Achieving quality spirometry in the office

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Summary

Ever since pioneering technology brought objective lung function measurement out of the laboratory with the introduction of "office spirometers" nearly 50 yrs ago, there has been a debate on whether nonspecialist practitioners can reliably achieve accurate lung function measurements. This debate continues today, because although it is certain that some users can achieve excellent-quality lung function measurements in general practice, occupational medicine and other nonspecialist practices, it is equally certain that some very poor-quality spirometry measurements are being performed. Examples of these poor quality measurements are presented as evidence that respiratory measurements should only be performed in controlled conditions by expert operators. Whether this is true can only be speculated upon, unless it is possible for an expert to review every spirometry measurement. You may think that this would be impossibly time consuming and expensive, but the internet, expert software and other technological advances have made this achievable and inexpensive; much cheaper than inaccurate lung function measurements.

Inaccurate measurements of lung function are useless and, in some cases, can lead to misdiagnosis or the administration of incorrect treatment. Indeed, in the case of acute diseases, such as brittle asthma, the patient could be put at severe risk. To put this in perspective consider ECGs. Achieving good-quality ECG results is comparative to good-quality spirometry. To obtain reliable results, many practitioners routinely use an "over-read" service. An expert over-reader has to be properly qualified, trained and certified. Equally, ECG devices must be certified, maintained and calibrated.

Both ECG devices and spirometers have

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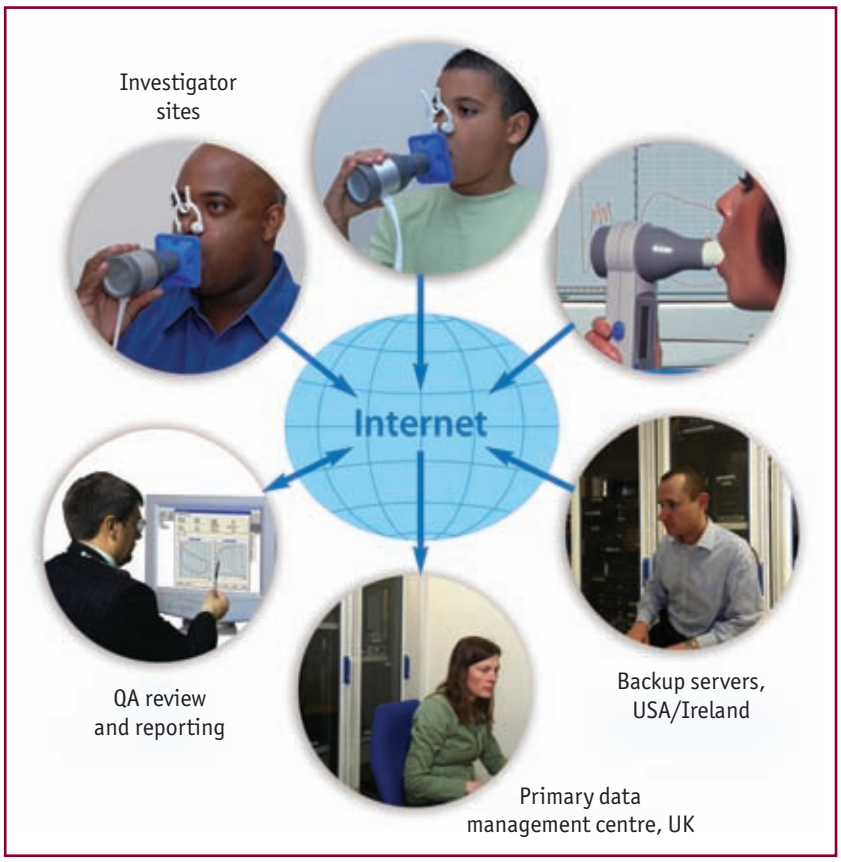


Figure 1
Centralised spirometry services.

a computer interpretation system; however, a computer-suggested interpretation cannot always be relied upon. The American College of Cardiologists/American Heart Association Clinical Competence Statement states "although computer interpretations of the ECG may have useful adjunctive value, they cannot substitute for interpretations by experienced electrocardiographers and should not be used in making clinical decisions" [1]. The joint statement from the American Thoracic Society (ATS)/European Respiratory Society (ERS) says "an interpretation begins with a review and comment on test quality. Tests that are less than optimal may still contain useful information, but interpreters should identify the problems and the direction and magnitude of the potential errors. Omitting the quality review and relying only on numerical results for clinical decision making is a common mistake, which is more easily made by those who are dependent upon computer interpretations" [2].

