The American College of Radiology

Lung Cancer Screening Registry (LCSR)

Measures

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American College of Radiology
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NRDR
LCSR™
LUNG CANCER SCREENING REGISTRY
AMERICAN COLLEGE OF RADIOLOGY

Contents

1. Appropriateness of screening by USPSTF criteria

Data Elements	Clinical Performance Measure
• Patient's date of birth • Number of pack-years of smoking • Number of years since quit • Smoking status	**Measure Description:** Percent of screening exams done on adults who are aged 55 to 80 years, have a 30 pack-year smoking history, and currently smoke or have quit within the past 15 years. **Numerator:** Number of exams done on patients aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. **Denominator**: Number of screening exams **Numerator and Denominator Exclusion:** None

2. Smoking cessation offered

Data Elements	Clinical Performance Measure
• Did physician provide smoking cessation guidance to patient?	**Measure description:** Percent of exams where patients are offered smoking cessation guidance. **Numerator:** Number of exams where smoking cessation guidance were offered **Denominator**: Number of screening exams **Numerator and Denominator Exclusion:** None

3. Smoking cessation offered among current smokers

Data Elements	Clinical Performance Measure
• Did physician provide smoking cessation guidance to patient? • Smoking status	**Measure description:** Percent of screening exams done on current smokers who are offered smoking cessation guidance. **Numerator:** Number of screening exams where smoking cessation guidance were offered **Denominator**: Number of screening exams where the patient currently smokes **Numerator and Denominator Exclusion:** None

4. Radiation exposure 1: Mean CTDIvol overall

Data Elements	Clinical Performance Measure
• CTDIvol (mGy)	**Measure description:** Mean Volumetric CT Dose Index (CTDIvol) across all screening exams performed **Numerator:** Total CTDIvol for all screening exams performed **Denominator**: Number of screening exams **Numerator and Denominator Exclusion:** None

5. Radiation exposure 1: Mean CTDIvol underweight (BMI<18.5)

Data Elements	Clinical Performance Measure
• CTDIvol (mGy) • Patient height (inches) • Patient weight (lbs)	**Measure description:** Mean Volumetric CT Dose Index (CTDIvol) across all screening exams performed on underweight patients (BMI<18.5) **Numerator:** Total CTDIvol across all screening exams performed on underweight patients **Denominator**: Number of screening exams where patients were underweight (BMI<18.5) **Numerator and Denominator Exclusion:** None

6. Radiation exposure 1: Mean CTDIvol normal (BMI 18.5-24.9)

Data Elements	Clinical Performance Measure
• CTDIvol (mGy) • Patient height (inches) • Patient weight (lbs)	**Measure description:** Mean Volumetric CT Dose Index (CTDIvol) across all screening exams performed on normal weight patients (BMI 18.5-24.9) **Numerator:** Total CTDIvol across all screening exams performed on normal-weight patients **Denominator**: Number of screening exams where patients were normal-weight (BMI 18.5-24.9) **Numerator and Denominator Exclusion:** None

7. Radiation exposure 1: Mean CTDIvol overweight (BMI 25-29.9)

Data Elements	Clinical Performance Measure
• CTDIvol (mGy) • Patient height (inches) • Patient weight (lbs)	**Measure description:** Mean Volumetric CT Dose Index (CTDIvol) across all screening exams performed on overweight patients (BMI 25-29.9) **Numerator:** Total CTDIvol across all screening exams performed on overweight patients **Denominator**: Number of screening exams where patients were overweight (BMI 25-29.9) **Numerator and Denominator Exclusion:** None

8. Radiation exposure 1: Mean CTDIvol obese (BMI of 30 or greater)

Data Elements	Clinical Performance Measure
• CTDIvol (mGy) • Patient height (inches) • Patient weight (lbs)	**Measure description:** Mean Volumetric CT Dose Index (CTDIvol) across all screening exams performed on obese patients (BMI of 30 or greater) **Numerator:** Total CTDIvol across all screening exams performed on obese patients **Denominator**: Number of screening exams where patients were obese (BMI of 30 or greater) **Numerator and Denominator Exclusion:** None

9. Radiation exposure 1: Mean DLP overall

Data Elements	Clinical Performance Measure
• **DLP (mGy*cm)**	Measure description: Mean Dose Length Product (DLP) across all screening exams performed Numerator: Total DLP for all screening exams performed Denominator: Number of screening exams Numerator and Denominator Exclusion: None

