Quality Assured Diagnostic Spirometry for Chronic Obstructive Pulmonary Disease

Importance of quality assured diagnostic spirometry

Most patients with chronic obstructive pulmonary disease (COPD) are undiagnosed: around 835,000 people have been diagnosed in England, while around 2.2 million people are still living with COPD, but do not know they have the condition.[1] Misdiagnosis is also common, around a quarter of people on general practice COPD registers do not meet the diagnostic criteria for COPD.[2] This level of misdiagnosis occurs because much of the spirometry performed in primary care fails to meet essential quality standards.[1-4] Issues such as having the right equipment, using it correctly and interpreting the results are common and can lead to erroneous diagnoses.[3]

Mis-diagnosis can lead to labelling people as having a serious lung condition and receiving treatment inappropriately. Under-diagnosis stops affected people from receiving advice on lifestyle, which can improve the prognosis and treatment for symptoms and exacerbations.[1, 3]

High quality, reliable, diagnostic spirometry (Quality Assured Diagnostic Spirometry: QADS) is necessary for the accurate identification and care of patients with COPD.[1] The Department of Health has issued guidance in 2013, which forms the basis of this module. The aim of which is to provide an overview of the role of QADS in ensuring the appropriate diagnosis of COPD.[5]

> *"It is mainly through early and quality assured diagnosis, a more comprehensive assessment of severity, effective proactive disease management and evidence based treatment interventions that lives from COPD will be saved and the burden on the resources of the NHS will be reduced"*
>
> *Department of Health, 2011[1]*

Selecting patients for QADS

The following patients should be considered for QADS:[6]

- Those over 35 years of age with a risk factor (generally smoking) and with any of the following symptoms:
  - Exertional breathlessness
  - Chronic cough
  - Regular sputum production
  - Frequent winter 'bronchitis' or wheeze.

In addition, patients must be clinically stable and should be assessed for the following contra-indications to spirometry:[5,7]

- Absolute:
  - Active infection e.g. sputum positive tuberculosis until treated
  - Conditions such as dissecting/unstable aortic aneurysm or current pneumothorax
  - Recent surgery including ophthalmic, thoracic, abdominal or neurosurgery.
- Relative:
  - Suspected respiratory infection in the last 4-6 weeks
  - Undiagnosed chest symptoms e.g. haemoptysis
  - Any condition which may be aggravated by forced expiration e.g. history of prior pneumothorax, unstable vascular status such as recent (within 1 month) myocardial infarction, uncontrolled hypertension or pulmonary embolism or history of haemorrhagic event (stroke)
  - Previous thoracic, abdominal or eye surgery
  - If the patient is too unwell to perform forced expiration
  - Communication problems such as learning disability or confusion.

Standardisation for QADS

All spirometers should meet the standards of measuring and recording as specified in international guidelines.[4] Spirometer manufacturers or agents should provide data showing that their instrument complies with ATS (American Thoracic Society) or ATS/ERS (European Respiratory Society) specifications.[4,8]

Standardisation of equipment

The spirometer should meet ISO standard 26782 and its software should be configured so that meaningful results can be produced.[9]

Adequate procedures for infection control and maintenance are essential, such as the incorporation of one-way mouthpieces and nose clips as well as bacterial filters.[4] Those considered at risk of transmitting infection (e.g. bronchiectasis) should use antibacterial filters, one-way valve mouthpieces suffice for low risk patients.

Operator standards

QADS may only be conducted by an operator trained and assessed to approved standards such as those published by Education for Health and the ARTP (Association for Respiratory Technology and Physiology), or any other training body which works to equivalent standards.[5,10] Such courses will provide a certificate and this must be in date according to the new guidance. Interpretation should only be performed by those trained and certified as able to interpret the results of diagnostic spirometry by recognised training bodies.[10]

Calibration

Each spirometer should have an annual calibration check and the three litre calibration syringes should also be checked at this time. All equipment should be regularly checked to ensure that it measures accurately.[4] It is suggested that verification should be performed prior to every clinic/session or after every tenth patient (whichever comes first).[4,5] This is expert opinion and there is little evidence to underpin the recommendation. Verification checks can be done using a three litre syringe or by biological controls - a fit adult can act as a standard.[5] The details of this technique are shown in the QADS standards document. (Available at: http://www.pcc-cic.org.uk/sites/default/files/articles/attachments/spirometry_e-guide_1-5-13_0.pdf. Last accessed July 2013.)

The standards for calibration:[8]

- Calibrate or verify the machine at the start of the reading using an annually certificated 3L syringe - **this must have an accuracy of +15ml**
- Measure height and weight using calibrated scales
- Keep a note of calibration and verification results, including a simple log of problems. Look out for any sudden or unusual changes in performance or readings
- Document all repairs and any computer software updates.

Cleaning

The equipment should be cleaned at the end of each spirometry session according to manufacturers' instructions[8] with reference to local guidelines and protocols.

Carrying out spirometry

Pre-spirometry advice to patients

All patients should be prepared in advance for any criteria which may affect results, as well as reviewing for potential contraindications.

Suggested pre-test advice for patients:[4-7]

- Bring all existing inhalers to the appointment
- Stop taking your bronchodilators. The period of time will depend on the type of inhaler, but this is usually four hours-36 hours beforehand. Your healthcare professional will advise you on the appropriate length of time
- Before the test, avoid:
  - Smoking for at least 24 hours
  - Eating a large meal
  - Exercise
  - Wearing tight clothing
- Let your doctor know of any pre-existing medical conditions or recent medical events and any allergies.

