Standard Operating Procedure:	Lung Function Reporting
Target Audience:	Respiratory Physiologists/Clinical Scientists/Doctors working within a Respiratory/Sleep Laboratory
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IQIPS Domain(s):	**Clinical domain (CL3): The service implements and monitors systems to assure the clinical and technical quality of the interpretation of diagnostic results and their reporting and communication in a timely manner.** C1 – There are defined roles and responsibilities for interpreting and reporting test results. C2 – There are systems in place to develop and agree the structure and content of diagnostic reports to meet local needs. C3 – There are systems in place to ensure that all appropriate staff are aware of the agreed formats for reporting/communication of results. C4 – There are systems in place to assure quality and accuracy of the interpretation and reporting of test results. C5 - There are systems in place to ensure communication of diagnostic reports to referrers and multidisciplinary team meetings within specified timescales. C6 – There are systems in place to manage alterations and amendments to diagnostic reports.

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1. Introduction

The author recognises and accepts that reporting methods and report structure will vary between individuals and services. The following document has been developed for guidance and support purposes only. The aim is to standardise the approach towards reporting lung function data for all healthcare professionals.

Suggested definition of a lung function report:

"*A specific, formal document to the referrer regarding the results of the lung function test. The main goal of the report is to provide a clear, concise, accurate, fully interpretative, and authoritative answer to the clinical question posed on the referral document*."

A lung function report and the associated interpretation ultimately starts with a review of test quality. Tests that are sub-optimal may contain information that is usable, but the technical error and their magnitude must be considered thoroughly by the reporter. Failing to review test quality and relying solely on numerical results for clinical interpretation is not recommended. This can be exacerbated further by those who rely on computer-generated reporting/interpretation.

Once the quality has been considered, the next phase is to compare the measured values with the reference values, followed by answering the clinical question initially posed by the referrer. Incorrect choices made during these steps increase the probability of inaccurate diagnosis and/ or misclassification of disease severity.

Lung function tests should never be used in isolation as a diagnostic tool. They should be reviewed in conjunction with the larger clinical picture (medical history, imaging, blood tests, etc.). Suggesting a specific diagnosis based solely on lung function abnormalities is not recommended, as the pattern seen in lung function may be seen in numerous diseases. Lung function test results highlight a possible site of abnormality (for example, the airway, chest wall, and alveoli) as well as identify the presence or absence of abnormality (i.e., obstructive, restrictive, or a mixed pattern). If an abnormality is identified, the test can be used to quantify the extent or severity of the disease (i.e., mild, moderate, severe, or very severe).

To report lung function tests, there must be an excellent understanding of respiratory physiology as well as the pathophysiology of the major respiratory and non-respiratory diseases. It is important to understand the effects on lung function of the major obstructive and restrictive lung diseases (for example, COPD, Interstitial Lung Disease, Asthma) and also non-respiratory disorders (such as rheumatoid arthritis and neuromuscular diseases). Lung function testing is also used in pre-operative assessment, so understanding the parameters that anesthetic and surgical teams look at is also useful to enable effective reporting of pre-operative lung function tests.

This standard operating procedure has been developed to help standardise the report writing process for those who have achieved relevant competencies for reporting Lung Function tests. The document should act as a supporting tool to ensure services maintain high standards of quality and accuracy when writing reports.
The document has been referenced against domains found within the IQIPS standards and criteria (see front page); this should enable physiology services to signpost this standard operating protocol as evidence required for IQIPS accreditation.

2. Scope and aims

Lung Function reports may commonly incorporate results from sleep and ventilation diagnostics, exercise physiology, and oxygen assessments. This procedure is aimed at writing a lung function report, which typically includes spirometry, gas transfer Factors, lung volumes, and reversibility testing. The principles laid out within this document can be transferable to most forms of Respiratory Physiological reporting and is applicable to both adult and paediatric services.

3. Lung Function Reporting

The report that accompanies the lung function report needs to be concise, informative, and address the clinical question. Look at the spirometry result below.

Spirometry	Predicted	Baseline	LLN	z-score	Post BD	% change
FEV_1	2.48	2.67	2.28	-0.51	2.94	+10%
FVC	3.34	3.45	2.67	+0.29	3.57	3%
FEV_1/FVC %	86	77	74	-1.20	82	

In theory, the report could have been written in any of the following ways:

- NAD (no abnormality detected).
- Normal spirometry performed.
- Spirometry is within normal limits.
- Test was performed to quality assured standards and is within normal limits.
- Test was performed to quality assured standards and is within normal limits; there is no significant response to bronchodilator.
- Test was performed to quality assured standards and is within normal limits. The flow volume loop appears normal. There is no significant response to bronchodilator. Asthma appears to be well controlled; however, spirometry cannot be used to confirm or exclude asthma. Consider FeNO testing and serial home PEF monitoring. Please consider result in light of clinical correlation.

Although you could argue that each of the reports above are correct, each example provides more relevant information that enables the referring clinician to make more of an informed decision regarding clinical care or next steps/further testing.

Use the following simple steps when reporting Lung Function tests:

- Review the referral.
- Consider the patient and the medical history provided.
- Review the lung function report; question acceptability and quality of the data if appropriate (see appendix 5.2 for acceptability and reproducibility criteria); review any graphical and tabulated data; consider and review any additional comments made during the test by the physiologist; look at any serial results – is there a significant change in lung function over time?
- Formulate your conclusions/impressions.
- Write your report.

When assessing the acceptability and quality of the data, consider the following:

1. Have the correct patient demographics and anthropometric data been entered?
2. Review technical or additional comments made by those performing the test; these may highlight issues relating to test data, patient effort, reproducibility, and acceptability. Have appropriate reference values been applied?
3. Did the patient adhere to the pre-test instructions? For example, did they refrain from prior use of inhalers? Could there be any residual effect from bronchodilators that dampen the response during any reversibility testing? When did the patient last smoke a cigarette? Was it within an hour of testing?
4. Review all graphs and flow volume loops.
    a. During spirometry, does the Flow Volume Loop (FVL) show a sharp rise to Peak Expiratory Flow (PEF)? Is there any early termination of the blow? Was a volume plateau achieved?
    b. Is there evidence of a slow start or poor effort with any forced spirometric blows? Was there any coughing during the test?
    c. Do the Forced Vital Capacity (FVC) and Slow Vital Capacity (SVC) agree? Is there any suggestion of dynamic compression of the airways or gas trapping (suggested by a “church steeple” shape/silhouette to the Flow Volume Loop)?
5. Was the transfer factor test performed to acceptable standards?
    a. Did the patient achieve 90% of their Inspiratory Volume (V_{in})?
    b. Was a correction made for haemoglobin (H_b) if appropriate?
    c. In normal and restrictive patients, the alveolar volume (V_A) should closely approximate the Total Lung Capacity (TLC). A V_A/TLC % <80% may indicate poor gas mixing.
    d. Is there any comment regarding smoking just prior to the measurement possibly reducing the gas transfer (TL_{co}) result?
    e. Was breath-holding time adequate? Was any leak noted during breath holding?
6. Review the raw data from static lung volume measurements.
    a. Body plethysmography
        i. Is there evidence of any thermal drift or leak (gradual and steady shift upwards in the tidal volume tracing)?
        ii. Does the tidal volume tracing remain level throughout?
        iii. Do the Thoracic Gas Volume (TGV) efforts made against the closed shutter indicate any technical errors such as mouth leak and thermal drift (bending of loops), incorrect panting frequency or panting too rapidly or deeply (open loops or no loops, no clear line of best fit), failure to inspire or expire against closed shutter?
    b. In gas dilution methods:
        i. Was there any drift that might indicate a leak?
        ii. Was an equilibrium point achieved?
        iii. Was the patient "switched in" correctly at Functional Residual Capacity (FRC) or at the end of a normal tidal breath?

When reporting, you must be able to justify your decisions and relate them to the physiology/pathophysiology. Know the guidelines[1] used but also recognise their limitations. Training to interpret lung function tests using z-scores/standardised residuals (SR) and lower limits of normal (LLN) is recommended and preferable as this is generally considered to be statistically superior to using %predicted and a fixed FEV_1/FVC ratio of <0.7 (70%) to identify airflow obstruction. Unfortunately, guidelines such as NICE COPD (2010) use %predicted FEV_1 to grade the

severity of airflow obstruction. We know from published data that % predicted can lead to an over-estimation of obstructive airway disease in the elderly population as well as under-estimate in younger adults. It is good practice to state which guidelines you have used to interpret the results. Appendix 5.3 shows the severity classification using z-scores.

Reviewing serial lung function data in patients with conditions such as interstitial lung disease (ILD) and chronic obstructive pulmonary disease (COPD) is important. Monitoring the decline in FEV_1 over time can be used as a prognostic tool in COPD and Cystic Fibrosis. Published studies suggest that a change in transfer factor (TL_{co}) >±1.60mmol/min/kPa over the short term and >10% in the longer term (over a year) probably reflect clinically significant changes.

It is important that the referral question is addressed and that any incidental findings are highlighted. Using the clinical information provided gives some context to the interpretation or recommends further investigations to assist with answering the clinical question. This last step can be difficult when the reporter is not the referrer due to the limited clinical information. Typically, the referrer is the best individual to form the clinical context based on the technical interpretation of the available data. Any additional findings should be reported back to the referrer. Ideally, the report should be in a standardised format which is used by all team members. A consistent format helps avoid omitting information and may speed up the reporting process. It is important to write the report clearly and confidently.

The structure and content of reports should be agreed locally in consultation with referrers and where applicable and should follow relevant national professional and regulatory guidance. All reporting staff, including those external to the service (if applicable) should be aware of the local agreement and be able to access it.

The local agreement should address who will report different types of diagnostic tests which also includes signing off training and competencies but also reporting timescales. A list of authorised reporters should be maintained. If certain reports/diagnostics cannot be reported within the service a procedure must be in place for transferring responsibility.

Results and reports should undergo regular audits by a supervising peer or quality reviewer to ensure that quality is maintained. A formal system of results review should be in place. Findings must be shared with all appropriate staff, and changes must be made to protocols if indicated. The supervising peer or quality reviewer should be an expert in pulmonary function testing and have extensive experience, both in direct testing and in monitoring testing performed by others. If more than one reviewer is used, comparisons across reviewers should be made to ensure consistency, for example, with blinded samples of good and bad test reports and testing sessions.

Suggested report headings might include:

- Clinical indication to test: what is the clinical question?
- Technical comments – Technical comments made by the individual who performed the test which might provide insight into the test performance.
- Results of the assessment/test – include text here that states the actual data when compared to the upper and lower limits of normal (ULN or LLN) or a reference value and predicted mean.
- Impression – An interpretation of the results in relation to the patient history and test data, here you might also suggest further testing when appropriate; use your knowledge and expertise of both physiology and

the available test procedures to recommend further testing; a summary of the results may be offered which may highlight the consistencies with a known pathophysiology.

- Closing statement – End your report with a closing statement that asks that the results are considered in light of the available clinical history and diagnostic test results. You may wish to use "Please interpret findings in light of clinical correlation" as a signing-off statement to highlight that the report should be considered alongside the patient's symptoms and other clinical information.
- Reporter details – include name, position, PIN/registration numbers, the date and a signature (if appropriate –? e-reporting/e-signatures).

Generally, a Lung Function report needs to address three important aspects that in one way or another, will impact the validity and quality of the measurements recorded and consequently affect the accuracy of the written report:

1. **Technical Comments (Technical Reporting)**
    a. Note the key aspects of the recent patient's medical history (e.g., surgery, chest infection, corticosteroid trial).
    b. Degree of cooperation and adequacy of technique.
    c. If acceptability and/or repeatability criteria were met or not met.
    d. Bronchodilator drug was used, as well as the method of delivery and dose administered.
    e. If haemoglobin/altitude correction was applied to transfer factor results or not (specify H_b value in g/L), also any CO correction if applied.

Technical reporting can generally be undertaken without a medical history or knowledge of the patient. It primarily describes test quality and any additional comments made by the operator.

2. **Pattern Recognition (Interpretative Reporting)**
    a. Comment on Spirometry with reference to shape of Flow-Volume loop; any dynamic airway compression, evidence of upper airway obstruction?
    b. Obstructive, restrictive, or a mixed pattern? Grade severity using z-scores (see appendix 5.3).
    c. If reversibility is performed, comment on the degree of reversibility.
    d. Comment on Lung Volumes, consider V_A/TLC%
    e. Comment on the Gas Transfer factor with reference to the V_A and K_{CO} relationship, if appropriate

3. **Clinical Correlation (Clinical Reporting)**
    a. Establish the reason for the referral or the referrer's concerns.
    b. Correlate test data with clinical history and other relevant investigations (e.g., imaging, blood tests, etc.).
    c. Provide a clear recommendation, if appropriate.
    d. Write a concluding statement, if there is a strong suspicion of a specific diagnosis. Suggest further tests that may aid the clinician/referrer.

