

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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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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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.

