



Joint statement from GOLD/GLI regarding the use of spirometry to define airflow obstruction and diagnose COPD

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GOLD and GLI agree on many important issues regarding diagnosing COPD with spirometry, sharing concerns about under-use and agreeing that, in the appropriate clinical context, the fixed ratio can be used to identify COPD-related airflow obstruction <https://bit.ly/4tB8cZt>

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Introduction

COPD is one of the leading causes of morbidity and mortality worldwide [1]. Spirometry provides an objective measure of airflow obstruction that, in the appropriate clinical context, confirms the diagnosis of COPD. However, globally, access to spirometry is limited, the test is under-utilised, and many people are either misdiagnosed [2] or under-diagnosed [3, 4]. The intrathoracic airway obstruction that characterises COPD can be detected by finding expiratory flow limitation on spirometry. A reduced forced expiratory volume in 1 s (FEV₁) to forced vital capacity (FVC) ratio demonstrates flow limitation, but for more than 30 years there has been an unproductive debate about which threshold should be used to define airflow limitation and identify airway obstruction in patients with suspected COPD. In this viewpoint article, we focus on the use of spirometry use in routine clinical practice to confirm or exclude a diagnosis of COPD, and aim to propose a way forward to end the debate.

What is the debate?

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommends that a *fixed ratio*, defined as a post-bronchodilator FEV₁/FVC <0.7, is used to define COPD-related airflow obstruction and confirm the diagnosis in people with a medical history suggestive of COPD [5, 6]. Since the original 2001 GOLD report [7], the GOLD committee has regularly reviewed this recommendation [8] and has left it unchanged, as it is simple and independent of reference values [5].

Although the 2004 American Thoracic Society (ATS)/European Respiratory Society (ERS) recommendations on the diagnosis and treatment of patients with COPD also recommends using the fixed ratio [9], the ATS/ERS statements on spirometry and interpretive strategies for routine lung function tests, and the Global Lung Function Initiative (GLI) recommend using a defined *lower limit of normal* (LLN) value for the FEV₁/FVC ratio to define airflow obstruction [10]. The LLN is a threshold that is based on a lower boundary defined by the distribution of measurements taken from a healthy population. The LLN is typically set at the lower 5th percentile of reference populations with similar age, height and sex [11].



Neither threshold is intrinsically right or wrong. Each threshold for defining airflow obstruction evolved to solve different problems, and discordance between the criteria reflect fundamentally different goals. The threshold proposed by GOLD was intended to be a pragmatic approach for confirmation of the diagnosis of COPD in everyday practice. The threshold proposed by GLI intends to reflect the variability in lung function measures observed between individuals in populations. Both approaches have been criticised. The fixed ratio has the advantage of its simplicity; however, it ignores potential age-related lung function changes and may identify fewer younger and more older individuals as having airflow obstruction [12, 13]. The LLN considers age-related changes in lung function, reflecting loss of tissue elasticity, but crucially depends on the characteristics of the reference population and assumes the reference population is “healthy”. Some individuals included in populations used to define “normal ranges” may have had undiagnosed or sub-clinical disease, leading to distortion of the LLN values. By considering age-related decline as physiologically normal, use of the LLN identifies more younger and fewer older individuals as having airflow obstruction. If used without reference to the presence of symptoms or exposure to risk factors for COPD, the LLN will falsely label some healthy younger individuals as having COPD.

There is increasing recognition of the importance of early detection in COPD and that COPD is a heterogeneous condition. The potential for the LLN to increase sensitivity in younger individuals with early COPD or at increased risk for COPD is especially relevant in this context. Detection of the condition earlier may allow for earlier intervention, but the potential for over-diagnosis of COPD by the LLN in younger people must also be considered [14–20]. In practice, both approaches are useful for confirming disease in people with respiratory symptoms and significant exposure history, and neither is perfect.