Figure 2
Over-read in action.

So how is it possible for an expert to review every spirometry measurement outside the lung function laboratory? The answer is an automated centralised spirometry service. Every spirometry result is sent to a centre where an expert reviews it. In the early days this was done by post and later by fax, but this is very time consuming and expensive. Sending spirometry reports by e-mail is an improvement, but this is still a long way from an automated centralised service. The reviewer is only looking at a report, not data and curves.

Today's centralised over-read service uses the

The following are essential ingredients for good-quality spirometry:

- Adherence to the applicable consensus guidelines and currently recognised "best practice" by the expert authorities.
- Having spirometer devices certified to conform to the applicable standards.
- The operator must recently have attended a recognised spirometry training course, and a validation process to prove competence.
- Having medical measuring devices which are properly maintained and having certified and current calibration.
- The operator must verify that the measuring device is functioning correctly before each use, as a minimum the daily accuracy check required by all spirometry standards and guidelines.
- Hygiene procedures relating to the facility, the measuring equipment, the operator and the test subject.
- Establishing and following test procedures to ensure that the test subject gives the best and most consistent measurements possible.
- Reversibility testing to ascertain if the subject has a significant response to a bronchodilator or bronchial provocation test.
- Immediate comparison of the data during testing with the previous test data, ideally from several test sessions or the entire history of the patient's measurements.
- Matching the subject to appropriate reference values for their population.
- Interpreting the results correctly to support or exclude a diagnosis.
- Independent quality assurance reviews of the test procedures and results.

internet to send anonymous, encrypted data to a web server (figure 1). This occurs automatically in the background without any or with minimal user intervention making it is very easy for the spirometer operator. In practice, there are very few web clusters with the security levels and registration required for medical data. Certainly, no normal web cluster could legally act as a centralised data centre for medical information. Under the Medical Devices Directive, such facilities must also pass regular stringent audits by the notified body [3] in the country where they are located.

Now, the expert over-reader does not have to be in the in the "centre". The expert does not even need to be in the same country, because everything is carried out securely over the internet. The expert could be one person or many experts, all working in different time zones. They use special software to quickly quality review each spirometry test result (figure 2).

With centralised spirometry quality management working across a group of users, the identification of poor quality gives a metric on the whole group, both within and between the members of the group. For example, an individual user's performance can be monitored over time, giving an objective measure of improvement or decline in spirometry quality. In the group, statistics can easily show which operators are the better and the poorer performers, the mean for the whole group and other useful metrics.

The use of centralised spirometry services allows the expert over-reader to identify poor-quality spirometry or confirm good-quality spirometry. In the case of poor spirometry, this is only the start of the process of corrective intervention; nonetheless, detection is the essential first step.

We will now examine each of the boxed points in more detail. Spirometry is, in essence, a simple procedure, but it can present many technical pitfalls that can falsely elevate or reduce results, leading to a false-negative or false-positive interpretation for a lung function abnormality or a change in lung function.

Guidelines and current best practice

There have been several advances in lung function testing expert consensus statements over the years; the latest ones were published in 2005 by the ATS/ERS, which issued a series of joint official statements on standardisation of lung function testing [2].

International guidelines and expert consensus statements issued on particular diseases contain useful guidelines on spirometry measurements; for example, the Global Initiative for Chronic Obstructive Lung Disease on COPD [4], the Global Initiative for Asthma on asthma [5] and the umbrella organisation for national primary care respiratory interest groups, the International Primary Care Respiratory Group, on spirometry and other topics [6].

