A critical evaluation of the guidelines of obstructive lung disease and their implementation

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Summary Guidelines or recommendations for diagnosis and treatment of obstructive lung diseases defined as asthma and/or chronic obstructive pulmonary disease (COPD) have been numerous in the Nordic countries during the last 25 years. A better-shared care between on one side the general practitioners or chest physicians and on the other side the patients and their closest surroundings of care has to be implemented in future guidelines. Guidelines are based on efficacy and not effectiveness studies, and do not properly focus the process of behavioural changes of health care professionals and patients. Primary care physicians treat the vast majority of patients with chronic airway disease of moderate severity. However, they find the evidence-based practice guidelines often complicated. Furthermore, less than 50% of the recommendations in guidelines may be evidence based. As rapid changes may occur in diagnosis and treatment options, future guidelines must be able to adapt to such rapid adjustments. No randomised studies are available on the effect of patient-relevant outcomes using guidelines on management of obstructive lung disease. More outcome research is necessary on both change of procedures and health endpoints after launching guidelines. Cost-effectiveness studies are important to make medical staff and administrative health care systems cooperate in the construction of future health care systems with both an improved medical and system quality.

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Introduction

The main goals of the guidelines of obstructive lung disease (asthma and/or chronic obstructive pulmonary disease (COPD)) are to achieve better service and standards for diagnosis, treatment, care and self-management, which should improve quality of life and prolong life time for individuals with chronic respiratory diseases. The major challenge is thus to develop user-friendly clinical guidelines that are easily understood and implemented by trainee physicians, general practitioners and patients. In the search for evidence, the focus is, however, on strictly designed randomised controlled trials that may detract from the crucial role played by patients in their own care. The collaboration between on one side the general practitioner or chest physician and on the other side the well disease-educated patient and his or hers relatives is rarely handled in a practical manner in the guidelines.

There are a growing number of Nordic asthma and COPD guidelines generated singularly and jointly by many national bodies, regional institutions or leading medical persons, all of which offer recommendations for the diagnosis and management of obstructive lung diseases. Almost all of these have been produced during the last 25 years. Today there is no sign that their numbers either as new statements or in revised forms are diminishing. These documents are important as they act as benchmarks against which current practice of asthma and COPD care is judged. They are also used as guides to what should or should not be funded in health care systems. But the increasing involvement of the medical industry in the development of such guidelines may cause serious restrictions for their use in various national health care systems where the majority of costs are paid by taxes. It is also important to recognise that some experts may have connections to the medical industry that may reflect their decisions in the panels. It is very important to be aware of the strength and limitations of the guidelines and relate their contents to the individual physician's approach to management of obstructive lung disease.

As the production of clinical guidelines became an industry of the nineties (Fig. 1), it was initially thought that physicians would follow those recommendations where the best evidence was distilled into single documents. However, the last decade has shown us the increasing importance of implementation of these guidelines. We have all learnt that change of management and treatment by physicians is not solemnly achieved by the production of guidelines. Further, the regular general practitioners may now have to use more than hundred guidelines, while a consultant in respiratory medicine may have 20 guidelines.

We wish to examine several features common to guidelines used in the Nordic countries for obstructive lung disease management, consider areas where their recommendations may change and

Figure 1 Annual number of new publications with key words "Asthma AND Guidelines" (drawn line) and "COPD AND Guidelines" (stippled line) identified through PubMed search.
finally suggest an improved approach to patient care based on a more effective implementation.

History

Individual review articles and text books have advocated approaches to asthma and COPD care for a long time. The first documents were expert consensus statements, reflecting knowledgeable but potentially selected reviews of the literature by the participants. One of the first guidelines in the Nordic countries was those developed for asthma and cough by the Swedish "Social styrelsen for läkemedelinformation"1 with Norwegian counterparts.

Finland has been a forerunner in the Nordic countries in developing National programs for Asthma and COPD. The success factor in Finland was the firm involvement of the Ministry of Social Affairs and Health, who created a platform for both a good system quality and medical quality in the handling of asthmatics and COPD patients at the community level.2 The Finnish programme on asthma emphasises the role of the primary health care team, with one general practitioner and one nurse in each municipal health centre who are trained to work as coordinator of local activities and taking part in counselling follow-up of patients. Training of all general practitioners was undertaken at national, regional and local levels, with 25 000 health care professionals receiving training in the first 5 years of the programme.3 Moreover, Finnish Medical Society Duodecim has launched evidence-based guidelines for COPD in 1999, asthma in 2000 and smoking cessation in 2002 based on systematic review of the literature by the leading experts of the country. Asthma and COPD guidelines have been recently updated. These web-based guidelines are short (4–5 pages) with links to more detailed recommendations and easily accessible via internet (www.kaypahoito.fi). Every health centre has access to these recommendations, which has also been shown to significantly improve the implementation of the local programmes of these same diseases. In addition to the recommendations intended to the professionals, short web-based guidelines were prepared for the patients.

