The need to change the method for defining mild airway obstruction

Dear colleagues, members of GOLD committee,

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 chronic obstructive pulmonary disease (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 vote 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, 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 (WHO), the European Respiratory Society (ERS), the American Thoracic Society (ATS), the Asian Pacific Society of Respirology (APSR), the Asociación Latinoamericana de Tórax (ALAT), and the World Organization of Family Doctors (WONCA) and many distinguished individuals have joined forces to increase awareness about the burden of disease, by publishing reports and guidelines for diagnostic procedures and interventions which have been adopted by numerous international and national organisations.

However, there is one area which has given rise to continuous published criticism: the criterion for confirming airway obstruction. It is well known that the forced expiratory volume in 1 s (FEV_1)/forced vital capacity (FVC) ratio declines with increasing age and height, even in healthy lifelong nonsmokers, in whom the lower limit of normal drops below a ratio of 0.7 from about 45 yrs of age [1–6]. It has been shown [4–27] 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 5th 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], the *European Respiratory Journal* [17], the *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 labelled 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 labelled become a target for individual and lifelong interventions which are associated with side-effects. This is all the more unacceptable since 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 FEV_1/FVC ratio.

We appreciate the consequences of changing course when so many societies and organisations 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 you, members of the GOLD committees, to change the method by which mild airway obstruction is defined by the GOLD guidelines in order to abandon the fixed ratio forever in favour of the lower limit of normal.

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