

STANDARDS DOCUMENT

Diagnostic Spirometry in Primary Care

Proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations

A General Practice Airways Group (GPIAG)¹ document, in association with the Association for Respiratory Technology & Physiology (ARTP)² and Education for Health³

¹ www.gpiag.org ² www.artp.org ³ www.educationforhealth.org.uk

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Received after pre-submission external peer review and approval by all associated organisations 12th July 2009; accepted 19th July 2009; online 14th August 2009

Abstract

Primary care spirometry services can be provided by trained primary care staff, peripatetic specialist services, or through referral to hospital-based or laboratory spirometry. The first of these options is the focus of this Standards Document. It aims to provide detailed information for clinicians, managers and healthcare commissioners on the key areas of quality required for diagnostic spirometry in primary care – including training requirements and quality assurance. These proposals and recommendations are designed to raise the standard of spirometry and respiratory diagnosis in primary care and to provide the impetus for debate, improvement and maintenance of quality for diagnostic (rather than screening) spirometry performed in primary care. This document should therefore challenge current performance and should constitute an aspirational guide for delivery of this service.

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ML Levy *et al.* *Prim Care Resp J* 2009; 18(3): 130-147.

doi:10.4104/pcrj.2009.00054

Keywords diagnostic spirometry, spirometry, COPD, diagnosis, guideline, standards, primary care, general practice

The full version of this paper, with online Appendices, is available online at www.thepcrj.org. See linked editorial by Jenkins on pg 128

Introduction

Health care should have quality at its heart,¹ and should also satisfy patients' desire for care closer to home.² Improved

recognition and care of patients with chronic obstructive pulmonary disease (COPD) is underpinned by a need for high quality, reliable, diagnostic spirometry.³⁻⁵ Spirometry is recommended for the diagnosis and management of asthma and COPD in national and international guidelines, and specialist respiratory groups such as the American Thoracic and European Respiratory Societies (ATS/ERS) have published guidelines on

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standards of spirometry.⁶ There are also specific guidelines⁷ for diagnosis of the numerous respiratory diseases presenting in primary care ('general' or 'family' practice).⁷⁻¹⁰ However, there are no overarching guidelines on current standards required for performing spirometry in the primary care setting.

Increased availability of spirometry in primary care (also termed 'office spirometry') is welcome since it provides rapid access to diagnosis and monitoring close to the patient's home. A recent UK audit of 9716 cases of people admitted to hospital with an exacerbation of COPD found a spirometry record within the last five years in 55% of their hospital records, and in 74% of their primary care records.¹¹ However, poorly performed tests and misinterpretation of the results can lead to misdiagnosis (or missed diagnosis) and inappropriate management, potentially putting patients at risk. Spirometry is effort-dependent, and the role of the person administering the test as 'coach' to the patient cannot be overestimated. Training and regular practice is vital. Likewise, the results of spirometry testing need to be properly interpreted in the light of the clinical history and presentation – ideally at the time of testing.

There is marked variability and inconsistency in the use of spirometry to diagnose COPD;^{12,13} this is related to the age of patients,¹³ the speciality of the clinician (primary or secondary care),^{13,14} and the severity of the disease.¹⁵ Variations in the presentation of results from different spirometers do not facilitate uniform interpretation.¹⁶ Where quality outcome initiatives for primary care are in place (e.g. the Quality Outcomes Framework (QOF) in the UK) there is little emphasis on the quality of spirometry performance and its interpretation.¹⁷ These factors all contribute to an ongoing national^{12,18} and international¹⁹⁻²⁵ debate about the delivery of spirometry in the primary care setting.

Diagnosis of any disease requires a complex series of decisions based on clinical history, examination and further investigations, where appropriate. Accurate spirometry is an essential part of clinical practice in primary care differential diagnosis and management,⁷ including monitoring of COPD and asthma.^{23,26} It is therefore essential that those performing spirometry are trained and able to demonstrate their competence to:

- do the tests,
- identify errors, and
- interpret the results at the point of contact

Primary care spirometry services can be provided by trained primary care staff, peripatetic specialist services, or through referral to hospital-based or laboratory spirometry. The first of these options is the focus of this paper. This guidance aims to provide detailed information for clinicians, managers and healthcare commissioners on the

key areas of quality expected for diagnostic spirometry in primary care – including training requirements and quality assurance. There will always be a gap between standards and practice, and therefore it is not the authors' intention that all these standards and recommendations be met immediately, or that spirometry should not be performed in primary care. Neither is it the intention of the authors to denigrate the quality of spirometry currently provided in primary care; whilst there are variations in delivery of this service, there are certainly examples of high quality performance.

Therefore, this Standards Document provides background information and specific recommendations on the key quality areas for performing spirometry in primary care. The authorship includes international experts on spirometry and representatives from the General Practice Airways Group (GPIAG), the Association for Respiratory Technology & Physiology (ARTP), and Education For Health (EFH). Comments from the British Thoracic Society (BTS) have been incorporated into the final document. The document is intended to provide the impetus for debate, improvement and maintenance of quality of diagnostic (rather than screening) spirometry in primary care. It should therefore challenge current spirometry performance – in order to raise standards – and act as an aspirational guide for delivery of this service.

Background literature: quality of spirometry performed in primary care

A literature search (keywords: 'spirometry'; 'quality'; and 'general practice or primary care or family practice') was undertaken, utilising the SCOPUS database (www.scopus.com) to identify papers that addressed three issues related to spirometry in primary care:

- the training received by primary care practitioners and the effect of this in practice
- the quality of primary care spirometry
- and whether any routine quality assurance is performed in this setting.

A recent survey by The British Lung Foundation (BLF) reported perceived difficulties with the accurate diagnosis of COPD and asthma; most of the 750 UK general practitioners (GPs) surveyed reported difficulty differentiating between asthma and COPD, as did their specialist colleagues who were surveyed.²⁷ Over 75% of these GPs owned or rented spirometers and in most cases spirometry tests in their practices are performed by nurses or health care assistants.

Whilst the survey did not elicit the level or quality of training, or the standard of proficiency attained by staff doing spirometry, less than a quarter of the GPs stated that they were formally trained to carry out spirometry testing themselves – unsurprising in view of the above – and more than a quarter had no training to interpret spirometry tests. Another recent UK survey found that only 20% of primary care nurses who always used spirometry to diagnose COPD had undertaken formal accredited training.²⁸

Training and effectiveness of spirometry in general practice

'Training' relates to the technical skills of the person conducting the test and also to the level to which patients are 'trained' or coached in performing the inspiratory and expiratory manoeuvres. In 1999 Eaton *et al.* studied the quality of spirometry in 30 randomly selected primary care practices.¹⁹ While significantly more spirometry tracings were of acceptable quality during the 16-week study (according to ATS Standards at the time), only 33.1% and 12.5% of patient tests, in groups with and without training, respectively, achieved the required minimum of two acceptable blows. Other studies at that time showed unacceptable variance between tests performed in primary care and those performed in pulmonary function laboratories.^{29,30} However, more recent studies have demonstrated that, with adequate and appropriate training, primary care practitioners are able to obtain high quality tests,^{21,31} to the extent that trained assistants performed better than trained technicians.²¹

Quality of primary care spirometry

From the primary care studies evaluated, the quality of spirometry performed by untrained personnel (GPs and nurses) varies. A number of primary care studies demonstrate that spirometry does not always meet good quality standards,^{29,30,32} whereas others achieve specialist standards.^{21,31} In a comparative study, trained nurses performed better than 'usual care' GPs, although ATS spirometry standards for acceptability and reproducibility⁶ were met in only 76% and 44% of cases, respectively.³³ The technical adequacy and accuracy of interpretation of primary care spirometry varies from unacceptable in one study¹⁸ to technically adequate in another (71% of 368 tests performed in 12 practices²⁶). However, most would argue that a level of 71% technically adequate tests falls short of an acceptable diagnostic standard.

