

Question by Question (QXQ) Instructions for the Pulmonary Diagnosis Form (PLD)

A Pulmonary Diagnosis Form is filled out by the reviewer for all medical records that are sent to them for review by the CSCC. Initially, events will be classified by 2 independent reviewers and disagreements will be classified by an adjudicator. Along with each medical record will be an Event Summary Form (ESF). The ESF is a 1 page summary of information abstracted from the medical records. It also contains selected information from the participants' study visit.

The first section of the form is called administrative information (0A-0D). When in electronic form, parts of this will be filled out by the CSCC. For training, please fill this out.

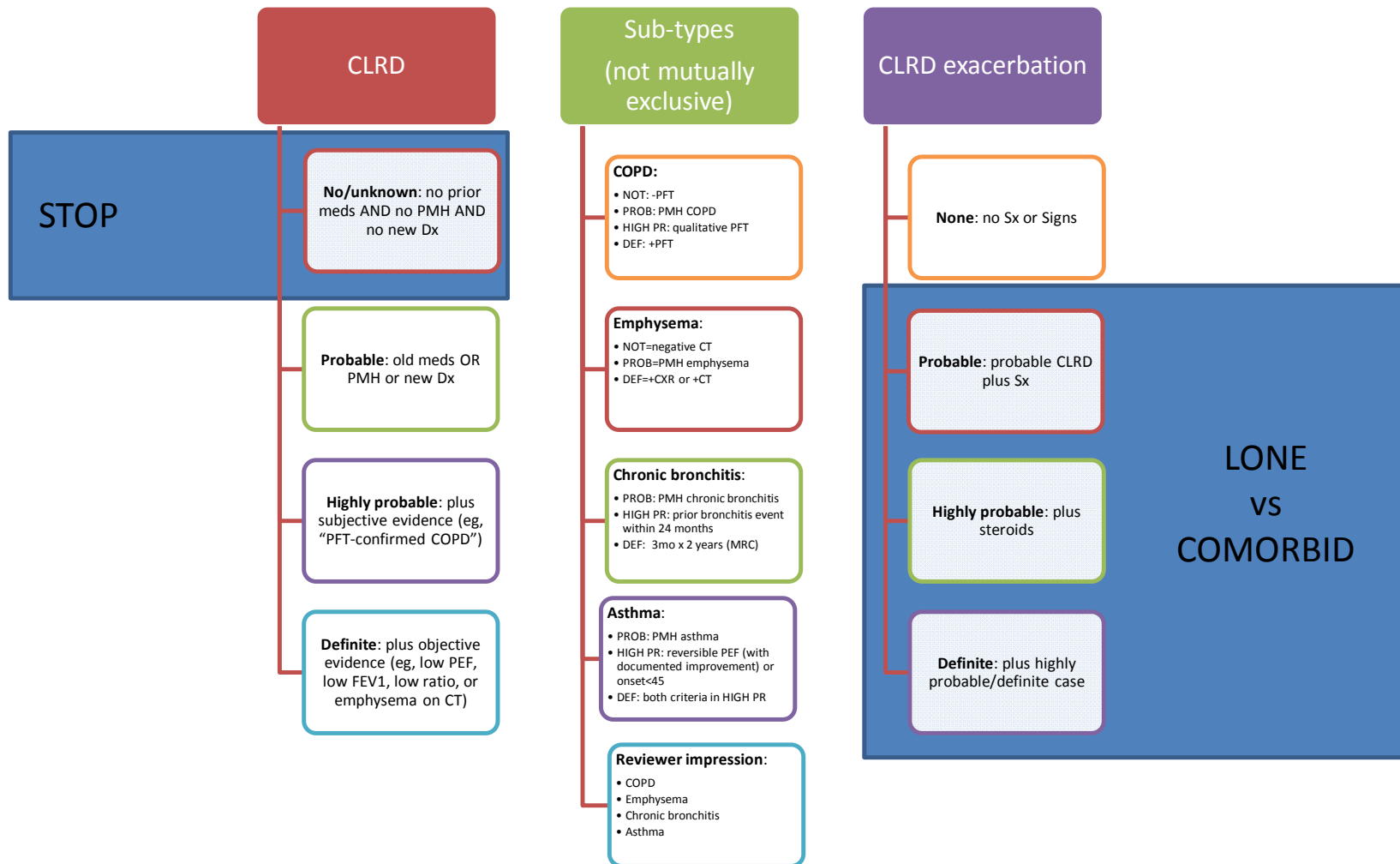
A0. Enter date that you (the reviewer) completed the form.

