Office Spirometry for Lung Health Assessment in Adults: A Consensus Statement from the National Lung Health Education Program

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Chronic obstructive pulmonary disease (COPD) is easily detected in its preclinical phase using spirometry, and successful smoking cessation (a cost-effective intervention) prevents further disease progression. This consensus statement recommends the widespread use of office spirometry by primary-care providers for patients ≥ 45 years old who smoke cigarettes. Discussion of the spirometry results with current smokers should be accompanied by strong advice to quit smoking and referral to local smoking cessation resources. Spirometry also is recommended for patients with respiratory symptoms such as chronic cough, episodic wheezing, and exertional dyspnea in order to detect airways obstruction due to asthma or COPD. Although diagnostic-quality spirometry may be used to detect COPD, we recommend the development, validation, and implementation of a new type of spirometry—office spirometry—for this purpose in the primary-care setting. In order to encourage the widespread use of office spirometers, their specifications differ somewhat from those for diagnostic spirometers, allowing lower instrument cost, smaller size, less effort to perform the test, improved ease of calibration checks, and an improved quality-assurance program. [Respir Care 2000;45(5):513–530] *Key words: chronic obstructive pulmonary disease, risk assessment, smoking, spirometry.*

Background

During the last 40 years, the desire to reduce the morbidity, mortality, and expense of common chronic diseases in the United States has led to successful programs designed to identify and[1] modify risk factors such as hypertension and hypercholesterolemia.[1,2] The primary and secondary prevention of disease through early recognition and intervention has become a key strategy, leading to the preparation of guidelines by various expert panels that recommend specific screening and monitoring programs.[3–5] Despite evidence documenting the very high burden of suffering and the economic cost of chronic respiratory diseases,[6] and despite calls for methods to reduce the impact of COPD,[7,8] recent consensus statements on the management of COPD have not addressed the early assessment of respiratory function in people at risk for chronic respiratory diseases.[9–12] Although standards for the performance of spirometry are well established,[13] and although diagnostic quality spirometers are widely available, pri-

mary-care physicians rarely use spirometry to detect COPD in smokers or to detect asthma or COPD in patients with respiratory symptoms.[14–17]

The failure of spirometry to meet the requirements for effective screening in general unselected populations (regardless of smoking status or symptoms) provided the basis for the unwillingness to support efforts to detect COPD early in its course, although the use of spirometry for "case finding" in patients who seek medical care for "unrelated" symptoms (during a clinical encounter), and who are at high risk for COPD due to a history of heavy cigarette smoking, was supported by a 1983 official statement of the American Thoracic Society (ATS).[18] Several lung function tests that initially were thought to be sensitive to early disease of small airways (closing volumes and nitrogen washout curves, for example) were too complex and were found not to predict the subsequent development of COPD.[19–22] When the use of spirometry was initially suggested for identifying smokers with asymptomatic lung disease,[23,24] little evidence could be found to suggest that early identification of COPD would have any impact on its course. Although there was mounting evidence that spontaneous smoking cessation improved the rates of decline in lung function toward normal,[25,26] selection bias and other factors may have accounted for these changes. Furthermore, outcomes in most smoking cessation programs were disappointing.

Since then, results from the National Health and Nutrition Examination Survey (NHANES) III and the multicenter Lung Health Study (LHS) have provided a new basis for early identification and intervention in COPD.[27,28] The LHS was the first study to demonstrate prospectively that early intervention in smokers identified to be at risk for COPD could modify the natural history of the disease. Both the NHANES III and the LHS also documented the ability of spirometry to detect mild air flow abnormalities in thousands of cigarette smokers, many of whom did not have symptoms that would have prompted them to seek medical attention.

Increased awareness of these issues has led to the formation of the National Lung Health Education Program (NLHEP), a project jointly sponsored by several professional societies crossing various medical disciplines and specialties.[29] The program is designed to increase the awareness of lung health in patients, health care practitioners, and health care organizations. As a part of the NLHEP, a subcommittee was organized to reevaluate the role of simple lung function testing as a tool for assessing lung and overall health. Following an extensive literature review, Gary Ferguson developed the first draft of this report in early 1998, which then was reviewed by the NLHEP spirometry subcommittee. The American College of Chest Physicians (ACCP) and the National Heart, Lung, and Blood Institute (NHLBI) then held a conference on

August 18, 1998, to review the report further. Paul Enright then revised the document based on discussions and comments from the conference attendees. The revised report was again reviewed during a second conference sponsored by the NHLBI in Bethesda, Maryland, on March 26, 1999. Both conferences included experts in spirometry and evidence-based medicine, including representatives from several professional associations and governmental agencies. This document represents the contributions of the participants of these conferences.

Indications for Office Spirometry

Recommendation

Primary care providers (PCPs) should perform an office spirometry test for patients $\geq$ 45 years old who report smoking cigarettes (current smokers and those who quit during the previous year) in order to detect COPD.

Rationale: Several well recognized criteria have been established for the use of medical tests that have been proposed for the early detection of disease,[30–34] and spirometry for the detection of COPD in adult cigarette smokers fulfills all of these criteria:

1. The disease, if not detected early, would go on to cause substantial morbidity or mortality;
2. Treatment is available that is more effective when used at the early stage before the development of symptoms than when used after the symptoms develop; and
3. A feasible testing and follow-up strategy is available that:
   a. minimizes the false-positive and false-negative rates,
   b. is relatively simple and affordable,
   c. uses a safe test, and
   d. includes an action plan that minimizes potential adverse effects.