Tuomisto *et al.* retrospectively assessed the quality of spirometry tracings enclosed with referral letters from Finnish GPs.³⁴ Whilst this paper does not provide information on the level of training acquired by those doing spirometry, the authors concluded that the majority of spirometry tracings were of a high standard. Conversely, den Otter *et al.* demonstrated that primary care spirometry does not always meet good quality standards.³²

Quality assurance in primary care

No formal studies of routine assessment or quality assurance of primary care practices providing spirometry could be found in the literature. White *et al.* studied the level of agreement between GPs and specialists in the assessment of quality and interpretation of spirometry.¹⁸ In 312 spirometry test results from six general practices there was significant disagreement in the interpretation of the quality of the tracings, the diagnosis, and the severity of airflow obstruction. In another study,³⁵ 28.6% of incorrect test manoeuvres were not recognised by GPs, and only 66% of their interpretations agreed with that of an expert panel. Therefore quality assurance of spirometry performed in primary care is highly desirable.

More data on the quality of training and competence in performing and interpreting spirometry is needed. However, it appears from the available data that the proportion of unacceptable tests performed in primary care is likely to be too high.

Recommendation: Individuals conducting spirometry should be trained and competent (accredited) in performing (and ideally, interpreting) the tests.

Recommendation: There is a need for systems for assessing the quality of spirometry tests, either by direct observation by trained individuals or by building in practical guidance in the form of immediate, software-driven feedback during the test procedure.

Spirometry equipment, provision of service, and quality assurance

Despite comparisons of spirometers using test rigs³⁶ there are few clinical comparisons of the performance of different spirometers.^{37,38} However, differences in forced expiratory volume in one second (FEV₁) and forced vital capacity (FVC) recordings between different types of office spirometers have been reported. Therefore, wherever possible sequential testing should be done using the same spirometer.^{16,39}

Types of spirometer

Flow vs. Volume

Currently most spirometers are flow-measuring devices. They are relatively low cost, and are small, more portable, and more widely available than volume-measuring devices.

Types of flow-measuring devices are:

- (i) Turbine/rotating vane,
- (ii) Pneumotachograph (Lilly or Fleisch type), or
- (iii) Ultrasonic designs.

All three types have their merits and drawbacks and each practice should seek advice from independent experts (e.g. local lung function technologists, local practice nurse expert or respiratory nurse specialist) about which device will best suit their requirements.

Hand held vs. bench top or personal computer/ electronic patient record-based spirometers

Stand alone, hand-held devices should be discouraged in favour of devices that allow data download and incorporation into medical records, and/or enable hard copy printouts of the results. For a practice-based service, bench top devices can be utilised at a 'spirometry station' where calibration, printing and patient safety can be upheld. Where data are stored electronically, this must be password protected.

Choosing a spirometer

The spirometer needs to be reliable and accurate. In particular, when switched on and left alone, the flow and volume output of the spirometer should be stable. The capital and running costs (consumables) of a spirometer need to be considered. Other desirable attributes include portability, robustness, ease of use, ability to upload data to a computerised medical record, and a real time graphical display which provides immediate patient and operator feedback on the acceptability of the patient's effort. The nature of the report format, including transferability to primary care computer systems, also needs to be considered. Reporting facilities need to be in line with international standards (see Table 1). Since many individual countries provide recommendations or 'buyers guides' for equipment, we have not referenced these here; the information can be obtained by searching the internet on 'Buyers Guide for Spirometers' by country.

In addition to equipment considerations, general practices will also need to think about:

- How the spirometer will be used (what categories of patients, referral processes).
- Who will be conducting and interpreting the tests (with consideration of training needs); ideally the same person should do both tasks.
- How many tests will be undertaken and whether this will be sufficient to maintain operator skills.
- If practices decide to perform spirometry on young children, computer software providing incentive graphics

to encourage children to perform the test are essential – e.g. an image of a lighted candle to blow out, or a fairground 'hammer and gong'.

Recommendation: Spirometer manufacturers or agents should provide a report or publication showing that their instrument complies with ATS or ATS/ERS specifications.⁶

Provision of spirometry; primary care or laboratory?

Whilst an expert service may be ideal, this may not be a practical solution for many primary care providers. Furthermore, given the prevalence of respiratory disease managed in primary care, there is a role for practice-based spirometry. This should include rigorous, assessed training for personnel, and high levels of quality control. The decision to undertake a practice-based spirometry service should include consideration of the realistic costs (both capital and revenue) necessary to deliver a service of reliably good quality.

Recommendation: Tests of pulmonary function require maximal subject co-operation and effort and therefore should be administered by trained, competent (accredited) and experienced personnel who are able to assess the correct performance of the test by the patient and the quality of the resultant tracings before the patient leaves the premises. This will avoid the need for patient recall if problems are identified during interpretation at a later stage.²²

Recommendation: Commissioners should ensure that local providers of spirometry meet quality assured standards. If the service is not able to be provided in a local primary care setting, alternatives should be commissioned to ensure patient safety. These could include utilisation of locally commissioned practice spirometry services or provision of a fully interpreted spirometry service with trained and experienced technicians.^{22,32,40,41}

Table 1. Choosing a spirometer: Features and Considerations.

Essential features	Desirable features	Considerations
Volume range: 0 to 8 litres (+/- 3% or 50 ml)	Display shows real-time, volume–time graphic and/or flow–volume curve *	Costs (capital and revenue)
Flow range: -12 to +12 L/s (+/- 5% or 0.2 L/s)	Hardcopy printout of all efforts produced (directly to printer or via personal computer)	Reliability and accuracy
Resistance: below 0.15 kPa per L/s (0 to 12 L/s)	Measures peak expiratory flow (PEF)	Complexity and ease of use (hardware and software)
Must measure/calculate: FEV ₁ , FVC, FEV ₁ /FVC, FEV ₁ /VC	Quality acceptance criteria.	Portability, size, robustness
Calibration: 1-L or 3-L syringe (with verification that test is acceptable)		Ease of cleaning; infection control measures
		Quality of the software

* Number-only displays are only of use for monitoring after reliable quality spirometry has been performed.

Quality control and governance

Calibration or verification with an annually certificated calibration syringe needs to take place at every spirometry session, or after every 10 patients for a busy service. The weekly use of biological controls (achieved by the use of a stable healthy individual⁴² as detailed in Box 1) is a less reliable method of checking long term stability of spirometers.

Careful and regular use of a spirometer should make the user familiar with common warning signs about its performance. Attention should be paid to unusual, sudden changes in performance. Keeping a simple log of problems is usually a good way to recognise faults that may develop or that may be common to that device.

The spirometer should be carefully checked after cleaning. Errors can occur at this time due to water penetration or faulty re-assembly. Any damage, breaks or dropping of devices will require checks to be made to confirm good performance.

Recording of test conditions is vital for accurate and repeatable spirometry. Expired gas should be corrected to body temperature and humidity (BTPS);^{6,43} the manufacturer should provide details of how this is determined. The patient's medication history prior to measurement, the time after their last meal, their position (preferably sitting) and patient cooperation should all be recorded. An example of a template that can be used for this purpose is shown online as Appendix 1 (available at www.thepcrj.org). This could be attached to each spirometry result to assist interpretation.

Infection prevention and control

Recorded cases of infection transmission from spirometry equipment, between patients, and between patients and staff, are rare.^{44,45} Cross contamination through mucosal contact with spirometry equipment and aerosolisation of infective

Box 1: Determining the normal range for a biological control.