The Spirometry Test[4-7]

1	• Assess patient for any **contraindications**
2	• **Record** height and weight • Age, gender and ethnicity should also be noted
3	• **Explain and demonstrate** vital capacity (VC) and forced vital capacity (FVC) manoeuvres • Use a new, disposable, one-way mouthpiece
4	• **VC:** Take a full maximal inspiration and then give a steady expiration for as long as possible • A minimum of three acceptable VC manoeuvres must be obtained with no more than 100 mls ideally (and certainly no more than 150 mls in the occasional highly variable patient) between each blow
5	• **FVC:** Without using noseclips, take a full inspiration and exhale fully using forced vital capacity manoeuvres. A minimum of three acceptable VC manoeuvres must be obtained with no more than 100 mls ideally (and certainly no more than 150 mls in the occasional highly variable patient) between each blow • A maximum of eight FVC manoeuvres should be performed in any one session
6	• **Record and code:** • FEV_1 • FEV_1% predicted • VC or FVC which ever is highest • Ratio of FVC:FEV_1 • Use the results to assess severity using validated measures of health status

Common errors:[7]

- Inadequate mouthpiece seal
- Poor inspiratory or expiratory effort
- Slow/false start
- Early termination of manoeuvre
- Coughing

Reporting results

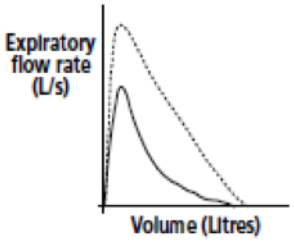
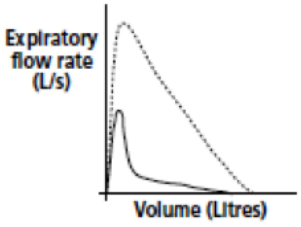
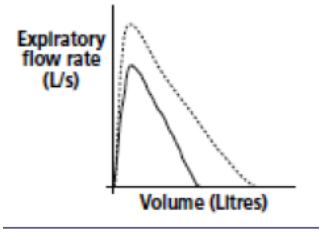
Most spirometers will automatically help to select the best results. The Department of Health Guidance recommends:[5]

- Selecting the highest FEV_1, VC and FVC from three efforts meeting repeatability criteria or within 5% of each other – whichever is smaller (below one litre) or higher (above one litre)
- Compare with reference values; values below the fifth percentile (lower limit normal: LLN) are regarded as abnormally low[11]
- Use the volume-time and flow-volume graphs to interpret the results.

Interpreting results

Spirometric tests generally lead to the following abnormalities: obstructive, restrictive and mixed (usually restrictive/mixed).[4,12]

Table 1: Interpreting flow volume curves

Obstructive abnormalities • Peak expiratory flow (PEF) reduced • Concave expiratory flow volume curve • Reduced FEV_1/FVC ratio	
Severe obstructive abnormalities • Flow volume curve has characteristic 'steeple' shape	
Restrictive/mixed abnormalities • Normal or increased FEV_1/FVC ratio and a low FVC, with the expiratory flow volume curve appearing convex	

--------- Normal curve

Reproduced and adapted by permission. The BTS COPD Consortium. Spirometry in Practice: A Practical Guide to Using Spirometry in Primary Care. Second Edition. 2005.[12]

If the pattern is obstructive, grade severity as per NICE 2010.[6]

Table 2: Degree of airflow obstruction

Severity of airflow obstruction	FEV_1 (% predicted)*
Mild	≥80%**
Moderate	≥50% – <79%
Severe	≥30% – <49%
Very severe	<30% (or <50% with respiratory failure)

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Interpretation of spirometry should not be determined by the automated report alone. The following details should also be included to ensure a thorough analysis:[5]

- The normality of the shape of the curves
- A comment on whether the pattern fits a normal, restrictive or obstructive profile
- Any comment on the quality of the measurements
- Suggestions for further tests, urgent treatment(s) or referral to a specialist.

Also, remember that diagnoses should not be based on just spirometry alone, but with a combination of prior evidence of disease, clinical symptoms and signs. Severity of COPD should not be based on airflow obstruction, but should use a multicomponent assessment *(please refer to the COPDexchange module TMT Assessing Disease Severity).*

What you need to know:

QADS should only be performed by people who have received training and certification to national standards, these include Education for Health, ARTP or any other training body which works to equivalent standards.

All equipment should be regularly checked to ensure that it measures accurately e.g. before every clinic/session or after every tenth patient (whichever comes first).

QADS should be performed on patients over 35 years of age with a risk factor (generally smoking) and with any of the following symptoms:

- **Exertional breathlessness**
- **Chronic cough**
- **Regular sputum production**
- **Frequent winter 'bronchitis' or wheeze.**

Patients should be free of any absolute (e.g. recent surgery) or relative (e.g. suspected respiratory infections) contraindications prior to QADS.

Spirometry reporting across healthcare communities should be provided in an agreed and uniform manner, ideally involving use of FEV_1, FVC and VC and using data highlighting lower limit of normal values.

Spirometric tests can show the following patterns: normal, obstructive, restrictive and mixed abnormalities.

It is important not to interpret the spirometry results in isolation. Diagnosis should always be based on the history, examination and measurement of airflow. If the diagnosis is not clearly established, referral for further investigation should be considered.

Think about…

- **Which of your patients are candidates for QADS?**
- **Have you access to an operator/equipment which meets the ARTP standards?**
- **Do you know how to prepare your patient for QADS? Are you aware of which conditions can adversely affect interpretation of results?**
- **Do you know how to differentiate between obstructive, restrictive and mixed spirometric profile?**

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