In Norway, Asthma schools were introduced in the 1990s and in 1999 the National Plan for Asthma Schools (NPAS) was launched. Its medical content originated from GINA.4 NPAS developed and implemented separate asthma education packages for adults, adolescence and children and also opened a website for teenagers (www.asthmasurf.com) and a PC program for primary care to help the general practitioners handle asthma and COPD and differentiate between them.

The Nordic consensus report on asthma management was based on a consensus of expert opinions and not on a systematic literature survey.9 An implementation plan for practical use was not developed for this guideline.

In asthma as well as in COPD, the large international professional societies formulated their views about management, the most important being those of the European Respiratory Society (ERS) and the American Thoracic Society (ATS).6 Finally, a group organised by the World Health Organisation/National Hearth Lung and Blood Institute in USA was founded and detailed recommendations were available through the Global Initiative against asthma4 and the Global Initiative for Chronic Obstructive Lung Disease.7 The first editions of these documents were available in 1995 and 2001, respectively.

The aims and key features of the GOLD programme represent a further advance. GOLD objectives were firstly, to increase awareness of COPD among health professionals, health authorities and the general public, secondly, to improve diagnosis management and prevention and, thirdly, to stimulate research. The documents have been widely distributed and national delegates of the GOLD programme have given regular feedbacks to the guidelines at the annual ATS and ERS meetings.

Grading quality of evidence and strength of recommendations

The scaling adopted for strength of evidence was initially relatively simple and will not meet the more recent and rigorous approaches advocated for evidence-based medicine. However, the criteria to assign evidence may differ in steering committees of the various guidelines. Furthermore, some groups advocate that meta-analyses or post hoc analyses of pooled randomised clinical trials are insufficient to provide definite statistically significant answers to main clinical questions,8 while others emphasise the conclusions from the Cochrane Library.9

The present Swedish Guidelines for a national programme for COPD10 are based on evidence from multiple systematic reviews or relevant studies.11 The Swedish Council on Technology Assessment in Health Care selected only mortality, health-related quality of life, symptoms, need for increased medication, emergency visits or hospital admissions as important outcome variables and excluded
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Defining obstructive lung diseases

A strict separation of adult patients with asthma or COPD is often not possible in clinical practice. Similar symptoms and signs are often present in both phenotypes of obstructive lung disease. When using the defining criteria in the guidelines of asthma and COPD, a large fraction of the patients can be defined as having both diseases. The statements in guidelines of effects of interventions lack mostly the narrow inclusion and exclusion criteria for the phenotypes of obstructive lung disease which gave the evidence for a specific recommendation.

Major symptoms of asthma are attacks of breathlessness and wheezing that may occur during both daytime and night. However, many patients with variable airflow obstruction may not have such clearcut symptoms and many individuals in the community report these symptoms without having variable airflow obstruction.

COPD guidelines emphasise airflow obstruction (reduced FEV<sub>1</sub>/FVC ratio) and lack of a large spontaneous variability. The definition does not account, however, for the heterogeneity of the disease and does not necessarily differentiate between “normal” ageing of the lung and disease.

The availability of quantitative computer tomography scanning may in the future provide a necessary stimulus to create greater knowledge into studies of the mechanisms of emphysema and air wall thickness. A prerequisite is that lung density measurement can be standardised and...
validated against traditional clinical outcome variables, and if proven it may be a new measurement that is objective, specific and sensitive for monitoring the effect of new drugs on the progress of emphysema in future randomised clinical trials. This approach may solve some definition problems but may create new diagnostic problems. We are still ignorant of the role of the various pathological phenotypes in the natural history of asthma and COPD. Long-term follow-ups as well as autopsies and histology are highly necessary for individuals with different patterns of symptoms, signs and possible causal environmental factors of obstructive lung disease.

### Classifying disease severity

Clinicians expect the guidelines to offer a practical approach to grade the severity of the disease and relate this to management decisions. In asthma, there has been a relation between the patient’s load of symptoms and the amount of medications suggested to control symptoms. The repeatability of this classification has not been thoroughly examined.

A completely different approach has been used in COPD. Until recently, most guidelines based their staging on the FEV₁ making the generally reasonable assumption that the lower the FEV₁ as a percentage of prediction, the greater the pathological and symptomatic severities. This approach has several limitations. Firstly, spirometry has not been widely available. This remains a problem, especially in primary care medicine. Secondly, the arbitrary boundaries selected for the severity classification have to be questioned. Patients who lie close to the selected boundaries may therefore be reclassified as more or less severe if seen on different days. Thirdly, the relatively poor relationship between health status and spirometry is obvious. For example, an individual patient with an FEV₁ of 65% predicted can be more symptomatic than one who’s FEV₁ is 40% predicted. Since the benefits of bronchodilator therapy and rehabilitation are based on symptomatic improvement rather
than altered lung mechanic, it may be irrational to base the management on a specified level of FEV₁. The very severe subgroup of COPD is chosen to highlight a population where persistent daytime hypoxaemia is more likely to be found. The weaknesses of a purely symptom-based method to identify a hypoxemic patient are overt. More knowledge must be acquired on the precision, validity and prognostic values as well as the applicability on treatment decisions of the present grading of disease severity of asthma and COPD.