- The person used as a biological control must be healthy and free of known respiratory disease
- Record your own spirometry every day (or that of a colleague if you have a respiratory condition) at the same time of day, on the same spirometer for 14 days. You will need a minimum of 10 recordings.
- Calculate the mean (average) for each spirometry parameter: i.e. add up all the readings for that parameter and divide by the number of recordings (e.g. mean 3.60 L).
- Now calculate 2.5% of the mean (i.e. $3.6 \times 0.025 = 0.09$ L):
- Finally, obtain the normal range for repeated measurements by adding and subtracting this 2.5% value to the mean value (i.e. $3.6 - 0.09 = 3.51$ L; and $3.6 + 0.09 = 3.69$ L so the acceptable range for the person tested would be 3.51 L to 3.69 L)

You can now use this person to check that the spirometer readings fall within this range to verify the accuracy of your spirometer on a weekly basis.

particles during forced expiratory manoeuvres are the main potential sources of infection.^{46,47} Measures to reduce the risk to both staff and patients⁴⁸ are summarised in Table 2.

Cross infection is more likely when inspiratory manoeuvres are undertaken. This is not routinely undertaken in primary care settings, but it can be difficult to prevent accidental inhalation through the equipment. Therefore disposable, valved mouthpieces should be used. If inspiratory manoeuvres are undertaken, disposable antibacterial and viral filters must be used.

Indications and contraindications

Clinical indications for spirometry

Respiratory symptoms are often non-specific. The indications

Table 2. Infection prevention and control measures. (Adapted from ref 6).

Infection transmission	Likely sources of contamination	Risk reduction
Direct contact – URTI, enteric infections, blood borne infection (from bleeding gums or mouth ulcers / sores)	<ul style="list-style-type: none"> • Mouthpieces • Nose clips • Tubing, flow heads 	<ul style="list-style-type: none"> • Do not test patients with known infection, if possible. <ul style="list-style-type: none"> - If tests are necessary, test potentially infectious patients at the end of a session and dismantle and sterilise equipment after use - Test vulnerable patients (e.g. immunocompromised) at the start of a session on newly sterilised equipment
Indirect contact (aerosol droplet) – TB, viral infections, opportunistic infections, nosocomial pneumonia	<ul style="list-style-type: none"> • Mouthpieces • Tubing 	<ul style="list-style-type: none"> • For infection control in these patients, use disposable nose clips and valved mouthpieces with an antibacterial filter. • Wash hands before and after handling equipment and between patients • Use disposable plastic gloves for handling mouthpieces and potentially contaminated surfaces • Wash surfaces in contact with mucous membranes in hot soapy water prior to decontamination and disinfection.

Box 2: Indications for spirometry.

Spirometry (in addition to other investigations) should be considered for:

- Patients presenting with undiagnosed respiratory symptoms:
 - Dyspnoea
 - Wheeze
 - Cough
- Patients with suspected COPD, in particular those with a positive smoking history and:-
 - Increasing age
 - Chronic cough
 - Breathlessness on exertion, and
 - Daily wheezing⁵²
 - History of recurrent winter 'chest infections'⁵³
- Diagnosis of COPD
 - *post-bronchodilator spirometry is required for QOF payment in the UK
- Monitoring patients with established COPD
- Diagnosis of asthma⁵⁴

*As stated in the NICE COPD Guideline:⁸ "In most patients, routine spirometric reversibility testing is not necessary as a part of the diagnostic process or to plan initial therapy with bronchodilators or corticosteroids. Making a diagnosis relies on clinical judgement based on a combination of history, physical examination and confirmation of the presence of airflow obstruction using spirometry."

for spirometry are summarised in Box 2.

Spirometry is an effective test for differentiating obstructive from non-respiratory disease. True restrictive ventilatory defects – i.e. conditions leading to an abnormally low total lung capacity (TLC) – are uncommon. An analysis of the Health Survey for England 1995-1996 data found that a 'restrictive pattern' compatible with a restrictive ventilatory defect occurred exclusively in 2.5% of symptomatic subjects and/or smokers (Personal communication, Philip Quanjer). Therefore this condition should only be considered if there is clinical evidence of it. Restrictive disease cannot be diagnosed solely by spirometry, but can be excluded in the case of a normal vital capacity (VC).

Recently there has been a great deal of interest in screening for early, asymptomatic COPD in primary care.⁴⁹ Focussing spirometry screening on smokers with chronic cough has been shown to be effective.³¹ Questionnaires are also an effective approach to screening.⁵⁰⁻⁵³

In the case of asthma, the British⁹ and International⁵⁴ guidelines emphasise the use of spirometry as part of the diagnostic process. Since many of these patients are children, there will be additional requirements for staff training for this purpose, including the use of graphic incentives during the test process.

Contraindications to spirometry

Spirometry is safe and there are no absolute contraindications. There are some relative contraindications⁵⁵ (see Table 3) where it might be advisable to delay testing or to seek advice from

the local pulmonary function laboratory.

Children under the age of five years are unlikely to be able to produce reliable spirometry and interpretation of the results can be complex.⁹ Referral to a specialist respiratory unit may be necessary.

Conducting the spirometry test

Competent spirometry requires adequate achievement of the following:

- Preparation of the equipment and patient
- Performance of the test to meet national/international standards
- Production of accurate results with reference values
- Interpretation of the results.

Preparation of the equipment

The spirometer should be calibrated or verified so that it measures accurately, and its software configured so that meaningful results can be produced. Adequate procedures for infection control and maintenance are essential.

Preparation of the patient

The patient needs to be prepared in advance in terms of criteria that can affect the results (e.g. tight clothing, same time of day if follow-up test, large meals, medication - if reversibility tests are planned). The patient should be seated for safety and any contraindications ruled out before progressing with the tests (see Table 3). Any unusual circumstances, conditions and events should also be recorded. Full bladders and stress incontinence may cause underperformance.

Performing the test

Some key points for performing spirometry and instructing a patient to perform a test using a forced expiratory manoeuvre^{24,56,57} are shown below:

- i) Measure the patient's height*and weight, and enter their date of birth and gender into the spirometer software. (*Self-reported heights should not be used.⁵⁸⁻⁶⁰)
- ii) Attach a new, disposable, one-way mouthpiece to the spirometer. (If the patient has an infection or if inspiratory manoeuvres are planned, a bacterial filter must be used.)
- iii) Place a nose clip on the patient, or instruct him/her to pinch the nose closed.
- iv) Instruct the patient to breathe in and out normally and then to inhale deeply through their mouth until the lungs feel absolutely full, and then while holding their breath, to seal their lips tightly around the mouthpiece.
- v) *With the minimum of delay between inhalation and exhalation, instruct the patient to blow the air out through the mouthpiece as forcefully and as fast as possible, using maximum effort, until there is no more air left to expel. Verbally encourage the patient to "keep blowing and keep blowing" until there is no more. (See below for instructions*

Table 3. Relative contraindications to spirometry. (Adapted from ref 6).

Relative contraindication	Rationale
Known or suspected respiratory infection	Potential contamination of equipment and cross infection risk Results unlikely to be meaningful, reliable or reproducible
Haemoptysis of unknown origin	Exacerbation of the problem and possible major haemorrhage. Possible active pulmonary tuberculosis leading to contamination of equipment and cross infection risk
Pneumothorax	Aggravation of the condition
Unstable cardiovascular status: recent (within 1 month) myocardial infarction, uncontrolled hypertension or pulmonary embolism	Forced expiration can worsen angina or cause potentially dangerous blood pressure changes
Uncontrolled hypertension or history of haemorrhagic cerebrovascular event	Precipitation of cerebral bleed
Recent thoracic, abdominal or eye surgery	Pain or incisional hernias. Raised intraocular pressure post ophthalmic surgery undesirable
Nausea, vomiting or pain	Effect on patient's ability to co-operate and perform the test
Confusion, dementia	Unlikely to be able to comply with instructions

Spirometry performed during an acute condition, be it an exacerbation of asthma, COPD or any other condition, should be repeated when the patient appears to be in stable condition. Expert opinion states that spirometry performed during the acute phase of a COPD exacerbation should be repeated after a suitable time period of 6-12 weeks. (The 6-12 weeks is arbitrarily chosen and further research is needed).

for performing a slow/relaxed VC manoeuvre.)