National guidelines from expert associations in a variety of areas also touch on the use of spirometry, such as the British Thoracic Society and Primary Care Respiratory Society [7] guidelines on asthma, cough, smoking and many other areas. Guidelines by insurance carriers and governmental organisations, such as the National Institute for Health and Clinical Excellence [8] and the Department of Health [9] in the UK, also contain some valuable information.

The relevant standards for spirometers

When purchasing spirometers and their software, the buyer should confirm that devices have undergone validation testing by a competent and properly equipped testing laboratory to demonstrate that they meet the International Organization for Standardization (ISO) standards detailed below.

The ISO issued a new standard in 2009 (ISO 26782:2009), which covers the essential technical operating characteristics and test methods for spirometer devices and software.

Prior to this, the ISO published standards (ISO 23747:2007) that detail the operating and test requirements for peak flow meters. Many spirometers measure peak flow as well as lung volumes, so these devices must also conform to this standard.

Recognised training and training validation

The goal of spirometry training courses is to provide users with the basic knowledge required to produce meaningful test results.

The user must be motivated to do the very best test on every subject and must also be able to judge the subject's degree of effort and cooperation [10].

The ERS is part of a task force with a specific interest in training and validation, called the "European Spirometry Driving Licence" [11].

In some countries, named bodies are designated as the agency responsible for reviewing and approving spirometry training courses. These bodies conduct on-site course audits and periodic reviews of course approval status, thereby monitoring the quality of approved courses on an ongoing basis. In 2005, the ATS/ERS endorsed the USA Occupational Safety and Health Administration/National Institute for Occupational Safety and Health-approved courses as prototypes for operator training [12].

Certificates of spirometry course completion usually expire after 5 yrs, requiring the user to attend a spirometry refresher course. Spirometry refresher courses focus on current best practice and practical spirometry issues. Periodic refresher courses update knowledge, review testing problems, and help maintain the essential enthusiasm required by the operator to conduct a good quality spirometry test.

Properly maintained and calibrated spirometers

National quality assurance standards require that spirometers acquire an annual certificate of calibration, traceable to international standards, which includes the precision syringe.

It is good practice to put a sticker on each device with a calibration expiry date.

All medical devices should be routinely maintained as recommended by the manufacturer and indicated by the facility risk assessment. This could entail any monthly or annual checks and procedures.

A service record must be kept for every medical device, including routine inspections, performing checks for safety, functionality and accuracy.

Services should only be delivered by trained operators using the manufacturer's recommended procedures.

Figure 3
Disposable respiratory test BVF.

A record must be kept of all parts, replacements and software/firmware upgrades

Daily procedures to ensure safe and accurate measurements

The 2009 ISO 26782:2009 standard and the 2005 ATS/ERS Spirometry Statement are in agreement that the accuracy of both volume- and flow-type spirometers should be checked at least daily when a spirometer is in use, regardless of the measurement technology or claims by the manufacturer of "no need" for the daily accuracy check.

Spirometer users must perform daily accuracy checks of the measuring devices so that defective spirometers can be removed from service until they are repaired.

The acceptable spirometer response to a standard 3-L calibration syringe injection is ±3.5% of the injected volume, or 2.90–3.10 L [12].

Hygiene procedures

It has been shown that the deposition of bacteria/viruses is directly proportional to the distance from the mouth, *i.e.* most deposition occurs within a few centimetres of the mouth, with corresponding decrease of deposition further away [13, 14]. Therefore, all types of mouthpieces, including respiratory test bacterial viral filters (BVFs), must be used by only one test subject (figure 3). Similarly, flow sensing type spirometers need much more frequent cleaning than volume displacement spirometers, simply because of the long breathing tube, which increases the distance from the test subject to the sensor. General rules to follow for hygiene are as follows.

- Change BVF or mouthpiece for every test subject.
- Inspect the spirometer daily for any deposits and clean daily or when necessary.
- Take special measures:
  - When performing spirometry on a test subject with known or suspected contagious disease.
  - When deposition is evident. Deposition can be very marked when testing individuals involved in dusty occupations, *e.g.* coal miners.
  - Annually during the preventative maintenance service.

Spirometers are classified as 'low risk' medical devices, and should be decontaminated according to recommendations made by the Medical Device Agency [15].