B0. Enter your staff or reviewer ID number. It is 3 digits.

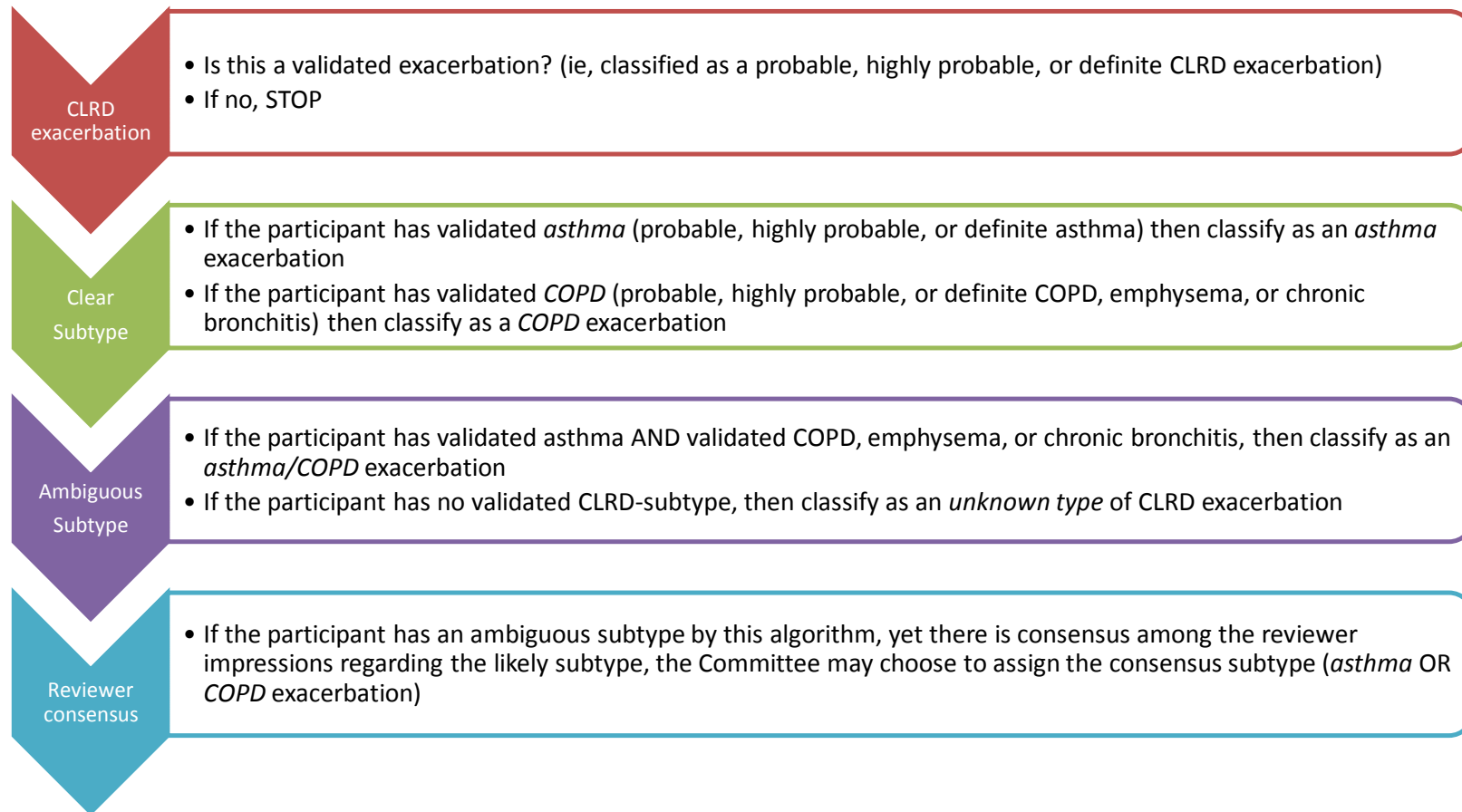
C0. Event ID. This number is assigned by the CSCC. It will start with a letter representing the HCHS/SOL field center site. It is stamped on the top of the medical record.