- vi) Carefully observe the patient throughout the procedure to make sure a good mouth seal around the mouthpiece is achieved, that there isn't a 'slow start' or any pauses while blowing, and that the patient has not coughed.
- vii) The patient should be encouraged to continue blowing continuously, without taking additional breaths, until a plateau has been reached on the volume/time graph. The end of the test should show a smooth plateau free from artefacts such as intermittent inhalation.
- viii) The spirometer should be set to indicate whether the tests meet the current standards for repeatability. Currently this means that the two largest FEV₁ and FVC (or other VC) readings must be within 150mL of each other.

It is good practice to do an initial slow (or relaxed) vital capacity manoeuvre. To do this, substitute the following instruction for point v) above:

With the minimum of delay between inhalation and exhalation, instruct the patient to blow the air out through the mouthpiece in a slow relaxed manner, continuously, without taking another breath, until there is no more air left to expel. Verbally encourage the patient to "keep blowing and keep blowing" until there is no more.

Whilst spirometry software will indicate whether many of the repeatability criteria are met, the operator must be trained to observe whether the test has been performed correctly. For a further example of instruction for patients see <http://www.spirxpert.com/performing2.htm>.

Interpretation

What follows is a detailed explanation of spirometry

interpretation. This is intended for those practitioners who have had training in performing and interpreting spirometry, as well as those clinicians (such as GPs or Nurses with a special interest in respiratory disease) who are practising at a more advanced level. For those health professionals wishing to access summary information, the GPIAG opinion sheet⁶¹ and the versions published on the GOLD website^{56,57} may suffice.

Reference values

Pulmonary function tests are not pathognomonic of any particular disease; interpretation begins with a differential diagnosis defining the pre-test probability of disease, which is assessed clinically. Results are then compared with reference values, appropriate for age, height, gender and ethnicity.

The European Community for Steel and Coal (ECSC) reference values⁴³ are most commonly used in European populations. Other equations are those from Hankinson⁶² (for white, African and Latin-American people age 8-80 yrs), Stanojevic⁶³ (for white people age 4-80 yrs), and Falaschetti⁶⁴ (for white people age 16-95 yrs). It is customary to use 'correction factors' (i.e. to multiply with derived indices) for other ethnic groups (see Table 5) but these are just 'ballpark' figures that correct for the average predicted value and not for the clinically more important Lower Limit of Normal (LLN). Free software with documentation for all ethnic groups is available.⁶⁵ Whichever reference values are chosen, it is common practice to regard values below the 5th percentile - the LLN - as abnormally low.⁶⁶

Indices

The spirometry indices used in primary care should be limited to a few key measurements, as detailed in Table 4. The FEV₁/slow vital capacity (SVC), FEV₁/FVC, or FEV₁/inspiratory

Table 4. Spirometry indices (Common indices used in primary care are listed in this table, in addition to some that might be reported by a specialist service providing spirometry).

PEF	Peak expiratory flow is the measurement of fastest flow measured by either a spirometer or peak flow meter. Because of equipment design these values vary from device to device and therefore, repeated PEF measurements should be done on the same device.
FET	Forced expiratory time is the total time it takes for a patient to complete their exhalation in a FVC manoeuvre.
FEV ₁	Forced expiratory volume in 1 second is the amount of air blown out fast in the first second following a maximal inhalation.
FVC*	Forced vital capacity is the amount of air blown out fast following a maximal inhalation (i.e. at total lung capacity) to empty (residual volume) in up to 12 seconds.
IVC*	Inspiratory vital capacity is the inspired volume after a maximal exhalation. This is not usually performed in primary care, and if measured must always be done using a filter.
SVC*	Relaxed or 'slow' vital capacity is the total expired volume from a point of maximum inhalation (at total lung capacity) by a "gradual exhalation but with some pace" to being 'empty' at residual volume.
FEF ₂₅₋₇₅ , MEF ₅₀	This is the mid expiratory flow between 25-75% of an expired blow (or 50% respectively) and is an indication of flow in the middle of an expiratory flow-volume curve. It used to be regarded as a more sensitive index of airflow obstruction. However, the reference ranges are often too great for these numbers to be helpful. 'Shape recognition' of a flow-volume curve is a more powerful tool to describe the presence of the obstruction.
Residual volume	This is the volume of gas remaining in the lung at the end of a full expiration. Only available in a lung function laboratory.

* While the IVC is the best measure, this is not often performed in primary care. In primary care the SVC should always be measured, as well as the FVC. The ratio (FEV₁/VC) should be calculated using whichever is the higher of the VC measurements obtained (FVC or SVC).

vital capacity (IVC) ratios are used to determine whether there is airways obstruction, and FEV₁ expressed as a percentage of the predicted/reference value is used to assess the severity of the airways obstruction (see Tables 5 and 6). The IVC, which is the gold standard vital capacity test, should only be performed in facilities where antibacterial filters are used, in order to reduce the risk of transmission of infection.

Using the indices - interpreting the results

Ratio of FEV₁ to vital capacity

The ratio of FEV₁ to all three of the vital capacity measurements (i.e. FEV₁/IVC, FEV₁/SVC, FEV₁/FVC) identifies the presence of airways obstruction – the FEV₁/IVC being the most and the FEV₁/FVC the least reliable of the three. While any of these ratios may be used in practice, it is uncommon for the inspiratory manoeuvre (which provides the most reliable measure of vital capacity) to be performed in primary care. Furthermore, while it is good practice, an SVC manoeuvre is not always performed in primary care. In primary care, therefore, whilst the FEV₁/SVC should be preferred, in the absence of a slow manoeuvre the FEV₁/FVC is the next best. If both SVC and FVC have been determined, use the largest one for the FEV₁/VC ratio.

Recommendation: In primary care the SVC should always be measured, as well as the FVC. The ratio (FEV₁/VC) should be calculated using whichever is the higher of the VC measurements obtained (FVC or SVC).

Percent predicted and 'normal distribution' of test results

The ATS and ERS^{43,66,67} recommend that an FEV₁/IVC, FEV₁/FVC or FEV₁/SVC ratio below the lower limit for age, height, sex and ethnic group is the best indicator of the

Table 5. Adjusting Caucasian reference values to other ethnic groups. To apply these, multiply FEV₁ and FVC by the factors. (Modified from ref 4).

Population	FEV ₁	FVC
Hong Kong Chinese	1.0	1.0
Japanese American	0.89	-
Polynesian	0.9	0.9
N. Indian and Pakistani	0.9	0.9
S. Indian, African	0.87	0.87

Table 6. Severity of airway obstruction based on the FEV₁ as a percentage of the predicted/reference value.

Degree of severity	FEV ₁ % predicted/reference value
Mild	> 80
Moderate	50-79
Severe	30-49
Very severe	<30

presence of any airways obstruction. In agreement with this recommendation, the GOLD Guidelines¹⁰ – which originally recommended an FEV₁/FVC ratio below 0.70 as indicative of obstructive lung disease – state:

"...because the process of aging does affect lung volumes, the use of a fixed ratio may result in over diagnosis of COPD in the elderly, especially of mild disease. Using the lower limit of normal (LLN) values for FEV₁/FVC, that are based on the normal distribution and classify the bottom 5% of the healthy population as abnormal, is one way to minimize the potential misclassification".

In keeping with the ATS and ERS recommendations – in order to avoid over-diagnosing (and therefore over-treating) elderly patients, and under-diagnosing younger patients – the GOLD guidelines¹⁰ now state that:

“...many experts recommend use of the lower limit of normal for each population”.