10. Radiation exposure 1: Mean DLP underweight (BMI<18.5)

Data Elements	Clinical Performance Measure
• DLP (mGy*cm) • Patient height (inches) • Patient weight (lbs)	**Measure description:** Mean Dose Length Product (DLP) across all screening exams performed on underweight patients (BMI<18.5) **Numerator:** Total DLP across all screening exams performed on underweight patients **Denominator**: Number of screening exams where patients were underweight (BMI<18.5) **Numerator and Denominator Exclusion:** None

11. Radiation exposure 1: Mean DLP normal (BMI 18.5-24.9)

Data Elements	Clinical Performance Measure
• DLP (mGy*cm) • Patient height (inches) • Patient weight (lbs)	**Measure description:** Mean Dose Length Product (DLP) across all screening exams performed on normal weight patients (BMI 18.5-24.9) **Numerator:** Total DLP across all screening exams performed on normal-weight patients **Denominator**: Number of screening exams where patients were normal-weight (BMI 18.5-24.9) **Numerator and Denominator Exclusion:** None

12. Radiation exposure 1: Mean DLP overweight (BMI 25-29.9)

Data Elements	Clinical Performance Measure
• DLP (mGy*cm) • Patient height (inches) • Patient weight (lbs)	**Measure description:** Mean Dose Length Product (DLP) across all screening exams performed on overweight patients (BMI 25-29.9) **Numerator:** Total DLP across all screening exams performed on overweight patients **Denominator**: Number of screening exams where patients were overweight (BMI 25-29.9) **Numerator and Denominator Exclusion:** None

13. Radiation exposure 1: Mean DLP obese (BMI of 30 or greater)

Data Elements	Clinical Performance Measure
• DLP (mGy*cm) • Patient height (inches) • Patient weight (lbs)	**Measure description:** Mean Dose Length Product (DLP) across all screening exams performed on obese patients (BMI 30 or greater) **Numerator:** Total DLP across all screening exams performed on obese patients **Denominator**: Number of screening exams where patients were obese (BMI of 30 or greater) **Numerator and Denominator Exclusion:** None

14. Lung Cancer Screening Abnormal Interpretation Rate

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category	**Measure description:** Percent of screening exams that have a Lung-RADS assessment of 3, 4a, 4b, or 4x (assessment categories that may lead to additional imaging or biopsy). **Numerator**: Number of exams that have a Lung-RADS assessment of 3, 4a, 4b, or 4x (assessment categories that may lead to additional imaging or biopsy). **Denominator**: Number of screening exams **Numerator and Denominator Exclusion:** None

15. Cancer Detection Rate (CDR) per 1,000 screening exams

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Exam date/Date of screening • Date of follow-up	**Measure Description:** Number of screening exams with a Lung-RADS assessment category of 3 or 4 that had a tissue diagnosis of cancer within 365 days of screening exam, per 1,000 lung cancer screening exams. **Numerator**: Number of screening exams with a Lung-RADS assessment category of 3 or 4 that had a tissue diagnosis of cancer within 365 days of screening exam. **Denominator**: Number of screening exams **Numerator and Denominator Exclusion:** None

16. CDR for prevalent cancers, detected at baseline exam per 1,000 baseline screening exams

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Indication for exam • Exam date/Date of screening • Date of follow-up	**Measure Description:** Number of baseline screening exams with a Lung-RADS assessment category of 3 or 4 that had a tissue diagnosis of cancer within 365 days of baseline screening exam, per 1,000 baseline screening exams. **Numerator**: Number of baseline screening exams with a Lung-RADS assessment category of 3 or 4 that had a tissue diagnosis of cancer within 365 days of baseline screening exam. **Denominator**: Number of baseline screening exams **Numerator and Denominator Exclusion:** None

17. CDR for incident cancers, detected at annual exam per 1,000 annual screening exams

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Indication for exam • Exam date/Date of screening • Date of follow-up	**Measure Description:** Number of annual screening exams with a Lung-RADS assessment category of 3 or 4 that had a tissue diagnosis of cancer within 365 days of annual screening exam, per 1,000 annual screening exams. **Numerator**: Number of annual screening exams with a Lung-RADS assessment category of 3 or 4 that had a tissue diagnosis of cancer within 365 days of annual screening exam. **Denominator**: Number of annual screening exams **Numerator and Denominator Exclusion:** None

18. Positive Predictive Value (PPV1)

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Exam date/Date of screening • Date of follow-up	**Measure Description:** Percent of patients recommended for biopsy who are subsequently diagnosed with lung cancer within 365 days of screening exam **Numerator**: Number of screening exams that had a Lung-RADS assessment category of 3 or 4 and a tissue diagnosis of cancer within 365 days of screening exam **Denominator**: Number of screening exams that had a Lung-RADS assessment category of 3 or 4 **Numerator and Denominator Exclusion:** None