Clinical reporting includes the above but is primarily an answer to the clinical question posed and is therefore reliant upon additional clinical information being available. It is best provided by the referring clinician, assuming they are proficient in lung function reporting. The clinical report will also provide advice and suggestions for further testing to aid diagnosis.

There are no agreed recommendations on the level of experience required to perform each of the different levels of reporting. In clinical practice, however, this would normally be performed by:

1. **Technical Reporting**
    a. All staff levels if deemed competent.
    b. It is a requirement to have achieved competency in a specific testing modality (e.g., Spirometry).
    c. Written by the healthcare professional who performed the test.
2. **Interpretative Reporting**
    a. Experienced Physiologists/Clinical Scientists, band 6 or above.
    b. It is a requirement to have attended relevant training and to demonstrate competency.
    c. Written by senior/registered member of clinical team.
3. **Clinical Reporting**
    a. Specialist/Highly experienced Physiologists/Scientists, band 7 or above.
    b. It is a requirement to demonstrate competency and hold professional indemnity insurance (if applicable).
    c. Written by Clinical Scientists, clinical fellows, specialist Registrars (SpR), and Medical Consultants.

The information above is not “set in stone”. Practice varies, so departments may have different arrangements for Lung Function reporting. What has to be clear is that all clinical reports carry liability; medico-legal implications may arise if the report is not accurate and/or fails to raise concerns identified within the recorded test data.

The Lung Function report should include within the demographics section, at the start of the report, a clear clinical question and the presenting symptoms. It is important that the referral question is addressed as well as any additional or incidental findings. Any additional findings should be highlighted back to the referrer. The report should be in a standardised format which is used by all team members. A consistent format helps avoid omitting information and may speed up the reporting process.

A good structure is essential for a good report. Use good paragraph and sentence structure and consider utilising report headings. It is important to write the report clearly and confidently.

When writing the report, consider the use of qualifiers. Qualifiers include the following:

- “Appears to be”
- "Maybe consistent with"
- “Suggestive of”

There are no universally accepted standards for report writing on lung function tests. It is important to keep it concise and simple; consider your target audience. The report should be clear and informative. A mere statement of which values are normal or low may not be helpful. When results are within normal limits, then they should be reported as being "*within normal limits for the patient*" and not simply normal. This is important as there is still a possibility that lung disease is present, which has yet to cause results to fall outside of the normal range. When a result is described as reduced, then it is below the Lower Limit of Normal (LLN); if described as elevated, then this is above the Upper Limit of Normal (ULN). Lung function measurements can also be described as "*borderline*”; these results will require careful consideration. Consider the use of stock phrases (see Table 1 below for examples) and try to refrain from over-interpreting the data as long reports can become confusing for the recipient. Keep it simple.

Interpretation of lung function has an element of subjectivity associated with it. This may impact on the management and care of the patient; the difficulty is therefore to keep subjectivity to a minimum. Subjectivity arises due to personal opinions, diversity in the literature regarding interpretation strategies, lack of data in interpreting certain tests or parameters and finally the knowledge of the clinical background of the patient.

To reduce subjective reporting, adhere to published interpretation strategies[1], agree locally what strategy is to be employed. All personnel locally should use a standardised reporting strategy which is peer-reviewed/audited regularly.

3.1. Clinical History

The principles of clinical decision-making should be applied to the interpretation, where the post-test likelihood of disease is estimated after considering the pre-test probability. This is quite often not possible because many or most tests are interpreted in the absence of any detailed clinical information. To improve this, it may be useful to ask the patient before and during testing why they have been referred, recording their symptoms and clinical history. It has been highlighted in a previous survey[2] that the clinical information disclosed in test referrals is often limited and, therefore, inadequate to allow for correlation with the test data to support a diagnosis. It is recommended practice, when the latter is true, for the healthcare professional conducting the test to take a brief history directly with the patient and/or by reviewing medical notes/clinical letters. This evaluation should address specific questions such as:

- **What is the presenting problem/complaint?**
    - Main symptoms reported by the patient (e.g., cough, dyspnoea, wheeze).
    - Characterise symptom(s) based on the onset, duration, severity, precipitating and relieving factors, associated features, and previous episodes.
    - Shortness of breath (on exertion, orthopnoea, at rest)
    - Cough (character – dry or productive), acute or chronic cough.
    - Sputum colour (consistency and amount)
    - Haemoptysis?
    - Chest pain (site, does it radiate, describe pain)
    - Systemic symptoms – night sweats, weight loss

- **Are you known to suffer from any other health-related conditions?**
    - This question should provide an overview of past medical and surgical history.
    - Specific follow-up questions, depending on the information disclosed, may be appropriate.

- **Family medical history?**
    - Details about the health of parents, siblings, and children
    - Any known heart or lung disease?

- **Past and current personal and social circumstances:**
    - Occupation and whether or not there may have been exposure to harmful agents.
    - Lifestyle and smoking history (should be quantified in pack-years); when did they last have a cigarette or smoke?
    - Any pets?
    - Recreational drug use (inhaled) – cannabis, heroin, etc.
    - Recent or past travel overseas.

- **Are you currently taking any medication?**
    - This includes current medication/dose and medication(s) that have been recently stopped.
    - Establish if there are any known respiratory side effects to the current medication.

See Appendix 5.1 for a sample template that can be used/adapted to obtain a brief patient clinical history to assist with result interpretation.

In a busy laboratory, it may not be feasible to record the information above due to time constraints. If this is the case it should still be highlighted in the test report that correlation between the test data and the patient's clinical history is essential. Efforts to ensure healthcare professionals are given adequate time to interact with patients must be considered a priority by service managers/clinical leads.

3.2. Sources of bias and confounding factors

An extensive description of factors to be considered before and during testing is well-described elsewhere[3]. Healthcare professionals who are responsible for reporting must be familiar with these factors to ensure the inferences from the data reflect only the patient's clinical status. This concept is particularly important when monitoring disease progression in patients with known chronic lung conditions. Examples include:

- Prior use of bronchodilators.
- A recent chest infection and if prescribed antibiotics.
- Routine medication.
- Time of the last cigarette.
- Facial paralysis/Bell's palsy (mouthpiece issues).
- Height estimated from arm span.
- Factors affecting accurate SpO_2 signals.