There is extensive evidence and argument that interpretation of pulmonary function tests should take into account the ‘distribution of normal’ test results in a population and thus inevitably rely on the lower limit of normal. This precludes the use of a fixed cut-off irrespective of age, height, gender and ethnic group.^{62,64,65,67,68-81}

Recommendation: Interpretation of pulmonary function tests should take into account the distribution of ‘normal’ test results in a population and will thus inevitably rely on the lower limit of normal (LLN), precluding the use of a fixed cut-off irrespective of age, height, gender and ethnic group.^{64,68-81} Implementation of this methodology will avoid over-diagnosing (and therefore over-treating) elderly patients, and under-diagnosing younger patients.

Standardised residuals

An alternative to the use of ‘percent predicted’ for reporting spirometry results is to encourage the use of standardised residuals (SR)^{6,68}. The standardised residual (also called z-score or standard deviation score) is the difference between the observed and predicted value divided by the standard deviation of the predicted value. In a healthy population 95% of the measured values should fall between a standardised residual of -2 and +2, and 90% should fall between -1.64 and +1.64.

Forced expiratory volume in six seconds (FEV₆)

There has been recent research interest in the use of the FEV₆ in primary care^{6,82-84} and this is discussed in the GOLD guidelines.^{10,56} However, at the current time we do not see a clear physiological or clinical use for such a parameter. In the case of diagnostic spirometry, we believe the more accurate FVC to be a better reflection of lung function. The reasons for this stance are as follows:

Literature on the FEV₆ shows that for many people with no lung disease or mild lung disease, the FEV₆ will be the same as the FVC. However, for those with more significant disease the FEV₆ will underestimate airway obstruction. The FEV₆ was introduced to ensure that people tried to exhale for at least 6 seconds so as to prevent underestimating the FVC. While this period is no problem at all for patients with airway obstruction, it is unattainable for many healthy people, particularly young ones; most children and adolescents can exhale a full VC in less than 2 seconds. The requirement for spirometry is that people exhale fully and that this shows up in a volume-time plateau. Whether this occurs within or after 6 seconds is not relevant. In patients

with severe airway obstruction the expiratory manoeuvre should not be extended beyond 10-15 seconds.

Recommendation: The person performing a spirometry test must ensure the patient exhales fully and that this is demonstrated on the graph showing a volume-time plateau.

Report format

As presentation of spirometry results varies from one manufacturer to another, it seems sensible for these to be reported in a uniform manner. For example, presentation of results could include figures related to the indices, tabulated by the pre- and post-bronchodilator values listed under the headings of ‘Actual’, ‘Predicted’, lower limit of normal (LLN), standard deviation score (SDS) and the level of severity, together with a graphic representation. For an example of a suggested output see Appendix 2, available at www.thepcrj.org.

Recommendation: Spirometry reporting across health care communities should be provided in an agreed and uniform manner, ideally involving use of FEV₁, FVC or SVC and using data highlighting lower limit of normal values.

Diagnostic considerations and timing

Due consideration should be given to the consequences of a false-positive or false-negative diagnosis; recent bronchodilator use and bronchodilator responsiveness should be taken into account and documented on the trace of the test.⁸⁵ Using the stepwise approach shown in Figure 1 may help avoid over-diagnosis.⁸⁶

Diagnoses should be based on prior evidence of disease, clinical symptoms and signs, and good quality spirometry. A diagnosis of a restrictive ventilatory defect requires referral for measurement of the TLC in a specialised laboratory; the centre box in Figure 1 has been shown to lead to high sensitivity and high specificity,⁸⁶ and helps to limit unnecessary referrals. (The sensitivity of a test is the probability that the test will be positive when given to a group of patients with the disease. The specificity of a test is the probability that the test will be negative among patients who do not have the disease.)

Spirometric tests lead to the following patterns: obstructive, restrictive and mixed abnormalities.

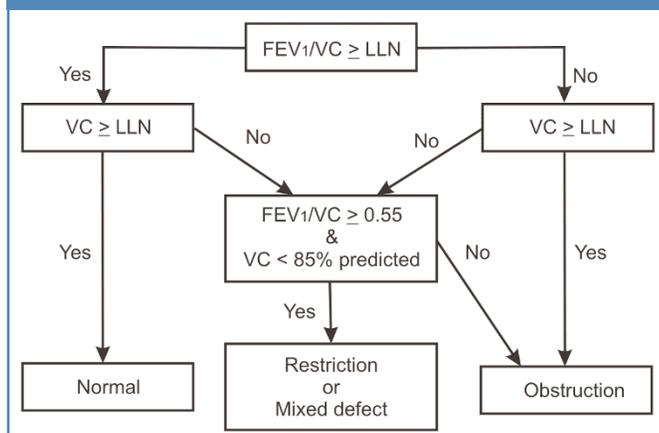
[In this section, for simplicity, reference is made to the VC – by this we mean the FVC, SVC or IVC, whichever is used in the particular situation where the spirometry is performed.]

Obstructive abnormalities

A reduction in maximum expiratory airflow relative to the maximum volume that can be expelled from the lung (the VC) reflects an obstructive ventilatory defect due to narrowed airways. In practice, the presence of airway obstruction is judged from the FEV₁/VC ratio.

Several organisations sought to simplify the diagnosis of airflow limitation by replacing the LLN with a fixed cut-off of

Figure 1. Schematic diagram for diagnosing airway obstruction, restrictive ventilatory defects and mixed defects. (Adapted from ref 86 with permission from the editor of *Chest*).



0.70.^{8,10,87,88} However, as mentioned above, since the FEV₁/VC ratio is dependent on age, height and sex, this leads to about 100% over-diagnosis of obstructive lung disease in elderly subjects, and to under-diagnosis in young subjects.^{64,66,69-81} Therefore, the presence of obstructive lung disease should be based on an FEV₁/VC ratio below the LLN.

As the IVC is less affected by airway obstruction than the FVC or SVC, the Tiffeneau index (FEV₁/IVC) is the preferred index in laboratories that routinely utilise inspiratory manoeuvres. It identifies more cases of airway obstruction than the forced expiratory ratio (FEV₁/FVC).^{66,89,90} However, in order to avoid cross-contamination the IVC is less practical in primary care, and as stated above, the best alternative ratio is the FEV₁/SVC.

Diminished expiratory flow towards the end of the forced expiratory manoeuvre, due to narrowing in the smallest airways and leading to a concave expiratory flow-volume curve, is thought to be the first sign of chronic obstructive lung disease. Therefore, flow measured after 75% of the FVC has been exhaled (FEF₇₅), or mean expiratory flow between 25% and 75% of the FVC (FEF₂₅₋₇₅) have been used to diagnose airway obstruction. These were not found to have advantages over the FEV₁/VC ratio. In advanced obstructive lung disease the VC will be reduced, but not in proportion to the FEV₁.

Restrictive and mixed abnormalities

The results of pulmonary function tests are highly dependent on patient co-operation. Premature termination of the FVC manoeuvre, or failure to take a maximal inhalation, can result in a high FEV₁/FVC ratio. A normal or high FEV₁/FVC ratio when the FVC is too low is most often due to incomplete inhalation or exhalation.⁶⁶

A TLC below its LLN is the hallmark of a restrictive ventilatory defect.⁶⁶ If not accompanied by airway obstruction

the following pattern of spirometry is observed:

- normal or increased FEV₁/VC* ratio
 - low VC, and
 - a convex expiratory flow-volume curve.
- *(VC may be FVC, SVC or IVC)

As explained above, however, this pattern of findings is usually due to suboptimal performance of the inspiratory or expiratory manoeuvre.⁶⁶

A true restrictive ventilatory defect may occur concurrently with airway obstruction if the TLC and FEV₁/VC are both below their LLN. This represents a mixed ventilatory defect, i.e. restriction and airway obstruction.⁶⁶ This diagnosis cannot be made on the basis of spirometry alone because the VC may be reduced due to airway obstruction without restriction. If tests are satisfactorily performed and the TLC is unknown, (which is often the case in the primary care setting), a restrictive ventilatory defect should only be considered if:

- FEV₁/VC > 0.55, and
- FVC < 85% predicted.⁸⁶

In these cases, if there is clinical evidence for restrictive lung disease, referral to a pulmonary function laboratory with facilities to measure TLC and gas transfer is recommended.