There are several kinds of disposable mouthpiece, which come in a variety of sizes, although it is best to use the standard 30 mm size to avoid the possible 'pea-shooter' effect of small diameter/oval-shaped mouthpieces that have been shown to give false readings:

- Standard cardboard tube type.
- SafeTway mouthpieces (Vitalograph, Maids Moreton, UK; with integral one-way valve).
- BVF (recommended and shown here).
- Disposable plastic mouthpieces.
- Bite-on plastic mouthpieces (normally only used in laboratories).

A simple cardboard tube type mouthpiece is no longer recommended as it will no longer satisfy current needs and expectations for equipment hygiene. Risk analysis on respiratory testing equipment by the manufacturer proves the need for a valve mouthpiece or a BVF to protect the test subject.

Note that all types of mouthpiece are for single use in the clinic and must be disposed of after each spirometry test. Some home-use devices have a washable plastic mouthpiece, but even when used on a single subject care must be taken with residual deposits that can cause infections.

BVFs protect the equipment from contamination by the subject, as well as protecting the subject from cross-infection. A BVF may be used for expiratory and inspiratory tests. The SafeTway mouthpieces are for expiratory testing only.

Establishing and following test procedures

Forced spirometry requires a lot of work from both the operator and the test subject [16].

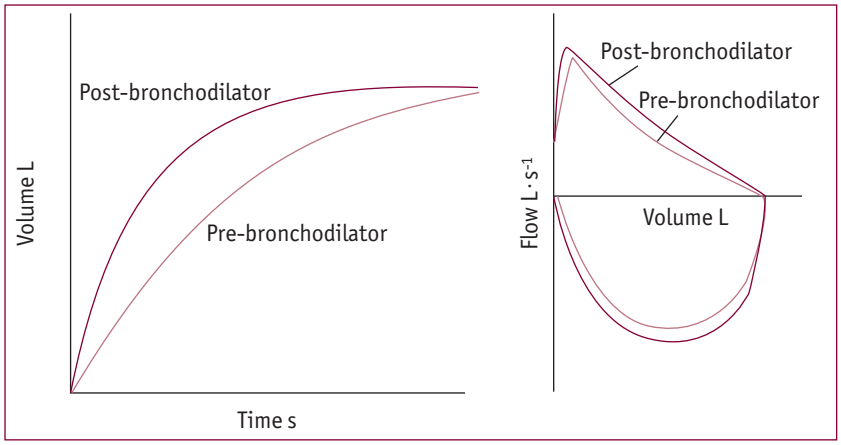
Best practice guidelines emphasise that operators should explain, demonstrate and coach subjects throughout their spirometry test.

- It is very important to demonstrate the use of a BVF or mouthpiece.
- Operators must emphasise maximal inhalation, hard initial blast and complete exhalation.
- The test should be conducted in an upright sitting position. The test posture must be documented, kept consistent over time whenever possible, and changes in test posture should be taken into account when interpreting results over time. Standing test results may be slightly higher than sitting, especially in overweight test subjects.
- Best practice guidelines recommend that a noseclip is used for all spirometry tests. This prevents extra breaths through the nose, a technical error that invalidates results but cannot be detected by spirometry software.
- There are two kinds of "good" blow identified in the ATS/ERS 2005 spirometry guidelines [6], usable and acceptable. Blows which are usable have a good, fast start and are free from abnormalities such as cough. Blows that are acceptable also have a good end of test plateau. Operators should strive to get acceptable blows.
- Forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV_1) repeatability within a spirometry test session (often misnamed as "reproducibility") should be ≤0.15 L. Lack of repeatability is often caused by a failure to inhale maximally.
- In order to obtain three good blows that are repeatable, operators should attempt to get the subject to blow up to eight times in a session, unless the subject is unable to continue with the test.

Reversibility testing for airway obstruction

Previously, the confirmation by spirometry of airway obstruction was an FEV_1/vital capacity (VC) ratio of <0.70. However, the FEV_1/VC ratio declines with age in normal people and it

Figure 4
Reversibility testing.



has been shown that this fixed ratio leads to a misclassification of 'obstruction' in older people and failure to detect obstruction in younger subjects [17].