3.3. Technical reporting

A technical report provides a clear and succinct evaluation of the quality of the data, as well as factors that may affect the validity of test results (e.g., pre-test considerations, pain, discomfort, recurrent cough, recent drug intake, smoking, chest infection). Deviations from established practice should also be documented. In addition to this, there are test-specific quality criteria that need to be adhered to [4,5,6,7,8,9,11,12,13,14] (see appendix 5.2).

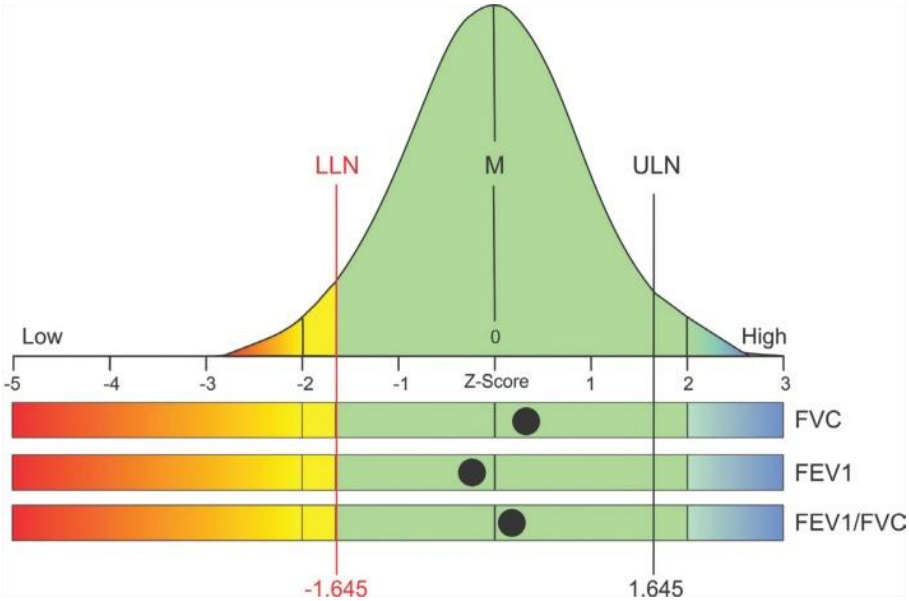
Technical issues can often be misinterpreted and lead to an incorrect assessment of the patient's clinical condition. It is essential to have competently trained physiology staff who have the ability to identify technical errors and add appropriate comments, which inevitably aid the final interpretation of the result.

Trained staff can also determine whether part of the measured data can be utilised. This is a key skill. Although there are several guidance documents related to achieving accuracy, reproducibility, and acceptability, it is also important that in some instances when technical accuracy cannot be guaranteed, the available data is not just simply discarded. With the use of appropriate statements that highlight the need for caution when interpreting, some of the measurements may still be of some clinical value. **Not achieving technical acceptability does not necessarily invalidate the result; they may just be less reliable. A single satisfactory result may still be valuable and answer the clinical question.**

3.4. Interpretative reporting

An interpretative report provides a descriptive evaluation of spirometry, bronchodilator responsiveness, lung volumes and gas transfer and the respective pattern based on their relationship regardless of clinical history. This particular type of report will focus on determining the most prominent pattern of disease, that being obstructive, restrictive or mixed. There should also be an attempt to comment on degree of severity (see appendix 5.3).

It is important to clarify that normality should no longer be defined by using fixed percentages but by the use of the Lower Limit of Normal (LLN) and/or z-score/Standardised Residuals (SR), as seen below.



(Courtesy of Morgan Scientific Inc., Haverhill, MA, USA)

Where it is not possible to infer with a degree of certainty the underlying disease pattern, it is important to consider the patient's ethnicity and whether or not the set of reference data used is appropriate. Patients at the extreme of age and height ranges can often show results that make no clinical sense. A brief comment on the potential caveat of the reference data is good practice[10]. Consider comments such as "*Treat predicted/reference values with care in a patient of this stature (height), age or ethnic origin – interpret with caution*."

Use familiar, commonly used terminology and avoid jargon. Try to distinguish between fact and opinion.

- Fact – Test results
- Opinion – What is inferred from the clinical history?

The goal is to reach a logical conclusion. To do this the results should be presented in a meaningful, orderly, functional manner. Group related pieces of information/test data together; for example, spirometry and reversibility testing.

All reports should include the author's full name plus their registration number and designation. It is good practice to use a medical stamp with the reporter's information and registration number/PIN if using paper reports; the date the report was formulated should be included.

Table 1 below lists "stock" comments or statements that may be used as part of a Lung Function report.

Table 1. Examples of reporting comments/statements.

Spirometry	
Normal FEV_1/FVC% >LLN* FEV_1 > LLN (F)VC >LLN	Spirometry is within normal limits for the patient **Remember the use of a fixed ratio of 0.70 (70%) to identify airflow obstruction should be discouraged as it may lead to either an overestimation or underestimation of obstructive lung disease.*
Non-specific ventilatory pattern	Spirometry shows a reduced (F)VC and or FEV_1 but with a normal FEV_1/FVC% (>LLN) and a normal TLC (>LLN)
Obstructive spirometry FEV_1/FVC% <LLN	Pre/Post bronchodilator spirometry is consistent with mild/moderate/severe/very severe airflow obstruction.
Restrictive spirometry (F)VC < LLN FEV_1/FVC% > LLN but can also be >ULN	Spirometry suggests a restrictive pattern (small lung volumes) indicated by a reduced vital capacity (typically in conjunction with a normal or elevated FEV_1/FVC %).
Restrictive pattern confirmation? - further tests (F)VC < LLN and TLC < LLN	A reduced vital capacity suggests a restrictive process; however, spirometry alone cannot confirm or exclude a true restrictive defect; the presence of a restrictive pattern (reduced volumes) should be confirmed by the measurement of static lung volumes. *Check BMI?*
Mixed obstructive and Restrictive spirometry FEV_1/FVC% <LLN (F)VC < LLN	Spirometry is consistent with an obstructive airflow pattern with a reduced vital capacity. The reduced vital capacity may be due to a true lung restriction or airflow limitation (gas trapping); however, spirometry alone cannot confirm or exclude a true restrictive defect; the presence of a restrictive pattern (reduced volumes) should be confirmed by the measurement of static lung volumes.
Upper Airways Obstruction (UAO)	The flow-volume loop is suggestive of a fixed/variable/ intra/extra thoracic airway obstruction. Extra thoracic – the flow volume loop could possibly show some decapitation/flattening of the maximal expiratory FVL or have a normal appearance, with a more extreme collapse of the FVL during inspiration. This may be due to the possible collapse of the trachea (this pattern can be seen in vocal cord paralysis/Goitre/tracheal lesion (above sternal notch).