Figure 2 shows a summary of the types of ventilatory defects and their diagnoses seen on flow-volume spirometry curves.

Upper and central airway obstruction

Where inspiratory curves are included, in rare cases the flow-volume curves may be indicative of central and upper airway obstruction (Figure 3). Referral to secondary care for confirmation of the diagnosis is recommended.

Severity of impairment

Lung function impairment has bearing on exercise capacity, disability and employment compensation, quality of life, morbidity and mortality.⁹¹ In several studies, FEV₁, post-bronchodilator FEV₁, post-bronchodilator FEV₁ percent predicted and FEV₁/height² were found to correlate best with all-cause mortality.⁹²⁻¹⁰⁴

For general purposes the severity of lung function impairment is based on FEV₁ percent predicted (Table 5), the scaling of which is arbitrary.⁶⁶ The scaling does not apply to upper airway obstruction; also, FEV₁ percent predicted correlates rather poorly with respiratory symptoms and quality of life.¹⁰⁵⁻¹⁰⁷

Bronchodilator response:

As stated in the NICE COPD Guideline⁸:

"In most patients, routine spirometric reversibility testing is not necessary as a part of the diagnostic process or to plan initial therapy with bronchodilators or corticosteroids. Making a diagnosis relies on clinical judgement based on a combination of history, physical examination and confirmation of the presence of airflow obstruction using spirometry."

Figure 2. Examples of expiratory flow-volume curves from a healthy subject, and in obstructive, restrictive and mixed pulmonary defects. Confirmation of restrictive defects (quite rare in general practice) requires measurement of the total lung capacity in a pulmonary function laboratory (right panel). (Reproduced from Quanjer *et al.*⁴³ with permission from the editor of the *European Respiratory Journal*).

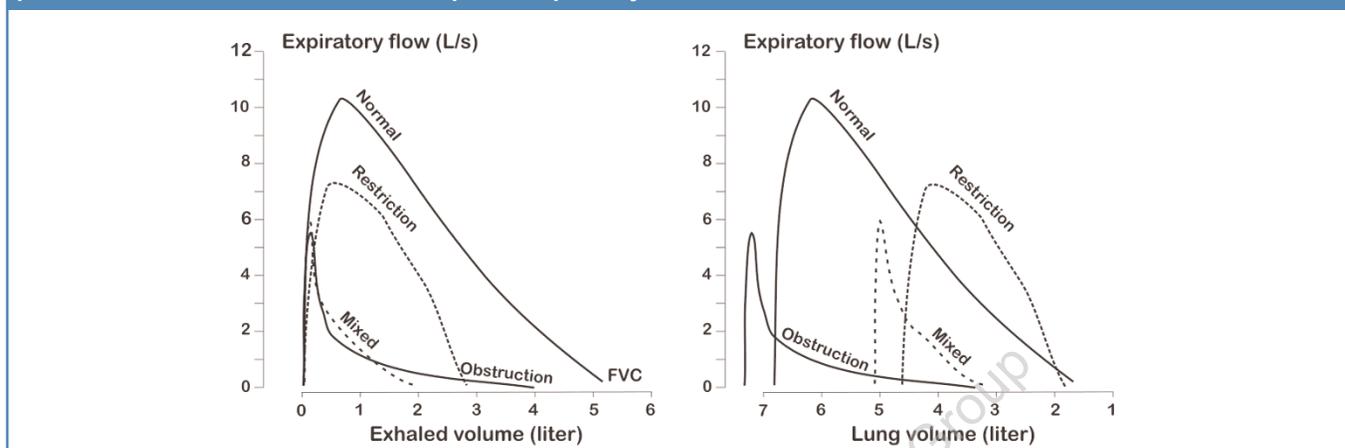
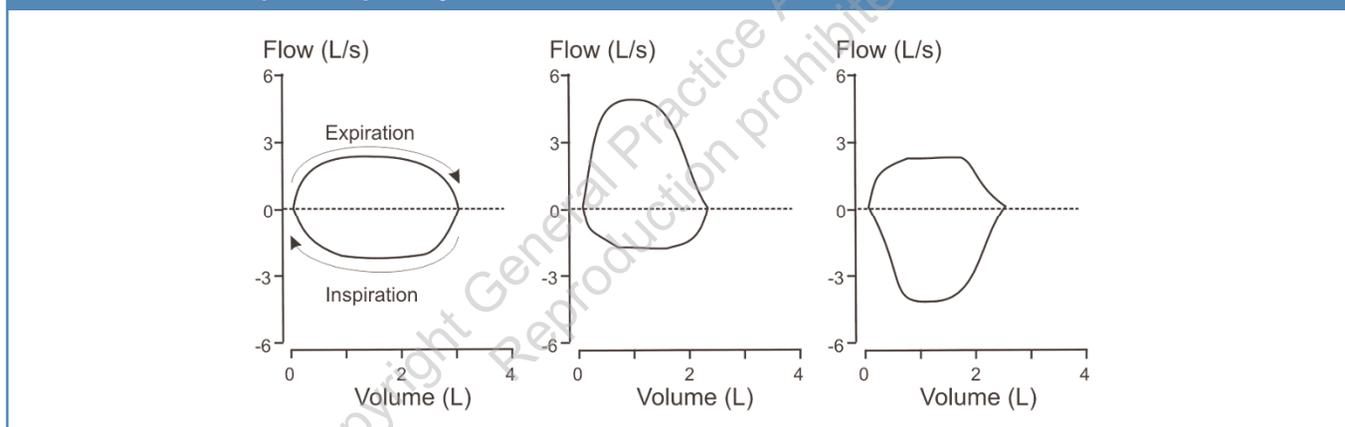


Figure 3. Examples of fixed large airway obstruction (left), variable large extrathoracic airway obstruction (middle) and variable intrathoracic large airway obstruction (right). (Reproduced from Pellegrino *et al.*⁶⁶ with permission from the editor of the *European Respiratory Journal*).



However, assessing the response to bronchodilator drugs is useful in assessing whether airway obstruction is reversible – a hallmark of asthma. Bronchodilator responsiveness is traditionally judged by an improvement in FEV₁.

Airway patency varies due to the circadian rhythm in biological functions and, in disease, to fluctuations in the activity of the disease process. Hence the response to a bronchodilator drug is generally poorly reproducible.¹⁰⁸⁻¹¹⁰ For the response to be regarded as positive it should exceed short term fluctuations in FEV₁ and the response in a healthy population. The effects of anti-inflammatory drugs can be assessed after a few weeks' treatment, whereas the effects of drugs that solely relieve bronchomotor tone can be studied within 15-30 minutes of inhalation, e.g. four separate doses of 100 mcg salbutamol by metered dose inhaler and spacer.