Best practice today is to use the FEV1/VC ratio being below the lower limit of normality (LLN), defined as 1.645 standard deviations (the 5th percentile) below the predicted value for the normal population. The difference in standard deviation from the population predicted is called the standard deviation score (SDS). It is also referred to as the z-score or standardised residual by statisticians. An SDS of ≤-1.65 for the FEV1/VC ratio can be used to define airway obstruction.

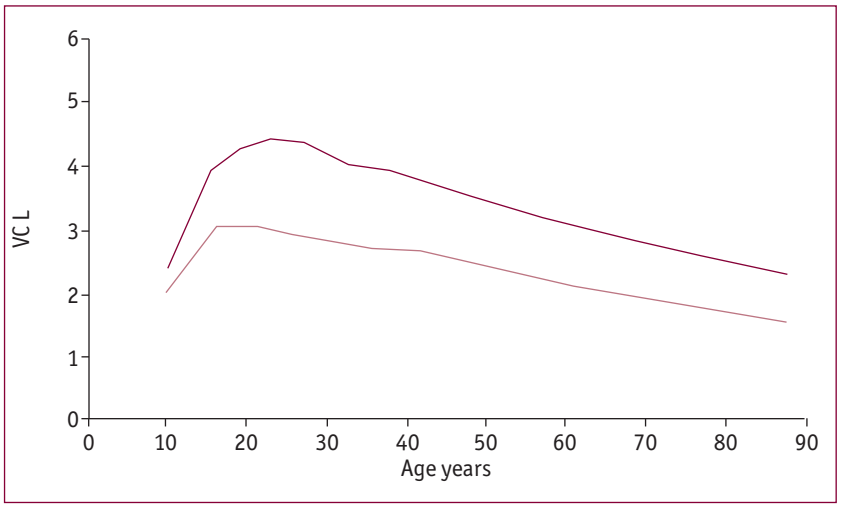
There is general agreement that a pre–post bronchodilator increase in FEV1 should be ≥12% of the initial value and 0.2 L to be regarded as "significant", *i.e.* a bronchodilator response that is suggestive of airways hyperreactivity (figure 4) [18].

Percent change from the initial value is calculated as ((initial value – post-bronchodilator value)/initial value) x 100.

However, failure to achieve such a response to bronchodilators does not completely exclude the possibility of reversible airways disease, and testing may have to be repeated more than once.

Bronchial provocation tests provide information on bronchial hyperreactivity that may not be evident in asthmatics at the time of presentation. Provocation testing methodology and equipment is normally regarded as complex, but following the European Mutual Recognition Procedure in 2007, approval was granted for a simple provocation test with an osmotic aerosol that makes it simpler allowing wider use in primary care [19].

Figure 5
Comparing current with previous tests.



Comparison of current and previous test results

Longitudinal spirometry evaluation is particularly important for people whose baseline pulmonary function is above average, since they can experience significant lung function decline without falling below the cross-sectional population LLN and are thus erroneously not labelled as "abnormal" on any single pulmonary function test. If high-quality serial spirometry tests are recorded over an adequate length of time, longitudinal evaluation may reveal deterioration earlier than repeated traditional cross-sectional evaluations [20].

The importance of conducting valid tests and maintaining high technical quality cannot be overstated when evaluating change over time [21]. As discussed previously, both over- and under-recording of results can be caused by errors in technique, flawed spirometer calibration or device problems that occur during the subject test.

Ongoing quality assurance reviews of spirometry test results can be helpful in such situations. Early detection of accelerated pulmonary function decline is only achievable with good quality spirometry.

However, some respiratory diseases also cause increased variability over time, and technical errors that are consistent over time may bias spirometry results without increasing their variability.

Since 1991, the ATS has recommended that a year-to-year change in healthy individuals should exceed 15%, after taking aging effects into account, before considering it clinically meaningful, so that "changes" in lung function are not likely to be caused only by measurement variability.