Studies have shown that older current and ex-smokers classified as obstructed using the fixed ratio but “normal” using the LLN (*i.e.* discordant results) have more respiratory symptoms, worse exercise tolerance, lower FEV₁ and FVC, lower gas transfer, more gas trapping, more structural abnormalities on computed tomography, an increased risk of exacerbations, COPD-related hospitalisations and death, and an increased prevalence of multi-morbidities, including cardiovascular disease [14, 15, 17, 21]. It appears, therefore, that using the fixed ratio can identify clinically relevant early disease in people at risk of COPD before overt obstruction is found by the LLN.

The divergent recommendations about spirometry interpretation have confused primary and secondary care clinicians, as well as pulmonologists. An unintended consequence, especially in primary care, has been the development of a perception that spirometry is a difficult test to perform and interpret, leading to under-use of spirometry to confirm the diagnosis of COPD [22, 23].

GLI and GOLD agree that the differences in recommendations about thresholds of “abnormality” are outweighed by shared concerns about the under-use of spirometry. The false dichotomy in applying thresholds and comparing these two approaches ignores the clinical context. In practice, only a small proportion of people are classified differently by the two approaches. The points of agreement are often overlooked and there is a widespread perception that there is strong disagreement between the organisations, with partisan views that one is right and one is wrong. This is far from the truth. GLI and GOLD share common goals and recently have worked closely together on these.

Spirometry is a key indicator of airflow obstruction, a hallmark feature of COPD

GOLD and GLI agree that COPD is characterised by airflow obstruction, and FEV₁/FVC measured by spirometry is currently the most appropriate objective biomarker of the airflow obstruction. GOLD and GLI agree that spirometry alone is not sufficient to make a diagnosis of COPD, and neither GOLD nor GLI recommend the diagnosis or labelling of patients with disease in the absence of a clinical history or based on a pulmonary function test result alone, and recognise the harms associated with diagnosing “disease” in a healthy individual.

Innovation may lead to the introduction of alternatives to spirometry and there may be ways of integrating complementary tests, such as oscillometry, CO₂ breath analysis, optoplethysmography or imaging techniques. Artificial intelligence (AI) may facilitate integration and may be more sensitive at detecting impairments, especially in the small airways or in patients with mixed patterns of restriction and obstruction [24]. However, these innovations may not be widely available and are unlikely to improve access to diagnostic testing.

Spirometry is under-utilised

Studies in many countries show that most people with a diagnostic label of COPD had not had spirometry performed [2, 22, 25–30]. Lack of access to spirometry, lack of confidence in interpreting the results, and

patient reluctance to attend and perform spirometry, have all been identified as barriers to its use [31, 32]. Education programmes can help overcome some of these [33] and AI may also help to improve spirometry quality in situations where confidence and understanding is poor.

Spirometry is a simple test to perform

GOLD and GLI agree that it is important to promote the message that spirometry is a simple and inexpensive test to perform. Spirometry is used in a number of contexts (diagnosis, disease management and research) and can be performed in various settings (primary care, community, occupational health, and secondary and tertiary hospitals). How spirometry is performed and used in each of these settings is different. Portable devices, improvements in software capabilities, ability to compare measured results with predicted values, including LLN, and real-time feedback have all helped to improve the simplicity and quality of testing. Hand-held devices with integrated instructions and feedback have fundamentally changed where and how the test can be performed. Interpretation may be further facilitated using AI approaches [34–37]. A recent randomised controlled trial in primary care found that AI-based decision support significantly improved clinicians' accuracy in diagnosing COPD [38].

Good quality testing is essential

GOLD and GLI agree that the differences between the two thresholds are irrelevant when the test quality is poor. Updated technical standards [39] and integrated algorithms (and in some cases AI) can help operators ensure good quality testing is performed in real time [24]. As a minimum, spirometry for confirming a diagnosis of COPD requires an individual to exhale forcefully, starting from a total lung capacity to achieve a plateau in expiratory flow and the manoeuvre must be free from artefacts. Effective coaching/encouragement is essential to ensure technically acceptable measures are collected. Modern spirometers can implement warning messages when these criteria are not met, simplifying and facilitating better testing.