19. PPV1 for lung cancers detected surgically

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Tissue diagnosis method • Exam date/Date of screening • Date of follow-up	**Measure Description:** Percent of patients recommended for biopsy who are subsequently diagnosed with lung cancer by surgical tissue diagnosis method within 365 days of screening exam **Numerator:** Number of screening exams that had a Lung-RADS assessment category of 3 or 4 and a tissue diagnosis of cancer within 365 days of screening exam where tissue diagnosis method was surgical **Denominator:** Number of screening exams that had a Lung-RADS assessment category of 3 or 4 **Numerator and Denominator Exclusion:** None

20. PPV1 for lung cancers detected on percutaneous biopsies

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Tissue diagnosis method • Exam date/Date of screening • Date of follow-up	**Measure Description:** Percent of patients recommended for biopsy who are subsequently diagnosed with lung cancer by percutaneous biopsies within 365 days of screening exam **Numerator:** Number of screening exams that had a Lung-RADS assessment category of 3 or 4 and a tissue diagnosis of cancer with in 365 days of screening exam where tissue diagnosis method was percutaneous **Denominator**: Number of screening exams that had a Lung-RADS assessment category of 3 or 4 **Numerator and Denominator Exclusion:** None

21. PPV1 for lung cancers detected on bronchoscopies

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Tissue diagnosis method • Exam date/Date of screening • Date of follow-up	**Measure Description:** Percent of patients recommended for biopsy who are subsequently diagnosed with lung cancer by bronchoscopy within 365 days of screening exam **Numerator:** Number of screening exams that had Lung-RADS assessment category of 3 or 4 and a tissue diagnosis of cancer within 365 days of screening exam where tissue diagnosis method was bronchoscopy **Denominator**: Number of screening exams that had a Lung-RADS assessment category of 3 or 4 **Numerator and Denominator Exclusion:** None

22. Positive Predictive Value 2a (PPV2a)

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Exam date/Date of screening • Date of follow-up	**Measure Description:** Percent of patients that had a Lung-RADS assessment category of 3 or 4a (typically associated with additional CT recommendation or PET/CT recommendation) and a tissue diagnosis of cancer within 365 days of screening exam **Numerator:** Number of screening exams that had a Lung-RADS assessment category of 3 or 4a and a tissue diagnosis of cancer within 365 days of screening exam **Denominator**: Number of screening exams that had a Lung-RADS assessment category of 3, 4a **Numerator and Denominator Exclusion:** None

23. Positive Predictive Value 2b (PPV2b)

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Exam date/Date of screening • Date of follow-up	**Measure Description:** Percent of patients that had a Lung-RADS assessment category of 4B or 4X (typically associated with biopsy recommendation) and a tissue diagnosis of cancer within 365 days of screening exam **Numerator:** Number of screening exams that had a Lung-RADS assessment category of 4B or 4X and a tissue diagnosis of cancer within 365 days of screening exam **Denominator**: Number of screening exams that had a Lung-RADS assessment category of 4B or 4X **Numerator and Denominator Exclusion:** None

24. Positive Predictive Value 3 (PPV3)

Data Elements	Clinical Performance Measure
• CT exam result by Lung-RADS category • Tissue diagnosis • Follow-up diagnostic • Exam date/Date of screening • Date of follow-up	**Measure Description:** Percent of patients that had a Lung-RADS assessment category of 4B or 4X (typically associated with biopsy recommendation) and with record of biopsy performed that had a tissue diagnosis of cancer within 365 days of screening exam **Numerator:** Number of screening exams that had a Lung-RADS assessment category of 4B or 4X and with a record of biopsy performed that had a tissue diagnosis of cancer within 365 days of screening exam **Denominator**: Number of screening exams that had a Lung-RADS assessment category of 4B or 4X and with record of biopsy performed **Numerator and Denominator Exclusion:** None

GLOSSARY OF TERMS

1. **Abnormal Interpretation Rate**: The percentage of exams interpreted as positive. For lung cancer screening CT, positive exams include Lung-RADS® Categories 3 and 4 assessments.

   Abnormal Interpretation Rate = (positive exams) / (all exams)

2. **Cancer:** Tissue diagnosis of non-small cell or small cell lung cancer.

3. **Cancer Detection Rate:** The number of cancers correctly detected at screening CT per 1,000 patients examined at screening CT. This may be calculated separately for PREVALENT cancers (those found at a baseline or first time lung cancer screening CT exam) and for INCIDENT cancers (those found at subsequent screening exams performed at or close to the recommended screening interval).

4. **False Positive (FP):** This includes each of the following three definitions.

