

The GOLD Guidelines Definition of Mild Airway Obstruction

This letter arises from discussions and correspondence between colleagues involved in respiratory research or the diagnosis and treatment of lung diseases, as well as from a review of the literature on COPD. As discussed below, it is written in the hope that we can persuade members of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) committee to change the method by which mild airway obstruction is defined by the GOLD guidelines.

We very much welcome the continued efforts of the GOLD group to stimulate interest and awareness of the high prevalence of COPD, its morbidity, and its effects on quality of life and on mortality. There is no doubt that COPD is a major public health problem of which the public, health workers, and health authorities were insufficiently aware. It is therefore an important achievement that the World Health Organization, European Respiratory Society, American Thoracic Society, Asian Pacific Society of Respiriology, Latin American Thoracic Association, World Organization of Family Doctors, and many distinguished individuals have joined forces to increase awareness about the burden of COPD, by publishing reports and guidelines for diagnostic procedures and interventions that have been adopted by numerous international and national organizations.

However, there is one area that has given rise to continuous published criticism: the criterion for confirming airway obstruction. It is well known that the FEV₁/FVC ratio declines with increasing age and height, even in healthy lifelong non-smokers, in whom the lower limit of normal drops below a ratio of 0.7 from about 45 years of age.¹⁻⁶ It has been shown⁴⁻²⁷ that using the fixed ratio causes up to 50% over-diagnosis (misclassification) above that age. Adult smokers suspected of having COPD are not at increased risk of respiratory symptoms, respiratory morbidity, or all-cause mortality until the ratio falls below the age-corrected fifth percentile lower limit of the normal range.^{26,28}

The present GOLD guidelines on the spirometric assessment of airway obstruction

are scientifically untenable^{1,29-31} and have given rise to editorials in *Chest*,³² *European Respiratory Journal*,¹⁷ *American Journal of Respiratory and Critical Care Medicine*,³³ *COPD: Journal of Chronic Obstructive Pulmonary Disease*,³⁴ and *Respiratory Care*,³⁵ with a plea for revision. The very significant over-diagnosis in elderly subjects due to this guideline is akin to selling sickness. There is considerable psychological impact, and there are wider health consequences of incorrectly being labeled as having COPD, a syndrome associated with a poor prognosis with regard to morbidity, quality of life, and mortality and therefore a psychological burden for the subject, his family, and wider environment. Subjects erroneously labeled become a target for individual and lifelong interventions that are associated with adverse effects. This is all the more unacceptable because evidence for the long-term effectiveness of treatment of mild COPD, apart from smoking cessation, is lacking.^{28,36} Erroneous interventions also constitute an unnecessary financial burden for society.

We applaud the GOLD committee for raising interest in COPD research. However, over-diagnosis will lead to the inclusion of subjects who do not have COPD into the research pool, thereby adding noise to any signals that researchers are looking for when trying to unravel the causes of COPD and hence find potential treatments. Also problematic is excluding younger subjects who may have airway obstruction (false negatives) when the fixed ratio is used.^{4-5,10,16,18,21,37-40} For research purposes it is far better to limit recruitment to subjects who definitely have the disease, but this urgently requires adjustment of the present guideline on a fixed FEV₁/FVC ratio.

We appreciate the consequences of changing course when so many societies and organizations will be affected by replacing the fixed ratio by the lower limit of normal, and more importantly, general practitioners and clinicians may have to review and revise previous diagnoses. However, in the light of new evidence it is never too late to change a decision made in good faith. We are therefore appealing to the GOLD committee to change the method by which mild airway obstruction is defined, in order

to abandon the fixed ratio in favor of the lower limit of normal.

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On behalf of the Pulmonaria Group; the Australian and New Zealand Society of Respiratory Science; Association for Respiratory Technology and Physiology; COPD and Asthma GP Advisory Group (CAHAG); Dutch Pediatric Respiratory Society; Education for Health, United Kingdom; National Respiratory Training Center, United States of America; Dutch Society of GPs (NHG); Dutch Thoracic Society, Dutch Society of Respiratory Technicians; Primary Care Respiratory Society, United Kingdom; Société Scientifique de Médecine Générale; World Organization of Family Doctors (WONCA); and 147 co-signatories from 27 countries.

The authors have disclosed no conflicts of interest.

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