The technical requirements for ruling out COPD are less rigorous than those for precise determination of lung volumes, and provided the core technical standards have been met, a more pragmatic approach may be acceptable in this setting. GOLD and GLI agree that if the FEV₁, FVC and FEV₁/FVC ratio are normal (however this might be determined) the results cannot occur because of a poorly performed manoeuvre, and COPD as currently defined can be excluded [5, 6]. If the FEV₁, FVC and FEV₁/FVC ratio are normal and there is a very high clinical suspicion of COPD, post-bronchodilator spirometry may occasionally reveal an FVC volume response and unmask obstruction. In the context of significant medical history and symptoms, a borderline value does not definitively confirm or rule out COPD. Respiratory symptoms are not normal and should be investigated until an underlying cause can be identified and treated.

There is a need for a minimum training level to be met in order to conduct good quality spirometry, but GOLD and GLI do not consider that advanced academic qualifications are required.

There is a degree of uncertainty

GOLD and GLI agree that COPD is a heterogeneous disease and spirometry measures are prone to measurement errors and biological variability; both of these contribute to uncertainty when interpreting results. The results of biological measurements used as diagnostic tests cannot always be empirically categorised as “normal” or “abnormal”. There are inevitably challenges with definitions that rely on thresholds of dysfunction, as biological dysfunction is a continuum and there is no value-free method for determining the boundary between what is abnormal and what is a result of biological variation [40, 41]. Thresholds lack empirical justification and can be subject to revision [42].

Much of the data used to discuss the rates of over- or under-diagnosis using either the fixed ratio or LLN is derived from healthy populations, not from populations with a high pre-test probability of COPD. In research cohorts of current and ex-smokers over 40 years of age, or patients with respiratory symptoms referred for investigation, the proportions with discordant results ranged from 8% to 18% [14, 15, 17, 21]. Like all physiological measurements, the FEV₁/FVC ratio shows intrinsic biological variability [43–45] and, in most cases, discordant values will fall within areas of uncertainty regarding interpretation (figure 1). For example, a ratio of 0.65 in a patient aged 80 years is above the LLN (~0.6) and below the fixed ratio of 0.7, but lies within the range of values where GOLD discourages making a firm diagnosis and recommends either further investigations or repeat testing at an interval. Furthermore, although the z-score used to identify the 5% LLN is fixed at -1.645, there is inevitably uncertainty in the population mean and standard deviation estimate which introduces an uncertainty interval around the estimated LLN, although a confidence interval for the LLN is not usually quoted. In most cases this uncertainty interval will overlap with that of the fixed ratio. Unavoidable variation exists in the measurement itself as, at their

