EDITORIAL

NICE versus nGMS: what the evidence tells us

Overall, the fact that the new General Medical Services (nGMS) contract requires those working in primary care to think about Chronic Obstructive Pulmonary disease (COPD) is to be warmly welcomed. There are a couple of areas where the quality markers deviate from the evidence, but I have no doubt that, on balance, the inclusion of COPD within the contract will benefit many patients with COPD.

As chairman and clinical expert to the National Institute for Clinical Excellence (NICE) COPD Guideline Development Group, I was surprised that there was no pre-arranged consultation between the contract negotiators and the guideline developers in order to ensure consistency. As a result, primary care physicians and nurses have been put in an impossible position as to whether to fulfil the requirements of the contract and collect the financial rewards offered by nGMS or to follow the evidence-based guideline. This would be a sterile debate if following nGMS had no adverse consequences. Unfortunately it does.

The NICE guideline [1], like other international guidelines [2,3] uses an FEV₁ below 80% predicted as part of the diagnostic criteria for COPD. This is because an FEV₁ less than 80% predicted is almost always a reflection of pathological airflow obstruction; the Global Obstructive Lung Diseases (GOLD) guidelines even describe a category of COPD where the FEV₁ is above 80% predicted but where there is evidence of airflow obstruction as assessed by the FEV₁/FVC ratio and patient symptoms [2]. Ignoring those patients with an FEV₁ between 70% and 80% predicted, as recommended by nGMS because this “enables clinicians to concentrate on symptomatic COPD” [4], denies those patients with the earliest signs of disease the benefits of

intensive smoking cessation advice and therapy as well as forcing them to be coded incorrectly as “healthy”. It is rooted in the old view of COPD, which suggests that the impact of the disease worsens in a step-like way as the FEV₁ declines. This view is now known to be seriously flawed. There is a poor correlation between symptoms or health status and FEV₁; significant numbers of patients with an FEV₁ more than 70% of predicted have impaired quality of life because of their disease [5], and some have exacerbations [6]. To ignore such patients, I believe, is bad medicine.

The issue of whether to do reversibility testing or not is the one area that appears to have caused the greatest concern in primary care and potentially the most practical difficulties. During the later stages of NICE guideline development and consultation, this topic was the subject of much comment. Some comments were based on the premise that the guideline would recommend that reversibility testing should never be undertaken. This was never the case - the Development Group always acknowledged that reversibility testing had a role in some cases, but we stated that it was not necessary to do routinely and that it could be misleading if reversibility testing was seen as being a “gold standard” for diagnosing COPD.

Part of the confusion appears to stem from the BTS/SIGN asthma guideline [7], which recommends that demonstration of reversibility or variability in airway calibre is necessary in order to make a diagnosis of asthma. Therefore, it is claimed that in order to diagnose COPD it must be necessary to demonstrate the absence of reversibility. The interpretation of the test depends on the pre-test probability of the diagnosis being COPD or asthma. The BTS/SIGN asthma guideline states, “marked

variability of peak flow and easily demonstrated reversibility confirms a diagnosis of asthma, but smaller changes do not necessarily exclude the diagnosis." For COPD this could be reworded as, "lack of marked variability of peak flow and lack of reversibility confirms a diagnosis of COPD, but changes in peak flow or evidence of reversibility do not necessarily exclude the diagnosis." If a patient has clinical features that lead to a diagnosis of COPD and they have airflow obstruction when assessed using spirometry, performing a reversibility test adds nothing to the diagnosis and has no relevance to selecting therapy.

The other justification for undertaking reversibility testing is to establish a post-bronchodilator FEV₁ which has prognostic significance. Whilst this is true, pre-bronchodilator reversibility also correlates with prognosis, and given the significant variability in the results of reversibility tests performed on different occasions [8]. I do not believe that this provides sufficiently robust information to justify routine reversibility testing.

The Development Group were criticised for making what was seen as a far-reaching recommendation based on consensus—i.e. "only grade D". In fact, there is good evidence (grades Ib and IIb [8–15]) about the limitations of reversibility testing. However, at the time the NICE guideline was published there was little evidence to support the recommendation that COPD and asthma can usually be differentiated on clinical grounds. Recently, data from Germany has shown that asking four simple questions about age of onset of symptoms, smoking history, atopic status and cough quality (i.e. none, dry or productive) has a sensitivity of 87.6% and a specificity of 87.2% for diagnosing COPD rather than asthma in a primary care population [16]. This confirms the NICE COPD guideline's recommendation—that in most cases, routine reversibility testing is not necessary in order to make a diagnosis of COPD.

This is far from being an obscure academic debate. Performing reversibility tests on patients with undoubted COPD and reclassifying them as being "asthmatic" if they show more than 15% improvement in FEV₁ following a "reversibility test", leads to an incorrect diagnosis, the withholding of important therapeutic options such as pulmonary rehabilitation, and incorrect assumptions about the ultimate prognosis. Most patients with COPD die as a result of their disease; most asthmatics do not.

It is also absurd to insist that COPD and asthma are mutually exclusive - some patients who have had asthma since childhood and who have smoked

heavily may well have both diseases. In these patients there is often an increase in breathlessness in response to triggers, as seen in asthma, but lung function cannot be normalised by therapy. Demonstration of large changes in FEV₁ (i.e. ≥ 400 ml) in response to bronchodilators in such patients confirms the presence of asthma, and the fact that their spirometry cannot be normalised confirms the presence of COPD.

The nGMS contract has undoubtedly catalysed interest in COPD, but the limitations of the Quality Outcomes Framework (QOF) must be acknowledged and amended in the review due in a year's time. The contract is just that, a contract; it is not an evidence-based statement of best practice. Clinicians must do what is best for patients.

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