	Intra thoracic – there is a reduction in airway patency during expiration, particularly early during expiration around PEF, with little or no reduction in the inspiratory loop. This pattern is typically seen in a retro-sternal goitre or a lesion below the sternal notch. Fixed UAO – due to airway narrowing, there is a fixed limitation in flow during both expiratory and inspiratory FVL. The Empey index, which assists in identifying upper/large airway obstruction, is >10 and adds diagnostic weight to the possible presence of UAO. N.B. Empey index =FEV_1 **(ml)** / PEF **(l/min)** An Empey index >10 can be helpful when considering UAO
Bronchodilator Response	
No response	Following administration of a bronchodilator for the assessment of reversibility, there has been no significant improvement. *+ or – the following technical comments* -However, it should be noted that the patient may have a residual effect from prior inhaler use, which may have dampened the possible response seen. -The reversibility test was performed using 400mcgs of salbutamol via a spacer; this does not exclude that the patient may respond to another bronchodilator drug or a different method of administration more effectively.
Significant response – Asthma?	Following administration of a bronchodilator there was a significant response seen in the FEV_1 which is ≥400ml. This is suggestive of reversible airflow obstruction and is generally seen in asthma.

Significant response *This is dependent upon which bronchodilator response criteria are used locally – note only two examples included here. Appendix 5.4 shows additional methods for calculating bronchodilator response. Appendix 5.5 shows various methods of expressing bronchodilator response.*	Post bronchodilator spirometry shows a significant improvement in accordance with the **ATS/ERS criteria of ≥200ml and a 12% increase in FEV_1 and/or FVC. Or>8% increase in FEV_1 % predicted, favors a diagnosis of asthma and active treatment[16]. A change in z-score of 0.7 has been proposed as a clinically meaningful change, FVC post BD z-score > 0.64 was more pronounced in severe obstruction, suggesting a clinically important relief of hyperinflation[17]. BD response should be expressed as a change in z-score for both FEV_1 and FVC, with the %predicted change being an acceptable alternative ** Please insert relevant guidance for measuring a bronchodilator response relevant to your area
FVL is normal post BD	Following administration of a bronchodilator for assessment of airway reversibility, there was a significant response as indicated by the spirometry parameters returning to within normal ranges post bd. Typically this response is seen in asthma. Reversible airflow obstruction.
Significant response - fixed airflow obstruction with a reversible element	Post bronchodilator spirometry shows a significant improvement in accordance with the **ATS/ERS criteria of ≥200ml and a 12% increase in FEV_1 and/or FVC. However, the post-bronchodilator spirometry still shows an airflow obstruction. ** Please insert relevant guidance of measuring a bronchodilator response relevant to your area
Static Lung Volumes	
Lung volumes within normal limits	The total lung capacity (TLC) is within normal limits for the patient.
Hyperinflation (FRC, TGV) Hyperinflation (TLC)	Static lung volume measurement shows a significantly elevated FRC or TGV/TLC% which would be suggestive of lung hyperinflation. (TLC > ULN). Static lung volume measurement shows a significantly elevated (>ULN) FRC or TGV, RV and the FRC or TGV/TLC%.
Gas trapping due to airflow obstruction TLC, FRC or TGV <ULN RV/TLC% > ULN	Static lung volumes show a significantly raised RV/TLC ratio >Upper Limit of Normal (ULN). This would suggest an element of gas trapping/poorly ventilated air spaces. This is typically seen in obstructive airway disease.

	+ or - the following -The TLC is normal or raised. Also check VA/TLC% ratio.
Restrictive TLC < LLN	The total lung capacity measured using static lung volumes is significantly reduced (<LLN). This is consistent with a restrictive lung pattern. *+ or - the following* -The RV/TLC% is elevated with a normal FRC or TGV (consider possible neuromuscular weakness)
Obesity?	Typically, in obesity (BMI >35. 0kg.m^{-2}) the Expiratory Reserve Volume (ERV) and Total Lung Capacity (TLC) can be reduced.
Technical – underestimation?	Lung volumes were measured using a gas dilution method (Helium dilution/Nitrogen washout). Typically, this method can under-estimate lung volumes in obstructive patients because of poorly ventilated air spaces or non-communicating regions being excluded from the measurement of the lung volume, impacting upon the dilution of gases within the lung. Plethysmography may over-estimate results when the measured mouth pressure changes are not equivalent to alveolar pressure changes, which typically occur in the presence of significant airflow obstruction.
Gas Transfer	
Reduced transfer factor – introductory statement V_A – Alveolar Volume, number of Alveoli available for gas exchange K_{co} – Gas transfer factor per lung unit TL_{co} – Transfer factor of carbon monoxide	A low gas transfer (TL_{co}) is due to either a low alveolar volume (V_A - the number of contributing lung units) or the diffusion coefficient (K_{co}) which informs us of the efficiency per lung unit or both
Normal (TL_{co} >LLN, V_A > LLN, K_{co}>LLN)	The transfer factor for this patient is within normal limits. There is no significant evidence to suggest a gas exchange abnormality.
TL_{co} > LLN, V_A < LLN	The transfer factor is within normal limits in the presence of a reduced alveolar volume.
TL_{co} < LLN, V_A>LLN TL_{co}<LLN, V_A<LLN, K_{co}<LLN	Transfer factor is reduced but in the presence of a normal Alveolar Volume. This pattern is seen in parenchymal or pulmonary vascular disease. Both transfer factor and alveolar volume are reduced with a decreased K_{co}, suggestive of parenchymal or pulmonary vascular disease.