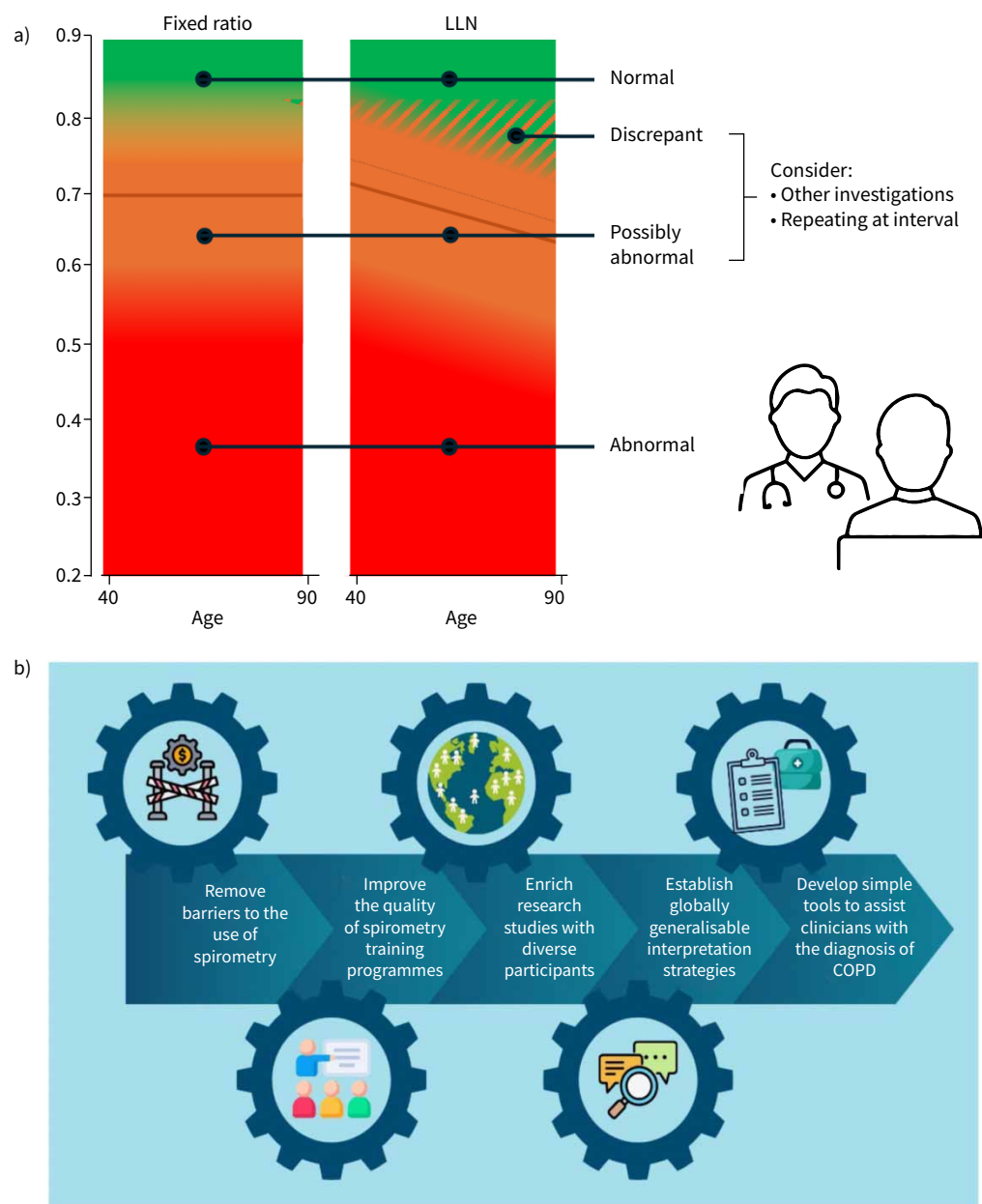


FIGURE 1 a) Interpretation of forced expiratory volume in 1 s (FEV₁) to forced vital capacity (FVC) ratio in a patient suspected of having COPD. b) Steps needed to improve the use of spirometry to confirm a diagnosis of COPD. LLN: lower limit of normal.

best, spirometers may show up to 5% variation in repeated test results [39]. In practice, therefore, it makes little difference whether the fixed ratio or LLN is used. Where there is a discrepancy, or more commonly where the result lies between 0.6 and 0.8, further investigations or repeat measurements should be performed to confirm or exclude a diagnosis of COPD (figure 1a).

When a spirometry result does not confirm airflow obstruction in a patient with symptoms and suggestive medical history, additional testing should be used to confirm a diagnosis. This could include measurement of the FEV₁/slow vital capacity (SVC). It is evident that neither the fixed ratio nor LLN adequately capture the heterogeneous nature of COPD, or the many factors that affect lung growth and development across the life course. It is also important to note that the FEV₁/FVC ratio is also dependent on factors that can affect the numerator and denominator independently (*e.g.* obesity causing a relative reduction in FVC), resulting in an apparent normalisation of the ratio.