D0. Event Date. Enter the date of arrival or the earliest date on the medical record.

CLRD Decision Flowchart



Subtyping CLRD exacerbations



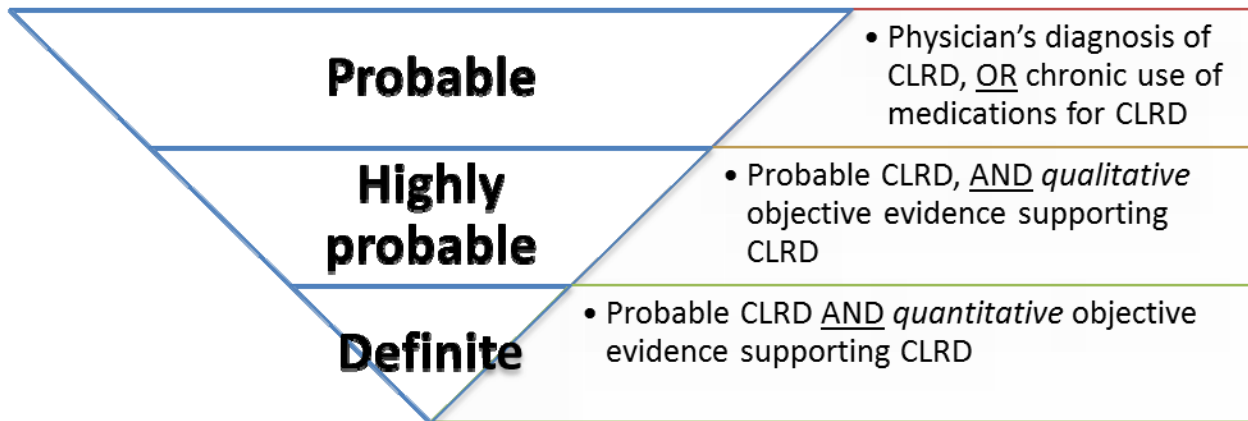
QUESTION 1: Defining cases of chronic lower respiratory disease (CLRD).

1. Does this patient meet SOL criteria for CLRD?

This question refers to whether this patient has a past medical history of CLRD OR a new diagnosis of CLRD. CLRD includes COPD, emphysema, chronic bronchitis, and asthma.

- Answer NO/UNKNOWN if the patient does not report a past medical history of CLRD, AND CLRD was not newly diagnosed during the admission, AND the patient was not chronically using CLRD medications prior to the admission.
 - If you answer NO/UNKNOWN to question 1, you should STOP. None of the subsequent questions are relevant. You may enter comments at Question 5.
- Definite, highly probable, and probable CLRD represent 3 levels of certainty for YES. SOL criteria for definite, highly probable, and probable are shown below.

HCHS/SOL criteria for CHRONIC LOWER RESPIRATORY DISEASE (CLRD)



Criteria for PROBABLE CLRD

- At least ONE of the following:
 - Physician's diagnosis, either *prior to* (i.e., "Past Medical History") OR *during* the admission, defined as:
 - COPD
 - Chronic bronchitis
 - Emphysema, OR
 - Asthma
 - Chronic use of medications for CLRD (prior to admission), defined as:
 - Tiotropium (Spiriva)
 - Atrovent or Combivent
 - Inhaled corticosteroids
 - Long-acting beta agonists (LABA)

- Combination steroid/LABA inhalers (e.g., Advair)
- Theophylline
- Roflumilast
- AND absence of a diagnosis of diffuse parenchymal lung disease