Appropriate reference values

Once the technical validity of the test has been established, spirometry results are usually evaluated at each measurement date, as well as longitudinally comparing results with previous test results (figure 5). Most available spirometers compare results with the normal range expected for a patient's current demographic characteristics. Fewer spirometers evaluate change over time or "trending", and criteria for longitudinal abnormality are less well established.

Reference values (or predicted normal values) define the expected average and lower boundary of the normal range for individuals with the same demographic characteristics as the test subject being tested. Reference values are generated from research studies of asymptomatic never-smokers of varying ages and heights, both sexes, and sometimes varying ethnic/racial backgrounds. Subject ethnic/racial group is based on self-report, and height should be measured periodically. The relationship of pulmonary function parameters with these four demographic variables are summarised in regression equations, which produce average "predicted" values and 5th-percentile LLN.

The European Community for Coal and Steel [22] and the ATS [23] have both published comprehensive lists of reference equations for spirometry.

In Europe, the combined reference equations published in the 1993 ERS statement [24] are widely used, but suggest the need for a new Europe-wide study to derive updated reference equations for lung function. Prediction equations are currently being created for pulmonary function, covering pre-school children to the elderly [25]. This process will take some time.

Correct interpretation of test results

For some decades, algorithms have been applied to spirometry pulmonary function parameters to interpret spirometry results. No interpretative algorithm is sufficient on its own because interpretation requires a comprehensive approach, including consideration of the clinical context, methodology, reference standards and an understanding of the consequences of a normal or abnormal designation. Indeed, some experts recommend that the spirometer-suggested interpretation be turned off.

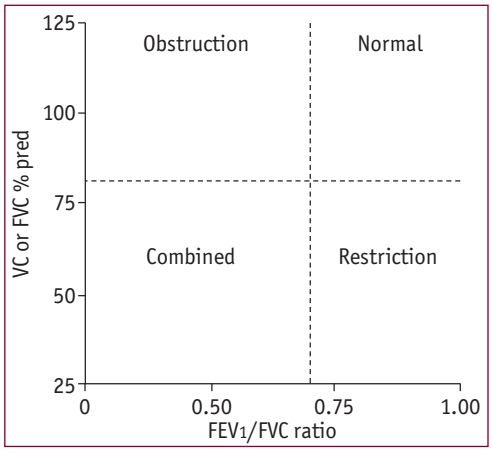


Figure 6
Correct interpretation of test results: the prediction quadrant.

Table 1 Classification of obstructive and restrictive diseases

	Obstructive	Restrictive	Mixed
FEV1	↓	↓ or N	↓
VC or FVC	N or ↓	↓	↓
FEV1/VC %	↓	N or ↑	↓

N: normal; ↓: decreased; ↑: increased.

There are two main classifications of disease pattern, obstructive and restrictive (figure 6 and table 1).

All spirometry interpretations are based on this premise, and add the concept of degree of severity and degree of reversibility.

Some interpretation algorithms are protected by law [26], but most are very similar. The use of these algorithms may be a political and economic issue. All patients deserve an accurate diagnosis to ensure correct treatment. There is an algorithm published by the ATS/ERS [2]. The algorithm can be used with forced expiratory volume in 6 s (FEV_6) and FVC.

- A consensus statement from the National Lung Health Education Program went so far as to state "office spirometers must only report values for FEV_1, FEV_6, and FEV_1/FEV_6", but, if the spirometer does not have the facility to calculate FEV_6, FVC could still be used [27].
- Special care should be taken with interpretation of values near the LLN, where misclassification is most likely to occur. Patients whose results are near the thresholds of abnormality are at a greater risk of misclassification.
- For prediction of obstruction, it does not apparently matter much whether slow VC, FVC or FEV_6 are used. For prediction of restriction, they are equally poor [28].
- In the 2005 guidelines [2], the ATS/ERS recommended grading restrictive impairment as well as airways obstruction using the FEV_1 % predicted. Both the FVC and FEV_1 are reduced as restrictive impairment progresses