Transfer factor reduced (<LLN) with a reduced V_A and K_{co} – in the presence of a significant obstructive defect on spirometry, lung hyperinflation, ↑TLC, ↑RV/TLC %	The reduced V_A likely reflects the poor uptake of the transfer gas in relation to the poorly ventilated air spaces (*check V_A against TLC from lung volume measurement, i.e. is the V_A/TLC% <80%)*. This leads to a possible underestimation in the number of contributing or "accessible" lung units. The resulting transfer factor reflects the gas exchange from ventilated tissue only. The reduced TL_{co} and K_{co} is a result of the decreased surface area available for gas exchange and alveolar destruction. Typically seen in emphysema.
TL_{co}<LLN, V_A<LLN, K_{CO} within normal limits	Both TL_{co} and V_A are reduced. As the K_{co} is within normal limits, pathology may be present when K_{co} is normal in the presence of a reduced TL_{co} and V_A. The result may be due to the loss of lung units (discrete or diffuse), poor gas mixing, parenchymal or pulmonary vascular dysfunction or a combination of these.
TL_{co}<LLN, V_A<LLN, K_{CO}>ULN	Both transfer factor and alveolar volume are reduced. The elevated K_{co} suggests that the reduction in TL_{co} is due to incomplete expansion of alveoli rather than parenchymal or pulmonary vascular disease. Extra-thoracic lung restriction – obesity? Muscle weakness? Correlate clinically. Check test quality – Incomplete inhalation to TLC?
Transfer factor (TL_{co}) within normal limits (but usually ↑ >ULN), V_A is within normal limits or reduced, ↑↑K_{co} > ULN	Transfer factor shows a raised TL_{co}. This may suggest polycythaemia, left to right shunt, pulmonary haemorrhage. Also seen in altitude, a Mueller manoeuvre (decreased intra-thoracic pressure, resistance breathing as in asthma), exercise, supine position (reduced surface area – not full inflation), Obesity (reduced surface area – incomplete unfolding of lung membrane).

3.5. Clinical reporting

A clinical report provides an integrative evaluation of all the available information in order to reach a possible diagnosis. Clinical reports may include further recommendations around treatment and other investigations. A good clinical report will aim to answer the questions of the referring clinician. Healthcare professionals who are competent in writing clinical reports will often require access to:

- Clinical documents library (clinic letters, GP referrals, blood test results).
- Imaging Reports (chest X-ray, CT scans).
- Cardiology results and reports (electrocardiogram, echocardiogram).

A good test referral will often avoid any additional “detective work” by the reporting clinician in obtaining the information required to report the test. A process whereby the quality of the test referrals are monitored can potentially highlight a better design for referral forms and consequently improve the quality of referrals.
Clinical reports will often carry, or would be expected to carry, guidance, recommendations for treatment, assessment of fitness for surgery and other information that attributes accountability to the reporting clinician.

Consider any further testing that may assist with answering the clinical question posed and add these suggestions to the final statements in the report. Provide advice on any treatment to be prescribed, and finally, sign and date your report.

Those who write clinical reports need to ensure statements, recommendations and comments made are within their scope of practice. All staff responsible for clinical reporting are advised to either hold or be covered by professional indemnity insurance and be professionally registered.

3.6. Release of reports

Processes should be in place and monitored to ensure that reports, particularly urgent ones or those with unexpected findings, are received by the referrer. Communication of reports should be documented either at the end of the formal report or in the patient's medical notes. A record of all verbal reporting including those discussed via the telephone, should be kept, ideally on the final report or again in the patient's medical notes. All urgent tests should be reported and communicated/processed as soon as possible after the test is concluded. In the absence of a suitable reporter, the team must ensure the referrer receives the technical data report. There must be robust systems in place to ensure reports are transferred between organisations, for example GP practices and other NHS trusts, securely.

In addition, processes should be in place to ensure that reporting staff have access to a second opinion when required.

Service managers, in consultation with referrers, must establish turnaround times for reporting. Processes should be in place to tackle reporting backlogs and any associated patient risks that may arise from delays. It is essential that these risks are escalated to senior management through governance processes.
There must be a documented procedure/protocol where pre-determined criteria are used to analyse, and report results and or to select which results can be released automatically either, with or without a written report.

If an already issued/released report needs any amendments or corrections, then there must be systems in place to either remove the erroneous report from the patient’s medical record or document any changes/amendments made. The revised report must be re-signed and dated by the reporter, and it must be documented that the amended report has been communicated/shared with the referrer again.

3.7. Staff competency

Competency in lung function reporting cannot be achieved by simply attending a reporting course (for example, the ARTP lung function reporting or masterclass courses). To confirm competency, it is imperative that the physiologist or clinical scientist in question is initially mentored and that there is a process of over-reading of any reports by competent staff until satisfactory competency has been achieved. Ongoing assessment of competency can be achieved using the following.

- Regular quality assurance checks: this may be a domain within the department's key performance indicators (KPIs) if applicable.
- Peer-review of reports: select a sample of reports and discuss them as a team or on a one-to-one basis.
- Inter-departmental review of results: This is particularly important when a new diagnostic test is introduced into the service, but it also acts as another form of external peer review.

3.8. Audit

In the interest of clinical governance, there has to be a certain number of processes in place to ensure the quality and accuracy of the reports are up to a high standard. This process is applicable to all three levels of reporting (technical, interpretative, and clinical). The review process should be open for all to attend and should take place either during or before clinical multidisciplinary team meetings (MDT). Test results must be anonymised, as well as the name of the healthcare professionals who conducted the test and wrote the clinical report. The discussions around test results and reports are not meant to be based on who "is right" and who "is wrong" but to determine whether or not the reports written are of an appropriate standard. Staff who fail to report to the required standard should not be allowed to report until satisfactory competence has been demonstrated.

In current practice, there are no established methods to evaluate clinical reports. The items below are considered to be the "spinal cord" of a clinical report and can be used as a template to discuss the appropriateness of test reports:

a. Accuracy
1. Are the comments relating to a pattern of disease and/or severity accurate?
2. Are the progression/stability (serial data) comments accurate?
3. Use: *Yes; No; No comment; Not applicable*

b. Specific
1. Are the concerns of the referrer and/or the reason for the referral addressed?
2. Use: *Yes; No; Not applicable*

c. Content
1. Are there any recommendations? If yes, are they appropriate?
2. Use: *Yes, appropriate recommendations; Yes, but inappropriate recommendations; No, no recommendations are needed; No, recommendations missed; Not applicable.*

d. Length
1. At least 10 and up to 50 words (note – report length will be locally agreed).
2. Use: *Short; Appropriate; Long, but justified; Long, not justified*

A report that meets items a, b, c, and d should be considered an appropriate clinical report. As part of the discussion during the MDT, ideally, there should be a chair who holds the final decision in regard to the items discussed above and whether or not the report, as a whole, is appropriate. Over time, by capturing this data, it will be possible to determine the underlying issues that need to be addressed in order to improve reporting standards.

As part of IQIPS it is important that services audit their reports; this can be achieved by having a survey sent to a selection of referrers for feedback on the reports received. The survey could include questions relating to report quality, timeliness of reporting, ease of understanding etc.

