vol. 12, pp. 273-276.

4. *Management of the Incidental Renal Mass on CT: A White Paper of the ACR Incidental Findings Committee.* **Hertz, Brian R.** 2018, American College of Radiology, Vol. 15, pp. 264-273.

5. *Management of Incidenal Liver Lesions on CT: A White Paper of the ACR Incidental Findings Committee.* **Gore, Richard M,.** 2017, American College of Radiology, Vol. 14, pp. 1429-1437.

6. *CT-based Visual Classification of Emphysema: Association with Mortality in the COPDGene Study.* **Lynch, David A. et. al.** 288, 2018, Radiology, pp. 859-866.

7. *Managing Incidental Findings on Thoracic CT: Mediastinal and Cardiovascular Findings. A White Paper of the ACR Incidental Findings Committee.* **Munden, Reginald F. et al.** s.l. : American College of Radiology, 2018, Journal of the American College of Radiology, Vol. 15, pp. 1087-1096.

8. *CT-Definable Subtypes of Chronic Obstructive Pulmonary Disease: A Statement of the Fleischner Society.* **Lynch, David A. et al.** 1, 2015, Radiology, Vol. 277, pp. 192-205.

9. *Association of Coronary Artery Calcification and Mortality in the National Lung Screening Trial: A Comparison of Three Scoring Methods.* **Chiles, Caroline.** 1, 2015, Radiology, Vol. 276, pp. 82-90.

10. *2016 SCCT/STR guidelines for coronary artery calcium scoring of noncontrast noncardiac chest CT scans: A report of the Society of Cardiovascular Computed Tomography and Society of Thoracic Radiology.* **Hecht, HS et. al.** 2016, Journal of Cardiovascular Computed Tomography.

11. *Managing Incidental Thryoid Nodules Detected on Imaging: White Paper of the ACR Incidental Thyroid Findings Committee.* **Hoang, Jenny K. et al.** 143, s.l. : American College of Radiology, 2015, Journal of the American College of Radiology, Vol. 12, pp. 143-150.

12. *Screening for Lung Cancer: CHEST Guideline and Expert Panel Report.* **Mazzone, Peter J. et. al.** 4, 2018, CHEST, Vol. 153, pp. 954-985.

13. *Managing Incidental Findings on Abdominal CT: White Paper of the ACR Incidental Findings Committee.* **Berland, Lincoln L. et. al.** s.l. : American College of Radiology, 2010, Journal of the American College of Radiology, Vol. 7, pp. 754-773.

14. Canadian Cardiovascular Society position statement on the management of thoracic aortic disease. **Boodhwani et al.** 60, 2014, Canadian Journal of Cardiology, Vol. 30, pp. 577-89.