

Editorial

The Case for the New GOLD Criteria

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Two years after the publication of the new criteria for the management of chronic obstructive pulmonary diseases (COPD) by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) [1], the utilization of these criteria in clinical and investigative medicine remains limited. Should clinicians use the “New GOLD Criteria” in the management of their patients with COPD? The simple answer is an emphatic *yes*. In this article we outline the rationale for the use of these criteria, the barriers to their implementation, and the steps needed to facilitate their utilization.

The New GOLD criteria have all the characteristics of effective clinical guidelines [Table 1] [2,3] whose implementation should result in a significant improvement in care and prognostication in COPD. In developing these diagnostic and therapeutic criteria and to ensure their validity, the Science Committee of GOLD employed an elaborate process of literature review with annual reporting of all published studies utilizing the original GOLD criteria of 2001 (updated in 2007) [1,4]. The updated criteria were therefore based on an amalgamation of peer-reviewed data collected over a ten year period incorporating the outcome of a large number of studies worldwide. This process not only incorporated studies with Category A and B evidence (randomized controlled clinical studies), but included a multitude of studies presenting Category C (Nonrandomized trials and Observational studies) and Category D evidence from expert opinion and panel consensus judgment [1]. The wealth of information and opinion that was used to develop the new criteria ensured their validity.

The consistency in the findings among studies from various sources confirmed the *reproducibility* of the criteria and their widespread applicability and acceptance by experts in the field. Reproducibility is also ensured when classification criteria are *clear and standardized*, as is the case with the New GOLD criteria. Having well-defined physiologic and clinical parameters that allow patients to be classified into one of four groups ensures that all patients have the same chance of being accurately diagnosed and started on generally acceptable therapeutic regimens right from the outset.

Yet reproducibility and standardization should not be achieved at the expense of individualization. In this era of individualized medicine, it is important that management plans are constructed to address the unique needs of individual patients [5]. The new GOLD criteria allow for such flexibility.

Whether dealing with the physiologic components or the clinical parameters incorporated into the classification system, there are provisions to account for progressively increasing level of complexity and severity (Table 2). The flexibility extends to the therapeutic options which include several classes of medications, devices and physical interventions. An important corollary to individualized care is the improvement in prognostication. The new GOLD criteria incorporate into the classification system progressive symptomatology and frequency of exacerbations, both of which are known to impact quality of life and mortality. Unlike the original GOLD criteria, the new ones may be able to help patients and physicians predict outcome.

Table 1: Characteristics of effective clinical guidelines

• Validity	• Ability to prognosticate
• Reproducibility	• Cost-effectiveness
• Clarity	• Clinical applicability
• Standardization	• Amenable to audits/monitors

Table 2: New GOLD Patient Groups.

Adapted from Vestbo et al.

A—Low risk, less symptoms

- 80% > FEV₁ ≥ 50%
- 0–1 exacerbation per year
- mMRC grade 0–1
- or CAT score < 10

B—Low risk, more symptoms

- 80% > FEV₁ ≥ 50%
- 0–1 exacerbation per year
- mMRC grade ≥ 2
- or CAT score ≥ 10

C—High risk, less symptoms

- FEV₁ < 50%
- ≥ 2 exacerbations per year
- or ≥ 1 hospitalization/year
- mMRC grade 0–1
- or CAT score < 10

D—High risk, more symptoms

- FEV₁ < 50%
- ≥ 2 exacerbations per year
- ≥ 1 hospitalization/year
- mMRC grade ≥ 2
- or CAT score ≥ 10

The New GOLD criteria do not include novel specialized testing or the use of sophisticated equipment and devices. Most of the information is obtained from old fashioned clinical interview and examination, spirometry, and review of the medical record. The process of accurately classifying the patient into one of the new 4 categories does not carry any extra cost. In addition, the therapeutic interventions are the standard treatment protocols applied in a more regimented manner. In the absence of an added cost to diagnosis and treatment, the implementation of the new criteria is likely to be *cost-effective*. It may also reduce cost by decreasing the need for frequent post-bronchodilator measurements that do not add to the accuracy of the diagnosis or monitoring of the progress during therapy.

Perhaps one of the most appealing features of the New GOLD criteria is their *clinical applicability*. Incorporation of clinical response data into the physiologic classification makes clinical sense and gives clinicians a tool to link disease severity to treatment plan, therapeutic modifications, outcome and prognosis. In the original GOLD classification which was based solely on spirometric measurements, there was little correlation between clinical presentation and disease classification. Patient with severe spirometric impairment may have few symptoms and few exacerbations while patients with mild disease may have crippling clinical manifestations [6]. These limitations are minimized when the New GOLD criteria are used.