Criteria for HIGHLY PROBABLE CLRD

- Probable CLRD, AND
- Intermediate objective evidence of airway obstruction or emphysema, as evidenced by at least one of the following:
 - Physician's qualitative report of PFT results consistent with an obstructive ventilatory defect such as asthma or COPD, without quantitative report of FEV₁/FVC values
 - Physician's qualitative report of PEF results consistent with asthma or COPD, without quantitative report of PEF values
 - Evidence of respiratory acidosis or CO₂ retention, not likely to be secondary to obesity hypoventilation syndrome (OHS) as evidenced by BOTH of the following:
 - On any arterial blood gas, pCO₂>50 with pH>7.4
 - No past medical history of obstructive sleep apnea or obesity hypoventilation syndrome

Criteria for DEFINITE CLRD

- Probable CLRD, AND
- Definitive objective evidence of airway obstruction or emphysema, as evidenced by at least one of the following:
 - Low PEF
 - Low FEV₁/FVC
 - Flattened diaphragms, hyperinflation, or emphysema seen on chest X-ray
 - Emphysema seen on CT scan

NOTE: The peak expiratory flow (PEF) and pulmonary function tests (PFTs) referred to here are those in the medical record and not from the HCHS/SOL study visit. PFTs from the study visit will not be used to classify events. *See PFT criteria page for definitions of obstruction.

2a-2d. If YES (definite, highly probable, or probable), which sub-type(s) of CLRD does this patient have?

NOTE: the sub-types of CLRD are NOT mutually exclusive. Please check off one box per sub-type as noted below.

2a. Asthma.

- PROBABLE: Answer PROBABLE if there is a past medical history of asthma, or if a physician writes that the patient has asthma.
- HIGHLY PROBABLE: Answer HIGHLY PROBABLE if there is evidence for low PEF that reverses (with documented improvement in PEF or clinical status after treatment), OR if physicians write that the onset of asthma was prior to 45 years of age.
- DEFINITE: Answer DEFINITE if patient with a history of asthma has a low peak flow with improvement with bronchodilators AND the onset of asthma is documented as less than 45 years of age.
- PROBABLY NOT/NO:
- UNKNOWN: answer UNKNOWN if there is no evidence or conflicting evidence regarding whether the patient has asthma.

2b. COPD.

- PROBABLE: Answer PROBABLE if there is a past medical history of COPD, or if a physician writes that the patient has COPD.
- HIGHLY PROBABLE: Answer HIGHLY PROBABLE if there is qualitative evidence in the medical record for prior PFTs consistent with COPD (e.g., “the patient has PFT-confirmed COPD”), without the quantitative PFT report.
- DEFINITE: Answer DEFINITE if quantitative PFT results are consistent with COPD.
- PROBABLY NOT/NO: Answer NO if PFTs (either quantitative or qualitative report) are not consistent with COPD.
- UNKNOWN: if there is no information regarding COPD, or if there is conflicting information as to whether the patient has COPD or not, then answer UNKNOWN.

2c. Emphysema.

- PROBABLE: Answer PROBABLE if there is a past medical history of emphysema, or if a physician writes that the patient has emphysema.
- DEFINITE: Answer DEFINITE if there is evidence of emphysema from a CT scan. You should also answer DEFINITE if the chest X-ray is consistent with emphysema (i.e., if it shows hyperinflation, emphysematous parenchymal changes, or flattened diaphragms).

- PROBABLY NOT/NO: Answer NO if there is a normal CHEST CT in which the lung parenchyma is reported as normal.
- UNKNOWN: If there is no information or conflicting information as to whether the patient has emphysema or not, then answer UNKNOWN.

2d. Chronic Bronchitis.

- PROBABLE: Answer PROBABLE if there is a past medical history of chronic bronchitis, or if a physician writes that the patient has chronic bronchitis.
- HIGHLY PROBABLE: Answer HIGHLY PROBABLE if the patient meets criteria for PROBABLE, and the medical record also indicates a prior bronchitis-related event (hospitalization, ED visit, or urgent office visit) within the past 24 months.
- DEFINITE: Definite chronic bronchitis is only a clinical definition. Answer DEFINITE if cough for at least 3 months of the year for at least two years in a row is reported.
- PROBABLY NOT/NO:
- UNKNOWN: Answer UNKNOWN if there is no evidence or conflicting evidence regarding chronic bronchitis.

