

# The National Lung Health Education Program and Managed Care

## The Importance of Early Identification and Intervention in Chronic Obstructive Pulmonary Disease

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### Abstract

The National Lung Health Education Program (NLHEP) is a new healthcare initiative which encourages the early diagnosis of and intervention in patients who are in the process of developing chronic obstructive pulmonary disease (COPD) and related disorders. COPD is primarily a smoker's disease. Lung injury is due to proteolytic and oxidative damage early in the course of disease and results in premature loss of lung function, as measured by forced expiratory volume in 1 second (FEV<sub>1</sub>). Smoking cessation will retard this rate of decline and improve prognosis.

The most common cause of death in patients with early stage COPD is lung cancer. Thus, the possibility of lung cancer should be investigated in patients with early degrees of **airflow** obstruction. The NLHEP Spirometry Statement encourages testing of all smokers aged over 45 years, and anyone with cough, dyspnea, mucus hypersecretion, or wheeze. The spirometry industry has responded to the NLHEP by developing simple, accurate, reliable, and inexpensive office **spirometers** for screening purposes. It is hoped that the widespread use of spirometry will begin to reduce the socioeconomic impact of COPD and related lung cancer. Managed care should endorse the goals and objectives of the NLHEP for the benefit of their patients, and to help contain costs.

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The objective of this article is to describe the goals and objectives of the National Lung Health Education Program, a new national healthcare initiative which encourages the early diagnosis of chronic obstructive pulmonary disease (COPD) and related disorders by the widespread use of spirometers in patients at risk.

### 1. Early Identification in Chronic Obstructive Pulmonary Disease (COPD)

The growing problem of COPD represents both a challenge and an opportunity for managed care. The natural history of COPD is marked by a progressive decline in lung function, usually in the absence of compelling symptoms.<sup>[1]</sup> This results in a gross under diagnosis of the problem in mild to moderate stages of the disease.<sup>[2]</sup>

Successful initiatives in screening for occult disease include the National Hypertension Education Program and the National Cholesterol Education Program.<sup>[3,4]</sup> These programs have had a tremendous effect in reducing the impact of heart attack and stroke in the US.<sup>[3,4]</sup> Both hypertension and hyperlipidemia have a long asymptomatic or insidious stage, which begin decades before symptoms of end-organ complications ensue. The same is true for COPD.

It is now well established that lung injury from tobacco smoking, mediated by oxidative and proteolytic damage to small airways and alveoli, begins to cause physiological changes early in the natural course of disease. This leads to accelerated losses in ventilatory function, as measured by the forced expiratory volume in 1 second ( $FEV_1$ ), the key indicator of airflow obstruction.

The second parameter, obtained by simple spirometric screening, is the forced vital capacity (FVC), the denominator of the  $FEV_1/FVC$  ratio; a normal ratio is above 0.7. When the ratio begins to fall below 0.7, this predicts premature losses in ventilatory function.<sup>[5]</sup> It is interesting that the FVC tends to increase in mild states of emphysema<sup>[6]</sup> due to loss of elastic recoil. This is why the simple ratio of  $<0.7$  is so exquisitely sensitive, but nonspecific in diagnosing the diseases characterized by

airflow obstruction. COPD and its components, chronic bronchitis, asthmatic bronchitis and emphysema, are progressive diseases with inexorable losses in  $FEV_1$  over time. In contrast, most asthmatic states, including chronic persistent asthma, tend to have a reversible component that can be improved and stabilized with the use of anti-inflammatory agents and bronchodilators.

To date, no medication has been shown to slow the rate of decline in  $FEV_1$  in patients with COPD.<sup>[7]</sup> The only thing that is likely to improve lung function in the early stages of the disease is smoking cessation.<sup>[8]</sup> This was shown in the Lung Health Study,<sup>[8]</sup> which enrolled 5887 patients between the ages of 35 and 59 years if they had smoked a pack of cigarettes a day for 10 or more years (10 pack-years). Patients with an  $FEV_1/FVC$  ratio of  $<0.7$ , and an absolute  $FEV_1$  of between 55 and 90% of predicted normal, were enrolled. In this study, sustained quitters had a slight improvement in ventilatory function and only a mild decline in  $FEV_1$  over 4 years of follow-up. In contrast, continuing smokers had a much more rapid decline in  $FEV_1$ , predicting premature morbidity and mortality in the vast majority of patients. Even with this rate of decline, the symptomatic range which is usually below an  $FEV_1$  of  $\geq 1.5L$ , was not reached.