Management

There is good agreement between the different management guidelines regarding goals of treatment in asthma and COPD and how to achieve these. The objectives are to (a) prevent disease progression and complications, (b) relieve symptoms, (c) improve health status, (d) prevent and treat exacerbations or attacks of breathlessness, (e) reduce mortality and (f) minimise side effects from treatments. These objectives provide a useful checklist both of the desirable attributes for any new treatment and to assess the effectiveness of an individual treatment strategy.

The four essential principles in medication for adults with asthma are (1) start effective treatment early, win the patient's confidence and improve the outcome, (2) treat according to disease severity, (3) treat exacerbations early and (4) educate the patient.

Since none of the existing medications for COPD have been shown to cure or modify the long-term decline in lung function, efforts in treatment have focus on the use of medications to control symptoms. Recent guidelines have emphasised other endpoints such as improvement in health status, exercise capacity and symptoms scores and in particular perceived breathlessness. Reducing the frequency and severity of COPD exacerbations and asthma attacks during the day or night is also recognised as an important goal of treatment. However, the use of health status questionnaires, exercise tests or symptom scores has not reached daily practice as they are time consuming and difficult to apply to individual patients.

Drugs

All current guidelines recommend the use of bronchodilators (beta-2-agonists, anticholinergics and methylxanthines) for the relief of symptoms. The response of an acute bronchodilatation test has, however, a limited predictive value for a long-term effect on other clinical outcomes. However, despite increased use of inhaled corticosteroids, a large majority of subjects with symptomatic asthma (especially men and smokers with asthma) do not use this treatment on daily basis. We need, however, appropriate studies of the safety of the long-acting beta-agonists with regard to severe asthma episodes and deaths when those episodes occur.

The sustained relief of symptoms, improvement in health status and reduction in exacerbation rates in asthma and in moderate to severe COPD may result in a change in the position of long-acting bronchodilatation drugs in future guidelines towards their use earlier in the course of COPD. The resultant increase in FEV₁ may be relatively small, but it is often accompanied by large changes in lung volumes, which is associated with reduced dyspnoea. All of the current guidelines recommend the use of the combination of bronchodilatators in patients to remain symptomatic. Theophyllines remain a treatment option in most COPD guidelines, but as a second line bronchodilatation therapy because of their systemic administration, narrow therapeutic index and their greater potential for side effects.

Inhaled glucocorticosteroids remain a controversial topic in the management of COPD. There is considerable evidence that the short course of oral glucocorticosteroids is a poor predictor of long-term response to inhaled glucocorticosteroids. The lack of the effect of inhaled corticosteroids on the decline in FEV₁ has been published from four large trials and the studies provide sufficient evidence that inhaled glucocorticosteroids at all stages of the disease do not influence decline in FEV₁. However, inhaled glucocorticosteroids in asthma and in severe COPD with several exacerbations per year do appear to affect symptoms and improve health status possibly by reducing exacerbations, asthma attacks and hospitalisation.

Patient education, rehabilitation and nutrition

The effectiveness of patient education has been clearly demonstrated in a Norwegian randomised, controlled study. Education in asthmatics was found to improve health-related quality of life, to reduce contacts with primary care physicians and sick days and to improve steroid inhaler compliance. A dominant cost-effectiveness strategy was
also found, implying better outcomes for the asthmatic at a lower cost in societal perspective. In patients with COPD, patient education reduced the need for general practitioners consultations and reduced the need for rescue medication.

There is consensus on the benefit of exercise training in symptomatic patients with asthma and COPD at all stages of the disease. In a rehabilitation programme, it is important to recognise treatable conditions like cardiac failure, peripheral muscle dysfunction, reduction in total and lean body mass, anxiety and poor coping skills. Little knowledge is available on whether repeated rehabilitation courses enable patients to sustain the benefits gained from the initial course of treatment. Home ventilation as non-invasive ventilation of severe COPD has so far not been recommended in any of the guidelines. Guidelines have a role in advocating the use of pulmonary rehabilitation, since in many countries pulmonary rehabilitation is only available in a minority of respiratory centres in spite of the fact that the evidence is overwhelming in support of a beneficial effect of pulmonary rehabilitation on health status. Indeed, the improvement in health status and exercise tolerance following pulmonary rehabilitation outstrips many of the pharmacologic interventions in COPD.