QUESTION 3. In your opinion, which CLRD subtype do you think is predominant?

Here, please use your clinical judgment to choose whether you think that the predominant underlying disease is COPD, emphysema, chronic bronchitis, OR asthma. These categories are mutually exclusive, so you may check ONLY one box.

Please note that your answer to this question may be used to classify the sub-type of CLRD exacerbation (if present) as an asthma exacerbation or a COPD exacerbation (inclusive of COPD, emphysema, and chronic bronchitis). This may occur if there is no validated sub-type of CLRD, which would otherwise be used to assign the exacerbation sub-type. Please refer to the schematic for sub-typing CLRD exacerbations for clarification.

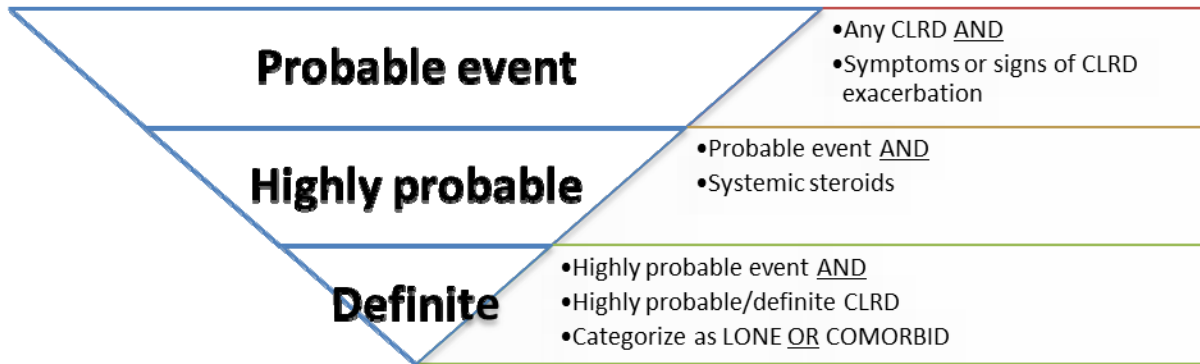
QUESTION 4. Is there evidence of other lung disease?

- Answer NO, if there is not a history of other lung disease or if it is unknown if there is a history of other lung disease. Do not include pneumonia as other lung disease. If NO, then skip to question 3.
- Answer YES, if there is a history of a lung disease other than those reported above.

4a. IF yes, specify lung disease. Fill in the blank with the name of the other lung disease. Lung diseases of interest may include but are not limited to pulmonary sarcoidosis, Wegener's, interstitial lung disease, pulmonary fibrosis, pulmonary hypertension, pulmonary embolus, bronchiectasis, pneumoconiosis, and pneumonitis.

QUESTION 5. Does this patient have an exacerbation of chronic lower respiratory disease (CLRD)?

- Answer NO/UNKNOWN if the patient does not demonstrate signs OR symptoms of CLRD, or if these are not documented. You should then STOP. You may enter comments at Question 5.
- Definite, highly probable, and probable CLRD represent 3 levels of certainty for YES. SOL criteria for definite, highly probable, and probable are shown below.



Criteria for PROBABLE CLRD exacerbation:

- Probable, highly probable, or definite CLRD, AND
- Signs OR symptoms of CLRD exacerbation:
 - New onset or worsening symptoms of CLRD exacerbation, defined as:
 - Dyspnea
 - Cough
 - Sputum production
 - Wheeze
 - Physical signs of CLRD exacerbation, defined as:
 - Use of accessory muscles
 - Respiratory distress
 - Wheezing
 - Prolonged expiratory time

Criteria for HIGHLY PROBABLE CLRD exacerbation:

- Probable CLRD exacerbation, AND
- Receipt of systemic corticosteroids (PO/IV) during admission

Criteria for DEFINITE CLRD exacerbation:

- Highly probable CLRD exacerbation

- Highly probable or definite CLRD

5.a. If YES to #5 (definite, highly probable, or probable CLRD exacerbation), then was there evidence for an alternate explanation for the event?