Bronchodilators do not reliably discriminate asthma from

COPD.^{108,110-116} Bronchodilator responsiveness is less in smokers than in non smokers,^{117,118} and correlates poorly with symptoms,¹¹⁹⁻¹²² prognosis and effects of treatment,^{109,122,123} and improvement in exercise capacity.¹²⁴ Conversely, lack of a significant response in FEV₁ can be associated with both significant improvements in resting and dynamic hyperinflation during exercise, and improvements in symptoms and exercise performance, particularly in severe COPD.¹²⁵⁻¹³²

According to most authors the improvement in FEV₁ in adults, expressed in mL, is independent of the baseline level. Hence, expressing the change as a percentage of the baseline FEV₁ exaggerates the response in those with the poorest FEV₁. Expressing the change in FEV₁ post-bronchodilator as a percentage of the predicted value eliminates this problem and adjusts for differences in lung size.^{108,109,117} A change > 12%

predicted and >200 mL^{109,133-137} during a single test session is accepted as denoting a statistically significant improvement. One guideline⁸ suggested, "on an arbitrary basis", that > 400 mL could be adopted as a clinically significant improvement following bronchodilation; however, against the background of published results¹³³⁻¹³⁷ it seems that this level is very strict indeed. In a clinical database (Erasmus University Medical Centre, Lung Department, Rotterdam) of 4,352 patients tested pre- and post-bronchodilator, a change in FEV₁ exceeding 400 mL was observed in 3.35% of patients, and > 200 mL in 14.96% of patients. As children have smaller lungs it has been suggested that the 200 mL criterion should be dropped.¹³⁵⁻¹³⁷

Recommendation: Post-bronchodilator spirometry:

- i) In the case of airway obstruction it is good practice to include post-bronchodilator spirometry testing, especially in newly-diagnosed patients.
- ii) In the case of diagnosis of COPD: post-bronchodilator spirometry is recommended by the GOLD and ERS/ATS COPD guidelines and is required to satisfy the requirements of the UK payment system for GPs – the Quality Outcome Framework (QOF).

Interpreting change

Tracking lung function changes over time within an individual is often more valuable than comparisons with predicted values. In healthy adults the decline of pulmonary function with age is about 20-35 mL per year. This is far smaller than the reproducibility of measurements made the same day, weeks or months apart. Small systematic errors – e.g. due to calibration or use of different apparatus – easily exceed the small annual declines.¹³⁸⁻¹⁴⁰ Establishing whether a decline is abnormal therefore requires many measurements over a number of years.^{138,141}

In patients with lung disease, variability in repeated measurements is larger than in healthy subjects;^{139,142,143} the coefficient of repeatability for FEV₁ between two visits has been estimated at 320 mL for men and 240 mL for women.¹⁴⁴ In another study, over 90% of participants had an inter-session difference of less than 225 mL in FEV₁, and 325 mL in FVC, irrespective of the severity of obstruction.¹⁴⁵ Therefore, in adults with lung disease, changes exceeding these figures are likely to be clinically meaningful.

Referral

In view of the unfavourable consequences for patients incorrectly diagnosed, whenever a primary care clinician is unsure of the diagnosis, referral is appropriate.

There are three clear situations in cases where abnormal primary care spirometry should prompt referral to specialist respiratory services for more detailed pulmonary function testing:

Recommendation: Where facilities to undertake or interpret spirometry are not available, or where clinicians feel uncertain in their diagnosis, referral to more specialised services is appropriate.

Recommendation: In cases where there is clinical and spirometric evidence for restrictive lung disease, referral to a pulmonary function laboratory with facilities to measure Total Lung Capacity (TLC) and gas transfer is recommended in order to confirm the diagnosis.

Recommendation: In cases where there is clinical or spirometric evidence of central or upper airway obstruction, referral to secondary care for confirmation of the diagnosis is recommended.

Quality control and training

Spirometric tests need to be administered by trained, experienced and preferably certified personnel. The European Respiratory Society is starting a certification programme for technicians and laboratories. Equipment, the administration of tests, the quality control of equipment and individual FVC manoeuvres, as well as the repeatability of FEV₁ and FVC should comply with ATS/ERS recommendations.⁶

It is therefore highly recommended to use equipment that provides online feedback on within- and between-manoeuve acceptability in accordance with ATS/ERS recommendations (see Table 7). In addition the software used should provide the LLN for FEV₁, FVC and FEV₁/FVC, since the diagnostic process should be based on the LLN (Figure 1), and on FEV₁ percent predicted for assessing the severity of airways obstruction⁶ (see Table 4).

The BLF survey concluded that primary care health professionals may have difficulty in acquiring enough expertise in differentiating these diseases.²⁷ However, greater routine application for diagnostic purposes should enable trained primary care staff to gain the necessary experience, obviating the need for referral to services for appropriate testing and interpretation. Nevertheless, in the absence of adequately trained and experienced primary care personnel it would be appropriate for patients requiring spirometry to be referred for testing and interpretation.

Over-reading services

While there is no substitute for accredited training and demonstrated competence by people performing and interpreting spirometry, quality control would be of benefit in determining the need for remedial training. For example, practices may benefit from a spirometry 'over-reading' service, where reports are sent for expert review. This would facilitate quality control of spirometry tests and their interpretation.

The use of one expert computer system has proved disappointing,³⁵ but this study did highlight that participating

Table 7. Summary of within- and between-manoeuve acceptability criteria. Reproduced from Miller *et al.*⁶ with permission from the Editor of the *European Respiratory Journal*.

Within-manoeuve criteria

Individual spirometers are "acceptable" if

- They are free from artefacts such as:
 - Cough during the first second of exhalation
 - Glottis closure that influences the measurement
 - Early termination or cut-off
 - Effort that is not maximal throughout
 - Leak
 - Obstructed mouthpiece
- They have good starts:
 - Extrapolated volume <5% of FVC or 0.15 L, whichever is greater
- They show satisfactory exhalation:
 - Duration of ≥ 6 s (3 s for children) or a plateau in the volume time curve or
 - if the subject cannot or should not continue to exhale

Between-manoeuve criteria

After three acceptable spirometers have been obtained, apply the following tests:

- The two largest values of FVC must be within 0.150 L of each other
- The two largest values of FEV₁ must be within 0.150 L of each other

If both of these criteria are met, the test session may be concluded

If both of these criteria are not met, continue testing until:

- Both of the criteria are met with analysis of additional acceptable spirometers, or
- A total of eight tests have been performed (optional), or
- The patient/subject cannot or should not continue

Save, as a minimum, the three satisfactory manoeuvres

FVC: forced vital capacity; FEV₁: forced expiratory volume in one second

For schoolchildren (6–<12 yr) the acceptability criterion for FVC and FEV₁ should be 'within 5% FVC or <100 mL if FVC < 1000 mL'.

GPs failed to recognise poor spirometry technique in nearly 30% of cases studied. Clinical trials utilising centralised spirometry with training, technician accreditation and prompt feedback can improve the quality of data collected.^{146,147} Over-reading services can therefore work as a quality assurance system within a health care community and possibly help to educate those involved in spirometry.

Training and CPD recommendations

Minimum training requirement

Spirometry training needs to include: awareness of the issues related to delivery of the service; competence in performing the measurements; and competence in interpreting and reporting of results. Some or all of these components may be required depending on the model of service delivered in primary care (see Boxes 3 and 4). Furthermore, these tasks may be performed by different individuals. The key issue is that these individuals should be trained to agreed national or international standards in order to perform the task.

A new ERS Task Force on spirometry training requirements

Box 3: Basic training in spirometry.

- Spirometry equipment
 - calibration
 - infection prevention and control measures
- Patient preparation
 - indications and contraindications for spirometry
 - accurate recording of height and weight
 - checking and accurate recording of patient data
- How to conduct the test
 - patient instructions and demonstrating the technique
 - relaxed expiratory manoeuvres
 - forced expiratory manoeuvres
 - techniques for obtaining maximum effort from patients
- Test validity and reproducibility
 - recognising non-reproducible results
 - recognition of errors in technique, so the test can be repeated while the patient is still in the office.
 - methods of correcting errors in technique
- Preparation of test results for reporting
- "Troubleshooting" and some understanding of the results to know that the test is satisfactory.

Box 4: Advanced training for primary care health professionals.