Another study,<sup>[9]</sup> which followed quitters versus persistent smokers over a 20-year follow-up period also provided strong evidence that smoking cessation preserves lung function and is associated with increased survival (fig. 1).<sup>[9]</sup> Thus, identification of patients at risk of premature morbidity and mortality through simple spirometric tests is the key to identifying those who absolutely must stop smoking and who may be candidates for pharmacological agents that can improve airflow. The study also shows that it is never too late to stop smoking, but it is best to stop smoking before excessive declines in  $FEV_1$  occur. In the Lung Health Study, inhaled ipratropium improved  $FEV_1$  compared with baseline throughout the study. However, the drug did not have an effect on retarding the rate of decline of baseline lung function.<sup>[8]</sup>

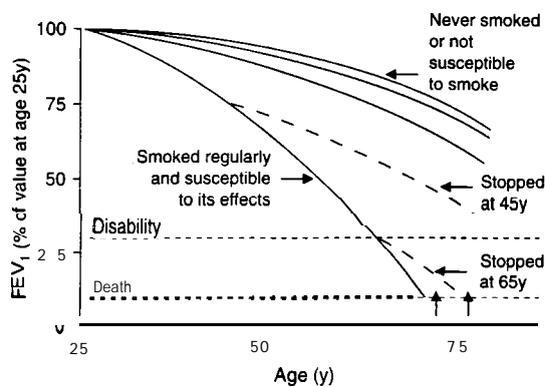


Fig. 1. The effect of smoking cessation at age 45 years on forced expiratory volume in 1 second ( $FEV_1$ ) followed-up over 20 years (from Peto et al.<sup>[9]</sup> with permission). The rate of decline paralleled that associated with a normal decline and that of smokers who were not losing ventilatory function prematurely because they were not susceptible to cigarette smoke. Even those patients with poor pulmonary function (i.e. only 30% of what was predicted for age 25 years), had a survival value on smoking cessation (see vertical arrows).

## 2. Early Intervention in COPD

Only approximately 20% of smokers are susceptible to lung damage.<sup>[10]</sup> Why 80% are not susceptible is not known. However, it is possible that genetically determined antioxidant defence mechanisms are protective.<sup>[11]</sup>

It is interesting that the most common cause of death in the Lung Health Study was lung cancer; 57 of the 149 total number of deaths were due to lung cancer over a 5-year follow-up period.<sup>[18]</sup> It is known that patients with airflow obstruction have a 4- to 6-fold increase in the prevalence of lung cancer compared with smokers with equal tobacco consumption and with those who have similar occupational histories and normal airflow.<sup>[12,13]</sup> Thus, the patients who are most likely to develop lung cancer are heavy smokers (i.e. smokers with more than 30 pack-years) with airflow obstruction. When these 2 conditions are met, there is an immediate 2% prevalence of lung cancer, which is usually *in situ* or Stage I disease.<sup>[14]</sup> Some 25% will have moderate or greater degrees of dysplasia, which are very likely precancerous lesions. These patients

should be the subject of surveillance for the emergence of lung cancer, and are probably candidates for trials of chemoprevention.

The National Lung Health Education Program (NLHEP) Spirometry Committee has recommended the testing of all smokers aged 45 years or older, with simple spirometric measurements:  $FEV_1$  and the forced expiratory volume in 6 seconds ( $FEV_6$ ), which is used as a surrogate for the full FVC.<sup>[15]</sup> Previous recommendations encouraged forced expiration for 12 or more seconds, which is difficult for people without airflow obstruction.<sup>[16]</sup> Normal lungs empty in 6 seconds. Forced expiration for the standard 12 seconds or longer is also difficult for older patients, who may become light-headed through the Valsalva maneuver with long forced expiration. It is now known that the  $FEV_1/FEV_6$  ratio is as accurate as the full  $FEV_1/FVC$  ratio, detecting those patients who will have a rapidly declining  $FEV_1$ .<sup>[17]</sup>

Whether knowledge of an abnormality in lung function will be a motivating factor in smoking cessation is the subject of a current study (Enright PL, personal communication). Although all smokers should be encouraged and assisted in quitting, the patient with airflow obstruction has a critical need to stop in order to prevent premature morbidity and mortality from COPD and related disorders.

Recently, a second Lung Health Study has been completed (Lung Health II).<sup>[18]</sup> This study included all patients who were enrolled in the first Lung Health Study.<sup>[8]</sup> Lung Health II investigated the role of inhaled corticosteroids in retarding the rate of decline in  $FEV_1$ .<sup>[18]</sup> No differences were observed in  $FEV_1$  decline in patients randomized to receive inhaled triamcinolone compared with placebo.<sup>[18]</sup> A reduction in symptoms and a decrease in the use of healthcare services for patients with COPD was found in the corticosteroid-treated group compared with placebo recipients.<sup>[18]</sup> However, these benefits and care resource savings need to be weighed against possible long term corticosteroid systemic adverse effects.