If there is objective evidence to suggest that the CLRD exacerbation may have been comorbid with another disease entity, such as acute decompensated heart failure or pneumonia and other conditions listed in question #4b, then indicate that this was a COMORBID CLRD exacerbation. If there was no objective evidence for any diagnosis besides CLRD, classify the event as a LONE CLRD exacerbation and SKIP to question 5 (COMMENTS).

5.b. If YES TO #5a (comorbid CLRD exacerbation), then indicate evidence for any of the following:

- 5.b.1. Pneumonia
 - Answer YES if Pneumonia on chest X-ray and/or chest CT
- 5.b.2. Pulmonary Embolus
 - Answer YES if Pulmonary embolus on CT and/or positive VQ scan
- 5.b.3. Pneumothorax
 - Answer YES if Pneumothorax on X-ray and/or chest CT
- 5.b.4. Acute myocardial infarction. Answer YES if all of the following are present:
 - Troponin/CK-MB greater than the upper limit of normal
 - Acute ECG changes (ST segment elevation/depression, new Q waves)
- 5.b.5. Acute Decompensated Heart Failure. Answer YES if there is the presence of all of the following:
 - Pulmonary vascular congestion on chest X-ray and/or CT
 - BNP or ProBNP greater than the upper limit of normal with Creatinine less than upper limit of normal
- 5.b.6. Other. If you believe that there was a comorbid diagnosis not included on the above list, indicate OTHER and describe it in the next question
 - 5b6a. IF YES to Other (c6), then what condition is comorbid? Fill in text box with comorbid condition.
 - If YES to 5.b.5. for Acute Decompensated Heart Failure, please use your clinical judgment to indicate the predominant type of heart failure:
 - 4b4a: Left-sided heart failure
 - 4b4b: Right-sided heart failure
 - 4b4d: Unclear if left, right, or biventricular heart failure

6. Comments. Write in any comments that you feel are pertinent to the classification of the event.

Criteria for Low Peak expiratory flow (PEF) and low FEV₁/FVC ratio

“Low PEF” is defined as PEF < 70% predicted. PEF predicted values will be based upon HCHS/SOL predicted values (currently pending) using age at time of clinical PEF measurement, gender, and measured height at HCHS/SOL exam. These 3 variables are included in the event summary form available with all medical records sent to reviewers.

Low PEF “w/ improvement” is defined as an increase in PEF of $\geq 30\%$ or, in absence of repeat PEF, clear improvement in clinical status.

“Low FEV₁/FVC ratio” is defined as pre-bronchodilator FEV₁/FVC < LLN (lower limit of normal). The LLN for FEV₁/FVC is based upon HCHS/SOL reference equations, determined on each individual patient, (currently pending) using age at time of clinical PFT measurement, gender, and measured height at HCHS/SOL exam.

“COPD” from PFT results are based ideally on post-bronchodilator PFTs; however, if not available then pre-bronchodilator PFTs are used.

The definition for COPD from post-bronchodilator PFTs is: 1) FEV₁/FVC ratio <0.70 or <LLN.

In absence of post-bronchodilator measures, the definition of COPD from pre-bronchodilator PFTs is: 1) FEV₁/FVC ratio <0.70 or <LLN AND 2) FEV₁ percent predicted <65%.

Interpretation for Pulmonary Function Tests and Peak Expiratory Flow (PEF) from Medical Records

- “Low PEF”
 - PEF < 70% predicted*
- Low PEF “w/ improvement”
 - Increase in PEF of $\geq 30\%$ or, in absence of repeat PEF, clear improvement in clinical status
- “Low FEV₁/FVC ratio”
 - Pre-bronchodilator FEV₁/FVC < LLN[†]
- “COPD”
 - Post-bronchodilator FEV₁/FVC ratio <0.70 or <LLN[†] AND FEV₁% predicted <80%[†]
 - In absence of post-bronchodilator measures, FEV₁/FVC ratio <0.70 or <LLN[†] AND FEV₁% predicted <65%[†]