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5. Appendices

5.1. Respiratory History Template

Respiratory History

Hospital Number _____ Surname _____
Test Date _____ Referrer _____
Clinical details (from referral form)

_____

_____

Hb _____ g/L BMI _____ Resting SpO_2 _____ %
Smoking Status: Current / Never smoked / Ex smoker / Social smoker
Time of last cigarette prior to test _____ hrs/mins
Years smoked _____ yrs Number smoked per day _____
Quit smoking(date) _____ Pack years _____ yrs

1 pipe = 2.5 cigarettes: 2 pipes per day = 5 cigarettes per day
Cigars: 1 café crème = 1.5 cigarettes, 1 hamlet = 2.5 cigarettes, 1 havana = 4 cigarettes.
Roll up tobacco 25grams or 1 ounce = 50 cigarettes e.g. 1 ounce of tobacco per week = 50 cigarettes / 7 days = 7 per day.

Shortness of breath: Sudden onset <4 weeks Chronic > 4 weeks

Ask: How far can you walk? Can you complete a flight of stairs? Does breathlessness vary from day to day? What makes it worse or better?

_____

_____

Symptoms: Cough/nocturnal cough/ cough after eating/ wheeze/ sputum (consistency, colour and amount)/ recent chest infection/ chest pain/ oedema/ finger clubbing

_____

_____

Medications (inhalers? – last used? Beta blockers, steroids, methotrexate, blood pressure meds)

_____

_____

Occupational exposures (main occupation – if now retired, ask about asbestos or volatile chemical exposure, mining?)

_____

Pets or organic dusts (birds? Farmer?)

_____

Past Medical History: recent trauma, surgery, MI, diabetes, hypertension, cardiovascular risk, stroke, rheumatoid arthritis etc.

_____

_____

5.2. Technical Reporting Quality Criteria

Relaxed Vital Capacity measurement

Acceptability	Reproducibility
Efforts/trials must be free from artefact	VC need to be within <150ml of each other.
No cough	A minimum of 3 efforts/trials
No leak or hesitation at the mouthpiece	A maximum of 5 efforts/trials
No obstruction of the mouthpiece with the tongue	
Plateau reached	
Was SVC submaximal	SVC not >150ml less than FVC

Dynamic Spirometry/Maximal Flow Volume Loop

Acceptability	Reproducibility
Efforts/trials must be free from artefact	A minimum of 3 efforts/trials
No cough within the first second	A maximum of 8 efforts/trials. After 8 attempts the probability of getting a better result is significantly reduced. Do not reject results, comment on repeatability and report best efforts.
Rapid rise to PEF (FVL). The highest reading of at least 3 technically acceptable blows should be recorded. A poorly co-ordinated start to the manoeuvre, indicated by a rise time of 10-90% of PEF of > 150ms or a back extrapolated volume of > 5% of the FVC or 0.1L if the FVC is < 2.0L. In subjects <6yrs back extrapolated volume <75ml or 10% of the FVC is acceptable).	The two largest values of FVC must not differ by more than 150ml of each other The two largest values of FEV_1 must not differ by 150ml of each other. PEF – approximately 90% of subjects can achieve three PEF measures within 30 L/min (0.5L/s), 95% of subjects are within 40 L/min. Maximum number of 5 attempts for PEF.
No early termination of expiratory effort, plateau reached (the volume–time curve shows no change in volume (<0.025 L) for last 1 second of the test). Note that if plateau has <u>not</u> been achieved the FEV_1 may still be of some use. Early termination is not a reason to eliminate all data obtained as indices such as FEV_1 may not be affected and will still be valid.	For those with a true FVC of ≤1.0 L, the two largest FVC and FEV_1 must be within 100ml of each other.
Forced Expiratory Time (FET) ≥3 s in children aged >6 and <10 years and ≥6 s in subjects aged >10 years. Consideration must be given to restrictive subjects (FET can be < 6seconds). Pre-school children can reach a volume plateau in <1 s. Do not report FEV_1 if FET <1 s. Instead consider using $FEV_{0.75}$/FVC%.	FVL reproducible in shape. This is particularly important when there is a suggestion of upper airway obstruction.

No obstruction of the mouthpiece with the tongue, distortion of mouthpiece due to excessive biting or obstruction by the teeth.	The chosen results should be the greatest values from three technically acceptable tests. FEV_1 and FVC may be taken from different manoeuvres.
Test performed with an open glottis	
No leak at the mouth (consideration must be given to patients with neuromuscular weakness and those with facial palsy)	
No extra breath taken during effort	
Maximal inspiration to TLC prior to forced expiratory effort.	If the maximum FVC is followed immediately by a full inspiration back to TLC and recorded as a single manoeuvre, then the FIVC must not exceed FVC by more than 100mL or 5% of the FVC, whichever is greater. If FIVC exceeds FVC by more than this then it suggests the blow did not start from TLC.

Static Lung Volumes (Helium dilution and Nitrogen washout)

Acceptability	Reproducibility
No excessive switch in error. Small differences in switch in volume (~50ml) can be discounted as being of little clinical significance. Larger differences of >500ml should result in test being abandoned and then restarted. For differences between 50ml – 500ml the subject should be maintained at the switch in volume and the difference subtracted (or added) to the measured FRC.	FRC_{He} – Obtain one technically acceptable result*. FRC_{He} inter-test variability is so small [7] that only one test needs to be performed, more attempts will improve accuracy. If a second FRC_{He} is made, there should be an interval equivalent to duration of first test or 10 minutes if equilibrium not reached. N_2 washout – The time between measurements must be at least twice the length of time of the previous test to allow alveolar gas concentrations to return to normal.
Time for equilibrium does not exceed 10 minutes. If equilibrium does exceed 10 mins, then a comment highlighting this should be included.	If a second FRC_{N2} is made, then there should be a rest interval equivalent to twice the time taken to complete the first measurement.
Equilibrium reached (He ± 0.02% or FRC ± ±0.025L over a 30 second period).	Ideally the reported FRC_{He} should be the mean value from two measurements, assuming there are no significant differences i.e. <200ml. Repeatability between technically acceptable FRC_{N2} should be within 10% and the average value is to be reported.
No equipment leaks. Volume of added O_2 exceeds 200ml – 250ml/min or 0.04L/kg/min.	The highest ERV and IC should be reported.
Stable baseline tidal volume achieved.	N_2 washout – Once FRC is complete, a minimum of 3 acceptable VC measurements should be made. At least 30 seconds' rest should be

	allowed between attempts. The two best VC measurements should be within 150ml.
No patient leaks (mouthpiece/nose/eardrum). During nitrogen washout the exhaled nitrogen profile will instantly display a "spike" should any leak occur. Test should be discontinued and not repeated until twice the duration of the failed test has passed.	
N_2 washout – the subject continues with tidal breathing on 100% O_2 until the concentration of expired N_2 falls below 1.5% for 3 consecutive breaths. If this is not achieved in 10 minutes the test should be terminated	

*There is no evidence to suggest this as best practice. A duplicate measurement should ideally be performed. ERS/ATS guidelines recommend performing 3 measurements.