The spirometry industry has now responded to the need for simple, accurate, inexpensive, and user-

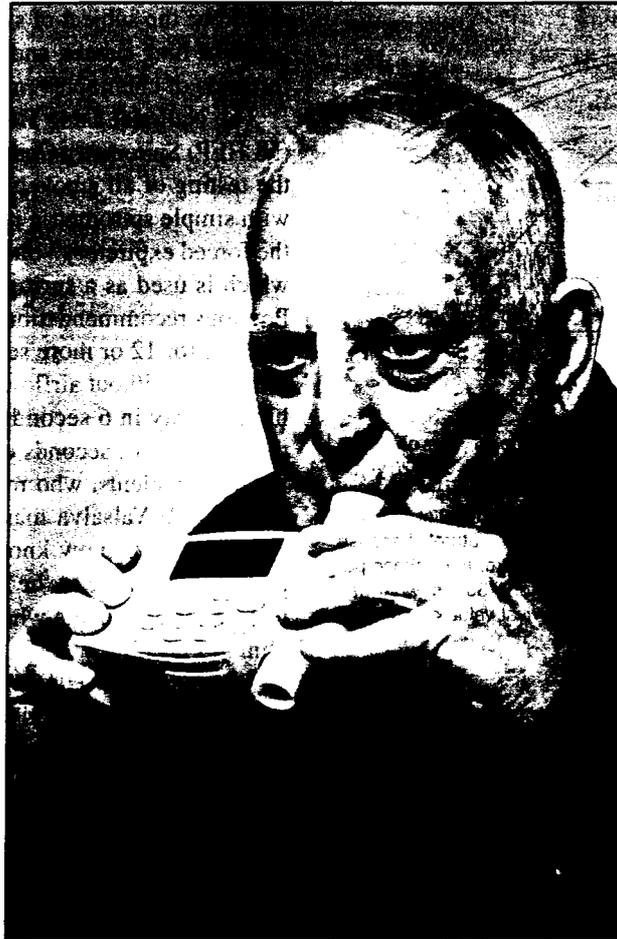


Fig. 2. A new handheld spirometer which is approved by the US Food and Drug Administration and meets the recommendations of the National Lung Health Education Program.<sup>[15]</sup>

friendly office devices, by producing a family of spirometers which cost less than \$US500 and which use disposable flow sensors (2001 values). Such a spirometer is illustrated in fig. 2. It is a fact that spirometric abnormalities are predictive of all-cause mortality.<sup>[19,20]</sup> This includes deaths from heart attacks, stroke, lung cancers, and many other diseases such as neuromuscular abnormalities, marked obesity, AIDS, and general lack of vigor. Thus, the spirometer becomes a key instrument in identifying patients at risk of many diseases that are amenable to management through preventive strategies such as the treatment of hypertension and

hyperlipidemia, smoking cessation, and other therapies.

The 1990 Surgeon General's report on the health benefits of smoking cessation, which cited more than 1000 studies, concluded that smoking cessation had many benefits, including the preservation of lung function and the reduction of risk of many diseases, including lung cancer, heart attack, and stroke.<sup>[21]</sup> The new Clinical Practice Guidelines Report by the Public Health Service offers evidence-based guidelines on new strategies in smoking cessation, including the use of 5 prescription drugs which help mitigate nicotine withdrawal. This ex-

tensive report concluded that smoking cessation is highly cost effective.<sup>[22]</sup>

COPD is now the fourth most common cause of death in the US, and the only disease which continues to rise in mortality stakes among the top 10 killers of Americans. The direct cost for managing COPD was \$US14.5 billion (in 1996).<sup>[23]</sup> Most of this money is spent on the cost of advanced stages of disease, including hospitalisation, oxygen, drugs, and surgery.<sup>[23]</sup> All other causes of death are dropping, largely due to efforts at early identification and comprehensive management. The emphasis on care is, or should be, shifting from crisis care to preventive care.

### 3. New Horizons in COPD

Many advances in drug therapy for patients with COPD are under development: they are purported to deal with the basic inflammatory mechanisms involved in COPD<sup>[24]</sup> which are quite different from those associated with asthma. These specific therapies are eagerly awaited.

### 4. The Health Maintenance Organization and lung Health

Lung health is the key to general health, as indicated by the arguments stated in this article. Although health maintenance organizations (HMOs) today often focus on short term outcomes, the great majority of Americans who receive their healthcare through HMOs (even if they transfer from one plan to another) will benefit in the long term from the early identification and prevention approach to COPD. The use of spirometry is the key to diagnosis and the assessment of responses to therapy.

### 5. Conclusions

COPD is a growing health problem. The NLHEP is designed to involve all primary care physicians in the early identification of and intervention in COPD. Simple office spirometry is required to find early cases of COPD. Stopping smoking is of key importance. Pharmacologic therapy may reduce

COPD symptoms. New COPD drugs are under development.

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