Bronchodilator response criteria

GOLD and GLI agree that there is widespread confusion between the terms bronchodilator response and bronchodilator reversibility. “Bronchodilator reversibility” refers to the improvement of an “abnormal” FEV₁/FVC ratio into the “healthy” range (either above 0.7 FEV₁/FVC or above the LLN for FEV₁/FVC) after a bronchodilator agent has been administered. Reversibility is often confused with “bronchodilator response”, which represents the magnitude of change in FEV₁ or FVC observed after a bronchodilator is administered, whether it returns values back to normal or not. Many patients with COPD show a change in FEV₁ and/or FVC in response to bronchodilators [46, 47], but this does not constitute bronchodilator reversibility if FEV₁/FVC remains below the diagnostic threshold. Initially GOLD recommended using post-bronchodilator ratio values in its clinical definition because it was thought that post-bronchodilator values were more reproducible and could exclude asthma [6]. It is now clear that pre-bronchodilator values are also reproducible [48] and obstruction found only on post-bronchodilator measurements is uncommon [49].

Classification of severity of airflow obstruction

GOLD recommends classification of severity based on percent of predicted values for FEV₁, while ATS/ERS recommend using age, height and sex standardized z-scores. z-scores appear more strongly associated with patient symptoms (e.g. dyspnoea [50]) and risk of hospitalisation [51], but both approaches were inferior to an absolute measure of FEV₁ when mortality was the outcome [52]. Disease severity does not always correlate with the severity of airflow obstruction and ultimately both the GOLD and ATS/ERS thresholds are arbitrary. Severity should ultimately be defined based on patient-reported outcomes reflecting their ability to function, or clinical outcomes, such as survival.

GOLD and GLI agree that race-based reference values previously used can lead to underestimation of severity of airflow obstruction and normalise disparities in lung health [36]. GOLD agrees that the race-neutral equations published by GLI in 2022 (GLI-Global equations) [36] are the most appropriate currently [53]. Both GOLD and GLI acknowledge that questions remain about the global validity of these equations as they are based on a weighted average of racial and ethnic categories, and were derived from a population that did not include participants from many countries or global regions [54–56]. Currently, no satisfactory method has been found to account for anthropometric differences in chest dimensions [57]. Sitting height has been suggested as a proxy, but the same early life factors that affect lung growth affect body proportions [36]. There is an urgent need for interpretation strategies that incorporate anthropometric variation in chest dimensions that can be used globally and equitably.

Conclusions

GOLD and GLI agree on many issues (box 1). A common goal for both organisations is to reduce barriers to the use of spirometry and make it more available and utilised worldwide (figure 1b). Early recognition of the signs and symptoms of COPD, together with a simple, accurate and consistently used diagnostic

BOX 1 Key points of agreement between the Global Initiative for Chronic Obstructive Lung Disease (GOLD) and Global Lung Function Initiative (GLI)

Differences in recommendations about thresholds of “abnormality” are outweighed by shared concerns about the under-use of spirometry to confirm the diagnosis of COPD

COPD is characterised by airflow obstruction and FEV₁/FVC measured by spirometry is an appropriate objective biomarker of airflow obstruction

Spirometry alone is not sufficient to make a diagnosis of COPD: a clinical diagnosis of COPD must be based on integrating a patient’s exposures, medical history and symptoms, together with a physiological measure of airflow obstruction

Spirometry is a simple and inexpensive test to perform

Spirometry results can be affected by measurement errors and biological variability which contribute to uncertainty when interpreting results

If the FEV₁, FVC and FEV₁/FVC ratio are normal, the results cannot occur because of a poorly performed manoeuvre

The differences between the fixed ratio and LLN thresholds are irrelevant when the test quality is poor

The race-based reference values previously used can lead to underestimation of disease severity and normalise disparities in lung health and should not be used

The race-neutral equations published by GLI in 2022 are the most appropriate currently available and should be used as standard

FEV₁: forced expiratory volume in 1 s; FVC: forced vital capacity; LLN: lower limit of normal.

test, is essential if we are to reduce the burden of this condition. Harmonising recommendations, including those of national and regional societies, such as ATS and ERS, is important to remove confusion. GOLD and GLI agree that the LLN can be used to identify airflow obstruction more broadly in populations, including younger patients with dyspnoea on exertion, but in the appropriate clinical context (e.g. a symptomatic patient with a medical and exposure history suggestive of COPD), recommend that the fixed ratio is used to identify COPD-related airflow obstruction and confirm a diagnosis of COPD.

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