Static Lung Volumes (Body Plethysmography)

Acceptability	Reproducibility
No excessive force when panting leading to hysteresis.	At least 3 technically acceptable TGV_{pleth} which agree within 5%. The mean value is reported (the difference between the highest and lowest values divided by the mean is ≤ 5%). Additional TGV_{pleth} should be obtained until three values agree within 5% of their mean.
Incorrect panting frequency (should be ˜ 1 breath/second), panting frequency > 0.5Hz < 1.5Hz	Shutter should remain closed for ˜2-3 seconds to obtain 2-3 slopes of ΔP_{mouth} versus ΔP_{box}
No excessive panting manoeuvre producing large, variable, invalid recordings	Panting pressures should not exceed ±1 kPa
No leak in box seal.	
No thermal drift	

Gas Transfer Test

Acceptability	Reproducibility
Rapid inhalation achieved within 1.5 – 2.0 seconds (normal and restrictive subjects) and ≤4.0 seconds in obstructive (FEV_1/FVC % < 50%)	A minimum of 2 and a maximum of 5 technically acceptable tests. 5 gas transfer factor tests will increase COH_b by ~3.5% which will ultimately lower measured transfer factor by 3.5%. The mean of two technically acceptable manoeuvres should be reported.
V_{IN}/VC% should be at least 90% of the subject's previous best measured VC. N.B. Evidence suggesting that by lowering V_{IN}/VC to 85% influences measured TLco by less than 5% should be reviewed with caution due to the	Criteria for reproducibility are at least two acceptable TL_{co} measurements. TL_{co} within 0.67 mmol/min/kPa. K_{co} within 0.1mmol/min/kPa/L Alveolar Volume (V_A) within 5%.

limited number of participants. It would be acceptable to suggest that if technically acceptable tests were obtained but a V_{IN} of 90% was not achieved, data from tests where a V_{IN} of 85% or more was achieved could be analysed and reported with caution.	
Breath holds time should be 10 seconds ± 2 seconds with no Valsalva or Müller manoeuvres.	The mean of two technically acceptable manoeuvres should be reported
Modern rapid gas analysis systems allow the operator to inspect the continuous exhaled gas concentration curves and accurately identify deadspace washout, this is vital in these systems i.e. the initial fall in exhaled tracer gas concentration from inspired values to the plateaus at expired values.	
Time between manoeuvres of at least 4 minutes. Patients with severe airflow obstruction may require longer.	
Expiratory time <4 seconds and to sample collection < 3 seconds	
No step wise inhalation or exhalation	
Exhaled volumes that do not exceed inhaled volumes	
No Inspiratory or expiratory gas leak	

5.3. Severity classification and probability of a result being found within a normal healthy population for various z-score thresholds

Threshold for Z-score	Severity Grading	Approximate chance of finding this result in a healthy population
< -1.645	Mild	1 in 20
< -2.00	Moderate	1 in 40
< -2.50	Moderately Severe	1 in 150
< -3.00	Severe	1 in 750
< -4.00	Very Severe	1 in 30,000

Severity classification in airflow obstruction is a two-stage process. The FEV_1/FVC (or FEV_1/VC%) must be below the Lower Limit of Normal or LLN (z-score < -1.645) to be classified as an obstructive pattern. Severity grading is then based on the FEV_1 z-score as above, with the exception that the mild classification includes any FEV_1 z-score ≤ 2.

5.4. Different methods for calculating bronchodilator response

1. *Absolute change (mL) from pre-bronchodilator value:*

Post bronchodilator FEV_1 – Pre bronchodilator FEV_1 (mL)

2. *Percentage of initial pre-bronchodilator value (% initial)*

$$\frac{\textbf{(Post BD FEV}_1\textbf{ – Pre BD FEV}_1\textbf{)} \times 100}{\textbf{Pre BD FEV}_1}$$

3. *Percentage of possible reversibility (% possible)*

$$\frac{\textbf{(Post BD FEV}_1\textbf{ – Pre BD FEV}_1\textbf{) x 100}}{\textbf{Predicted FEV}_1\textbf{ – Post BD FEV}_1}$$

4. *ECCS Recommendation*

$$\frac{\textbf{(Post BD FEV}_1\textbf{ – Pre BD FEV}_1\textbf{) x 100}}{\textbf{∑(pre BD FEV}_1\textbf{ – Post BD FEV}_1\textbf{)/2}}$$

5. *Percentage of predicted (% predicted)*

$$\frac{\textbf{(Post BD FEV}_1\textbf{ – Pre BD FEV}_1\textbf{) x 100}}{\textbf{Predicted FEV}_1}$$

6. *Δ Z-score*

$$\textbf{Δ FEV}_1\textbf{ = Post, z FEV}_1\textbf{ – Baseline, z FEV}_1$$

5.5. Methods of Expressing Bronchodilator Responsiveness

ATS (1991)	≥12% and >200ml increase (FEV_1 or FVC)
Quanjer et al (1993)	Change in FEV_1 > 9% predicted value
BTS/ARTP (1994)	160ml increase in FEV_1; 330ml increase in VC
Siafakas et al (1995)	Change in FEV_1 >10% predicted value
BTS/SIGN (2003)	≥200ml + ≥15% increase in FEV_1 from baseline
NICE (2004)	Change in FEV_1 > 400ml
ATS/ERS (2005)	>12% + >200ml increase in FEV_1 and or FVC
GOLD (2007)	>200ml + >12% increase in FEV_1 from baseline
BTS/SIGN (2012)	Change in FEV_1 >400ml
Ward et al (2015)	>8% change in FEV_1 % predicted
Quanjer (2017)	>8% change in FEV_1 % predicted > +0.78 in z-score in FEV_1 from baseline > +0.64 in z-score in FVC from baseline
ATS/ERS (2019)	The % change and absolute change in FEV_1 and FVC compared with pre-bronchodilator values are reported. The change in FEV_1 as a %predicted FEV_1 or as a z-score avoids sex and height bias.
Aggarwal et al (2019)	≥12% and ≥ 200ml increase (FEV_1 or FVC)

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