Further education and training is needed for personnel responsible for interpreting spirometry results or for supervising others conducting the tests. This should include:

- Analysis of normal and abnormal patterns of spirometry
- Identification of errors in measurement and therefore that the test needs to be repeated.
- Supervision and quality control of others conducting spirometry tests
- Analysis of the relationship between patho-physiological changes in the lung and measurements obtained from dynamic lung volumes
- Ability to advise on subsequent patient management, based on the results of the spirometry.

will report in 2009. Discussions so far indicate the need for training – consisting of practical demonstration of competence in equipment maintenance and interpretation of results.^{19,21,148,149}

In the UK, the Association for Respiratory Technology and Physiology (ARTP), in conjunction with the BTS through the BTS/ARTP Liaison Committee, have established a qualification to assess the competence of practitioners to perform such measurements. The ARTP/BTS Certificate in Spirometry has been introduced to give a recognised national qualification for those practitioners who complete an approved spirometry assessment course - and this ARTP/BTS course is also provided by Education for Health (see Box 5). The standards required for attainment of this certificate include a recommendation that

Box 5: Education and Training organisations in the United Kingdom.

The following organisations offer ARTP approved spirometry training, resulting in the award of the ARTP/BTS Certificate

- ARTP/BTS Spirometry Courses and Assessment www.artpweb2.f9.co.uk
- Education for Health www.educationforhealth.org.uk (Spirometry module also accredited by the Open University – 15 level 2 CATS points)
- Primary Care Training Centre www.primarycaretraining.co.uk

Spirometry courses also available from:

- Respiratory Education UK www.respiratoryeduc.com (modules offered at diploma and degree level, accredited with University of Edge Hill)
- ERS European Spirometry Driving Licence which will be available within the next few years.
- Various spirometer manufacturers provide training. The quality of these varies – ideally they should be accredited by an appropriate body.

Basic training is often available locally

practitioners should have performed a minimum of 10-15 examples of varied disease types (obstructive, restrictive, errors). This is supported by one study which demonstrated a positive correlation between the number of spirometry tests performed and their acceptability.¹⁴⁸ The qualification requires on-going validation of competency which has to be renewed every two years. According to expert opinion at least five tests a week (20/month) would be adequate to maintain competence in staff who had achieved initial competence. Indeed, if spirometry in primary care becomes more routine, there should be ample opportunity for a satisfactory level of experience and expertise to be maintained in primary care. However, this will mean continuous investment in those primary care settings where trained spirometry staff (e.g. practice nurses) may stay for only a limited number of years – thus making the system “unstable” with varying quality over time – with the resultant need to ensure ongoing training of newly-employed staff.

Currently there is no requirement for accreditation of primary care practitioners performing spirometry and there is a need for widespread and easy access to specific training, tailored to their needs. It is necessary that those providing this service should be fully trained to do so. There are appropriate training courses in different countries; in the UK, the type of qualification offered by the ARTP/BTS qualification is one that could be considered for primary care practitioners – hence the rationale for making this type of qualification more widely available through training organisations other than the ARTP in order to widen access so that more practitioners are trained to acceptable standards.

Recommendation: Training should be subject to

assessment (according to national and international standards) and trainees should be able to demonstrate:

- sound knowledge of the role of spirometry in respiratory disease assessment
- competence and safe practice in both the technique and interpretation of spirometry.

Recommendation: Health communities need to develop clear recommendations on minimum standards for spirometry testing, and systems to ensure that appropriate training, updating and quality assurance are maintained to minimise inappropriate diagnosis and interventions to the patient population.

Conclusion

These proposals and recommendations are designed to raise the standard of spirometry and respiratory diagnosis in primary care. We believe high standards of spirometry are achievable in most managed health care systems. The guidance requires strategic managerial input to implement within communities, and individual clinician responsibility to ensure standards are achieved.

We recognise that, in a laudable effort to simplify the diagnosis of COPD in elderly subjects, organisations abandoned the scientifically sound use of the lower limit of normal (LLN) and advocated the use of a fixed FEV₁/FVC ratio to diagnose airway obstruction. However, there is overwhelming evidence for the massive overdiagnosis of disease in the elderly and underdiagnosis in young subjects when using a fixed ratio. In addition, a guideline for COPD in elderly subjects does not cater for respiratory disease in younger subjects. Hence, given the available research evidence^{43,62,64-74,80,85,150} and with support from the GOLD¹⁰ and ATS/ERS⁶⁶ recommendations, the use of LLN values puts respiratory medicine in line with most other areas of investigation (e.g. blood parameters and dexta scanning). Most software packages provided by major spirometer manufacturers already provide LLN data. There is considerable evidence that high quality diagnostic spirometry is achievable and will improve clinical care. We recommend that health care commissioners set challenging, but achievable, targets in order to realise the recommendations documented in this guidance, and provide the necessary support and advice to help those involved deliver high quality spirometry in their communities.

This document will be updated in 2011.

Acknowledgement

The GPIAG was provided with an unrestricted educational grant by Vitalograph Ltd for the development of this paper. The manuscript was not seen by the sponsors before it was finalised by the authors, who were solely responsible for the writing.

Conflict of interest declarations

MLL has accepted sponsorship for attending conferences from, has accepted lecture fees from, or has been on advisory boards or provided consultancy for, the following companies; GlaxoSmithKline (GSK), AstraZeneca (AZ), Chiesi, Merck Sharpe and Dohme (MSD), Merck, Altana Pharma, Novartis, MEDA Pharmaceuticals, 3M Pharmaceuticals, Schering Plough, Boehringer Ingelheim (BI), Alk-Abello and Ranbaxy. He is the Editor-in-Chief of the *PCRJ*, but was not involved in the editorial review of, nor the decision to publish, this article.

PQ: no declared conflict of interest.

RB: no declared conflict of interest.

BC: no declared conflict of interest

SH has accepted sponsorship for attending conferences from, has accepted lecture fees from, or has been on advisory boards or provided consultancy for, the following companies; Altana Pharma, AZ, BI, GSK, MEDA Pharmaceuticals, MSD, Chiesi, Novartis and Schering Plough.

IS has received honouraria and support to attend international meetings from GSK, AZ, BI/Pfizer, Nycomed, TEVA and Chiesi. He is a trainer for Education for Health.

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Appendix 1 Template of spirometry check list.

Please complete for each patient and attach the spirometry print out to the form for reporting.

Date Time of testing
Patient Name:..... DoB.....

Form with 4 sections: 1. Smoker? (Yes/No checkboxes), 2. Eaten in the last two hours? (checkbox), 3. List all current medication (Name/Last taken), 4. Check contraindications (Current chest infection, Heart attack or surgery in previous 6 wks?, Coughing blood or history of pneumothorax?, Previous stroke or uncontrolled high blood pressure?).

Measured height (without shoes) Weight.....
Position for testing (sitting or standing).....

Please record how well the patient was able to co-operate and whether you experienced any difficulty with the recording.
.....
.....
.....
.....
.....
.....
.....

Your name (in print)
.....

Appendix 2 Example of spirometry printout.

Name : John Doe	Patient ID: 03091964	Gender : male
Age: 44	Date: Jan. 14, 2009	Ref.values: Stanojevic 2008
Height (cm): 184	Time: 11:44	Physician:
Weight (kg): 86	Ethnicity: white	Technician: NN
BMI : 25.4		

	Pre Bronchodilator						Post Bronchodilator				
	Actual	Pred	LLN	SDS	%pred	Obstr	Actual	SDS	%pred	%Change	Obstr
FEV ₁ /FVC (%)	51.7	78.3	69.3	-3.85		<	55.8	-3.42			<
FEV ₁ (L)	2.59	4.46	3.54	-3.33	58.1	↓↓	2.97	-2.65	66.6	14.7	↓↓
FVC (L)	5.01	5.67	4.58	-0.99	88.4		5.32	-0.53	93.8	6.2	
Acceptability/Repeatability	+ / +						+ / +				

< below LLN; Obstruction: - No; ↓ mild; ↓↓ moderate; ↓↓↓ severe; ↓↓↓↓ very severe