Exacerbations and acute attacks of breathlessness

Impact of exacerbations of COPD and severe attacks of asthma on health care utilisation and the detrimental effects on the health status of patients is emphasised in all guidelines. Important targets for therapeutic interventions are attacks of asthma and exacerbations. Similar pathologic patterns have been observed in severe asthma attacks and exacerbations of COPD.

Asthma attacks should be recognised earlier and treated promptly with glucocorticosteroids. The use of antibiotics in exacerbation of COPD remains somewhat controversial. Although, there is an increasing evidence that supports their use in exacerbation with clinical signs of airway infection defined as increased sputum volume, purulence and increased breathlessness. Recent studies have shown significant benefit of oral glucocorticosteroids in the treatment of exacerbations of COPD. The guidelines give criteria for hospitalisation, admissions to an intensive care unit and inpatient oxygen therapy, but the recommendations are not well documented. There is now also a consensus for the use of non-invasive ventilation in COPD, but the exact timing of this intervention is unclear. Mortality has been reported to be lower in patients receiving non-invasive positive pressure ventilation for COPD than in those receiving both conventional mechanical ventilation and optimal medical therapy alone.

Implementation

Major gaps in knowledge of diagnosis and treatment of obstructive lung disease have been shown in general practitioners and hospital doctors in the Nordic countries. In spite of recommended guidelines, 20% of the doctors did not perform any kind of spirometry when diagnosing obstructive lung disease. Many health professionals do still only use symptomatic and physical criteria to define disease. Only about 35% of the physicians required spirometry to measure the effects after inhalation of bronchodilators or corticosteroids. A correct diagnosis is a prerequisite for giving precise treatment. Many cases of mistaken diagnosis have been leading to erroneous treatment. The gap between guidelines and reality is in alignment with the gap between efficacy and effectiveness studies.

Many physicians are not giving smoking cessation counselling and not administering influenza and pneumococcal vaccination to COPD patients. Pulmonary rehabilitation is recommended only by a minority of the doctors. Small differences were observed in the diagnosis and treatment between health professionals of general internal medicine and general practitioners or between private and hospital practices and between board-certified physicians and those in training. Data from several studies have demonstrated that the health services change by slow evolution and not by revolution—humans are generally resistant to change.

Changing clinical behaviour is much more than writing guidelines. Previous efforts to get the physician to follow guidelines have overlooked the importance of clear and concise recommendations. Guidelines that are written clearly and specify the precise behaviours required (i.e. who, what, when, where and how) are most likely to be implemented. Specifying the required behaviour also facilitates audit of behaviour. Behaviour analysis of the controlling antecedents and the consequences of implementation may help develop effective intervention. In order to increase the effectiveness of guidelines, it is suggested that guidelines of the future guidelines are published in three forms: (1) comprehensive referenced text containing an executive summary, (2) quick reference guide for clinicians that contains the key points, presented in
a problem-orientated form, with management protocols and (3) educational guide for patients. Scientists and teachers of medical students and physicians should for the future take the increasing amount of evidence from disciplines other than medicine, concerning how people learn.

Communication skills should form part of medical training so that clinicians understand that the relationship with patients is an alliance or partnership. Attentiveness is required to communicate well with patients, using open-ended questions in order to understand their fears and concerns about the disease and its treatment. No implementation of guidelines should be recommended without patient education.

The general practitioners in the local health communities and the chest physicians in the county and regional hospitals should review their existing practice for their management of obstructive lung disease against the guidelines as they develop their local health delivery plans. The review should consider the resources required to implement the recommendations including people and process involved. A timeline should be planned, and it is in the interest of patients that the implementation timeline is as rapid as possible. If relevant local clinical guidelines and care pathways are available, this should be reviewed in the light of new international guidelines and revised accordingly.

Usual ways to examine gaps between guideline recommendation and practice are (1) surveys of general practitioner and physician self-report, (2) prospective chart review and (3) patient self-report. Obstacles of previous guideline have been (1) lack of awareness or willingness to be read by the health professionals, (2) not clearcut recommendations, (3) wish to interpret the literature themselves, (4) use recommendations of local colleagues or (5) the recommendations are not compatible with current local values. Effective interventions to alter clinical practice have been educational outreach visits, combinations of audit and feedback, reminders, local consensus and interactive educational meetings.

Conclusions

The future guidelines of asthma and COPD management must be more dependent on evidence from effectiveness studies and not only from randomised controlled trials involving narrowly defined patient population and conducted by those with a specialist interest in the disease. There are a number of ways in which guideline implementation could be improved: (a) rewriting the guidelines to ensure that they give clear, concise and specific recommendations; (b) ensuring medical and system quality and (c) educating patients.

References

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