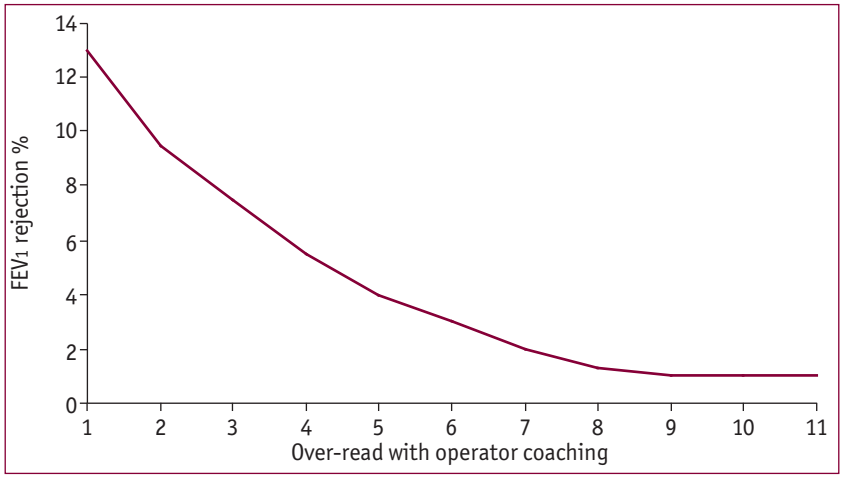


Figure 7
The benefits of over-reading: an excellent means of conducting independent quality reviews.

and the common technical problems of early termination of manoeuvres and zero-flow errors are less likely to impair the accuracy of FEV_1 than FVC. However, for test subjects with mixed impairment patterns, grading the restrictive impairment using FEV_1 % pred may slightly overstate the severity of restriction due to the coexisting obstructive reduction of FEV_1.

- The 5th percentile, below which only 5% of normal subjects in a population fall, should be used as the LLN. The ATS/ERS continues to strongly discourage the use of 80% pred as an LLN [29]. As pulmonary function declines with age, the 5th percentile LLN also declines, labelling only 5% of normal individuals in each age group as "abnormal." In contrast, increasing proportions of nonexposed healthy individuals fall below 80% pred as they age, creating an increasing pool of false-positives.

Independent quality assurance

In addition to emphasising operator training, ATS/ERS spirometry statements strongly recommend that spirograms be reviewed periodically to provide regular feedback on the quality of each operator's testing [2].

In the absence of a subscription to a centralised spirometry service, quality assurance reviews can be performed on copies of spirograms with the full session spirometry report. However, if performed manually, the workload is so great that that a statistical sampling method is normally used. Appropriately sized samples of randomly selected tests are selected, plus all invalid tests and tests with abnormally low or improbably high results.

This brings us back to expert over-read as an excellent means of conducting independent quality review on an ongoing basis. A high standard of spirometry can be achievedin clinical trials and it is the author's view that spirometry over-reading can become a useful tool in primary and secondary care [30, 31].

The employment of centralised spirometry [32] has increased over recent years as it has been seen to reduce the variability of spirometry [33]. The services can include data capture with over-reading, monitoring of calibration and remote web-based coaching to ensure better data quality overall. It can also be used for operator accreditation.

Ideally, the individual spirometry sessions are over-read within 24 h of receipt by the expert over-reader(s) for acceptability and repeatability using a semi-automated process, with encouragement and recommendations where required.

The question of the effectiveness of over-reading data has been quantified from two very similar international multicentred studies that were retrospectively analysed [34]. Where feedback and comments were given to the operator within 24 h, the trend of rejected sessions fell from 13% to 1% over a series of iterations (figure 7) [35], whereas giving study feedback only to the project manager resulted in a much lower improvement.

Where spirometers of several different types are used in a centralised spirometry project, over-reading can still be provided *via* web capture systems. The operators upload their spirometer reports and curves to a secure website, typically as scanned images.

Conclusion

The fast and timely review of spirometry data for acceptability and repeatability is becoming increasingly important to ensure both data quality and to reduce time-related costs. Achieving quality spirometry has many components, but all the essential ingredients can, with care, be achieved by any healthcare professional or group. Centralised spirometry with over-reader feedback within 24 h, together with training and technician accreditation, significantly improves data quality.

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