   - FP_1: No known or presumed tissue diagnosis of lung cancer within 1 year of a positive screening exam (Lung-RADS® Category 3 or 4).
   - FP_2: No known tissue diagnosis of cancer within 1 year after recommendation for biopsy or surgical consultation on the basis of a positive examination (LungRADS® Category 4B or 4X)
   - FP_3: Benign tissue diagnosis within 1 year after recommendation for biopsy on the basis of a positive examination (LungRADS® Category 4B or 4X).

5. **Lung cancer screening CT exam:** is one performed on an asymptomatic individual to detect early, clinically unsuspected lung cancer.

6. **Lung RADS category:** This 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
   - 0: recalls (incomplete screen)
   - 1: normal, continue annual screening
   - 2: benign appearance or behavior, continue annual screening
   - 3: 6 month CT recommended
   - 4A: 3 month CT recommended; may consider PET/CT
   - 4B: Additional diagnostics and/or tissue sampling recommended
   - 4X: Additional diagnostics and/or tissue sampling recommended

   *It is our recommendation that the CT report contain the Lung-RADS category. If the category is not specifically stated in the report, then assign a category to the LCSR registry case record (this is sufficient documentation from the registry perspective)

http://www.acr.org/~/media/acr/documents/pdf/qualitysafety/resources/lungrads/assessmentcategories.pdf

Lung-RADS™ Version 1.0 Assessment Categories Release date: April 28, 2014

Category	Category Descriptor	Category	Findings	Management	Probability of Malignancy	Estimated Population Prevalence
Incomplete	-	0	prior chest CT examination(s) being located for comparison part or all of lungs cannot be evaluated	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed	n/a	1%
Negative	No nodules and 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	< 1%	90%
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			
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	1-2%	5%
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	5-15%	2%
		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.	> 15%	2%
		4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			
Other	Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)	S	modifier - may add on to category 0-4 coding	As appropriate to the specific finding	n/a	10%
Prior Lung Cancer	Modifier for patients with a prior diagnosis of lung cancer who return to screening	C	modifier - may add on to category 0-4 coding	-	-	-

7. **Negative lung cancer screening CT exam** is one that is negative or has benign findings (Lung-RADS® Categories 1 and 2).

8. **Per 1,000 exams:** Measures defined *per 1,000 exams* are calculated as below: If there are 12 screening exams with a Lung-RADS category of 3 or 4 that had a tissue diagnosis of cancer within 365 days of screening (numerator) exam out of 2500 screening exams (denominator), the CDR per 1000 exams =12/2500*1000= 4.8

9. **Positive Predictive Value (PPV):** This includes the following three definitions:
    a. PPV_1 (abnormal findings at screening): The percentage of all positive screening exams (LungRADS® Categories 3 and 4) that result in a tissue diagnosis of cancer within 1 year.

An initial screening assessment of Category 3 or 4 is expected to occur approximately 10% of the time, and is more likely to occur on a baseline lung cancer screening CT exam for which the stability of baseline findings has not yet been established.

PPV1 = TP / (number of positive screening exams)

OR

PPV1 = TP / (TP + FP1)

- PPV_2 (additional CT imaging recommended): The percentage of all lung cancer screening CT examinations recommended for 6 month LDCT, or 3 month LDCT with or without PET/CT, (LungRADS® Categories 3 and 4A) that resulted in a tissue diagnosis of cancer within one year.

  PPV2 = TP / (number of screening examinations recommended for additional CT imaging)

  OR

  PPV2 = TP/(TP + FP2)

- PPV_3: The percentage of all known biopsies done as a result of positive screening with or without subsequent PET/CT or diagnostic chest CT examinations (LungRADS® Categories 4B and 4X) that resulted in a tissue diagnosis of cancer within 1 year. PPV3 is also known as the Biopsy Yield of Malignancy or the Positive Biopsy Rate (PBR).

  PPV3 = TP / (number of biopsies)

  OR

  PPV3 = TP /(TP + FP3)

10. **Positive screening exam** is
    - one that requires a 6 month interval low dose chest CT (Lung-RADS® Category 3),
    - one that requires a 3 month interval low dose chest CT (Lung-RADS® Category 4A), or
    - one that requires chest CT with or without intravenous contrast, PET/CT and/or tissue sampling (Lung-RADS® Category 4B)

11. **Tissue diagnosis**: A pathologic diagnosis rendered after any type of interventional procedure, such as CT or fluoroscopy guided biopsy, bronchoscope biopsy, lobar Broncho alveolar lavage or excisional biopsy (VATS or open resection)

12. **True Positive (TP):** Tissue diagnosis of cancer within 1 year after a positive exam (Lung-RADS® Category 3 or 4).