Finally, the New GOLD criteria can be easily *monitored and audited*. All the components of the classification, whether physiologic, spirometric, or clinical are part of the medical record. In the era of the electronic medical record, it is easy to track the parameters used in the classification, assure their accuracy, and provide modifications if necessary. Such audits can be an integral part of a quality improvement program, a pay-for-performance plan, or a system-based evaluation program required by the Joint Commission and the Accreditation Council for Graduate Medical Education. The New GOLD criteria can be extremely valuable to support educational, programs, quality improvement plans and sound fiscal strategies.

Despite these clear advantages, the New GOLD criteria have not yet been widely adopted by clinicians. On first glance this might be intriguing. However, one has to be cognizant of the various barriers to implementation. Studies have shown that even when new guidelines appear to have merit, their implantation may be hampered by perceived obstacles [7]. Burgers et al identified several deterrents to implantation of effective guidelines [7]. These include situations where the guidelines include the use of a complex decision tree, the need to acquire new skills and knowledge, or the need to introduce major changes in behavior or organizational structure. All of these potential barriers are conceptually possible during the implementation of the New GOLD criteria. The decision tree is relatively complex, multi-dimensional, and includes the incorporation of three sets of data: physiologic, subjective and clinical [1]. Clinicians need to learn new methods to survey patients regarding their dyspnea scores [8] and also need to change the way they manage patients by actively retrieving from the medical record information about exacerbations, admissions and emergency department visits [1].

Whereas these are important barriers, they are not

insurmountable. With proper education, structured routines to obtain dyspnea scores, and systematic review of the electronic medical record to retrieve exacerbation data, the information may become easily available and practical to use by most clinicians. However, there are two more fundamental barriers that need to be addressed by the pulmonary community. The first relates to the rather loose definition of what an exacerbation of COPD really is. At this time, the definition is not standardized. Is an exacerbation a situation where the patient has to be admitted to the hospital, to the ICU or to an observation unit? What about a visit to the Emergency Department or the clinic? Or could an increase in the use of rescue inhalers be a surrogate marker for an exacerbation? If so then how much? All of these apparently simple questions can add to the complexity of the decision making process and inhibit clinicians from adopting these criteria. The second barrier is the paucity of prospective randomized and controlled studies that evaluate the usefulness of the New GOLD criteria in assisting physicians treat patients or prognosticate. At this time and age, medical practice needs to be evidence-based. There are only few published studies that describe the clinical utility of the New GOLD criteria.

Two recent retrospective studies evaluated the New GOLD criteria in large cohorts of COPD patients. A study from Denmark [8] included 6,628 patients with COPD including inpatient and outpatient exacerbations. Another study from Spain [9] reviewed 3,633 patients with inpatient exacerbations. Both studies used the Modified Medical Research Council (mMRC) Dyspnea Scale for symptom classification [10]. Follow-up times for the 2 studies were 4.3 years and 10 years, respectively. There were fundamental differences in the results obtained from the 2 studies. In both studies, the majority of patients were classified as GOLD A or GOLD D (and very few GOLD B and C). The Danish study found that the New GOLD criteria predicted future exacerbations, an observation that would be very helpful to clinicians planning future management plans and follow up frequency. Mortality data seemed to progressively increase as the GOLD class increased. However, the trends showed inconsistencies indicating that comorbidities may have influenced mortality results and precluded the detection of a direct relationship between the New GOLD criteria and mortality. Another retrospective study [11] applied the New GOLD criteria to the data collected from the ECLIPSE study and found a step wise increase in the risk of exacerbations over a 3. from A to D. Similarly, the hospitalization rate and mortality increased from A to D, although the 2 middle categories (B and C) appeared to be equivalent. The authors concluded that their analysis supports the use of the New GOLD criteria and not limit assessment to the use of FEV1 only. The small number of studies reporting on the utility of the New GOLD criteria coupled to some internal inconsistencies may delay widespread adoption of these tools.

In conclusion, the New GOLD criteria have all the characteristics of effective clinical guidelines and should be adopted by clinicians caring for COPD patients. The New GOLD criteria are clinically applicable and will be instrumental in providing systematic yet individualized care to these patients. Before these criteria gain universal acceptance, barriers should be circumvented. Specifically, the pulmonary community should establish standardized criteria for diagnosing and scoring the

severity of COPD exacerbations. In addition, clinical services should establish procedures for systematically surveying patients to establish an initial dyspnea score. Finally, professional societies, academic centers, funding agencies and practicing physicians should fund and conduct prospective studies providing evidence-based peer-reviewed publications to support the implementation of New GOLD criteria. When such studies demonstrate to the practicing clinician mortality and morbidity advantages, the widespread use of the criteria will follow.

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