The above criteria are usually applied to screening tests, defined as medical tests done for individuals who have no symptoms or signs that suggest the possibility of disease. Office spirometry is considered to be a *part of a clinical evaluation* and does not fall under the definition of a screening test when performed for patients with respiratory symptoms who are seen during a clinical encounter (whether or not they have a history of cigarette smoking). Also, if the patient has been diagnosed as having tobacco addiction (a disease with a code in the International Classification of Diseases, ninth revision), office spirometry may be indicated to assess the severity of that disease and is not then considered to be a screening test. Although the NLHEP does not recommend office spirometry for screening un-

selected populations or for testing patients who have no cardiopulmonary risk factors, the next section of this document provides evidence that office spirometry fulfills all of the criteria listed above when it is used to detect COPD in adult smokers.

The Disease, If Not Detected Early, Would Go On to Cause Substantial Morbidity or Mortality

COPD is the most important lung disease encountered and the fourth leading cause of death in the United States, and it affects at least 16 million people.[7,35] Of the top causes of mortality in the United States, only the death rate for COPD continues to rise, increasing by 22% in the past decade. The 10-year mortality rate for COPD after diagnosis is > 50%.[36] In addition, the number of patients with COPD has doubled in the last 25 years, with the prevalence of COPD now rising faster in women than in men.[37] Although the frequency of hospitalization for many illnesses is decreasing, the number of hospital discharges for COPD rose in the last decade. COPD causes 50 million days per year of bed disability and 14 million days per year of restricted activity.[38,39] COPD causes about 100,000 deaths per year, 550,000 hospitalizations per year, 16 million office visits per year, and $13 billion per year in medical costs, including homecare.[35]

Treatment Is Available That Is More Effective When Used at the Early Stage of COPD, Before the Development of Symptoms, Than When Used After Symptoms Develop

COPD is a slowly progressive, chronic disease characterized by cough, sputum production, dyspnea, air flow limitation, and impaired gas exchange.[40] The early and common symptoms of chronic cough and sputum production usually are ignored by the patient (and often their physicians) as normal or expected for a smoker, and no intervention is deemed necessary. The disease usually is not diagnosed until the patient experiences dyspnea with only mild exertion, which interferes with the patient's quality of life. The diagnosis of COPD is made by clinicians (1) by noting the presence of at least one risk factor in the patient's medical history (usually > 20 pack-years of cigarette smoking), (2) by documenting moderate to severe air flow limitation using a diagnostic spirometry test, and (3) by excluding heart failure and asthma as the causes of air flow limitation.[12]

The LHS was a randomized clinical trial that demonstrated that COPD could be detected in its early stages in smokers with few symptoms.[28] Spirometry tests were performed for > 70,000 women and men who were current smokers (without regard to symptoms), 35 to 59 years old, from nine United States communities and Winnipeg, Canada.[41] About 25% of those tested were found to have borderline to moderate air flow obstruction. An additional 5% had severe air flow obstruction (< 50% of predicted), and they were excluded from the study and referred for treatment. Those taking medications for asthma also were excluded. About 6,000 smokers with borderline to moderate air flow obstruction were recruited and were followed up for 5 years. About half of the participants reported chronic cough (with a wide range of 26 to 81%, depending on gender, age group, and clinic site). Wheezing on most days and nights was reported by about one third of participants; only 2.8% reported a current diagnosis of asthma but were not taking any prescription medications for asthma.[42] Those who continued to smoke were documented to have faster rates of decline in lung function. Importantly, participation in a smoking cessation program significantly decreased the rate of decline in lung function in these individuals relative to those who continued to smoke. Those participants who continued not to smoke (sustained quitters) showed a small improvement in lung function over the first year compared to continuing smokers (mean rise in FEV_1, 57 mL vs mean fall in FEV_1, 38 mL, respectively) and had reduced rates of decline over the remaining 4 years of study (mean rate of decline in FEV_1, 34 vs 63 mL/yr, respectively).[28] Thus, the rate of decline of FEV_1 following successful smoking cessation was very similar to that seen in healthy nonsmoking adults (28 to 35 mL/yr).[43,44]

In addition to documenting the benefits of smoking cessation in modifying the natural history of COPD, the LHS documented the ability to successfully intervene with an intense smoking cessation program in relatively asymptomatic smokers.[28] At least 35% of the subjects studied were able to quit smoking for extended periods of time, and 22% of the subjects were able to quit and sustain smoking cessation for 5 years (as compared to 6% in the usual care group). The smoking recidivism rates during the 5 years equaled the repeat quitter rates, such that 35% of the subjects were nonsmokers at any cross-sectional period of time. Of course, smoking cessation rates are likely to be lower in primary care settings when compared to a clinical trial.[33,34]

Effective smoking cessation methods available to primary care practitioners have dramatically improved in the last several years. Detailed recommendations are now available that synthesize the expanding smoking cessation knowledge base.[45,46] Awareness of different stages in the process of behavioral change have allowed for more focused efforts on subjects likely to quit smoking.[47,48] In addition, increasing success with repeated attempts at smoking cessation now is recognized. Significant advances in the understanding and treatment of nicotine addiction also have occurred.[49] Nicotine gum and patches[50] are now available over the counter in the United States. Bupropion hy-

drochloride (Zyban, Glaxo Wellcome, Research Triangle Park, North Carolina), an oral medication that is even more effective than nicotine patches,[51,52] now is available by prescription in the United States. Comprehensive and effective community based smoking cessation programs also are available in most communities in the United States.[53]

Recognizing that individual rates of decline in lung function vary, the LHS clearly documents that spirometry can identify large numbers of adult smokers at risk for COPD, and that smoking cessation programs can impact positively on the progression of COPD in those smokers who successfully quit. The regular use of β agonists or ipratropium in current or former smokers with airways obstruction, but without asthma, apparently has no effect on COPD progression.[28,54,55] However, there is some recent evidence that high-dose inhaled corticosteroids given to smokers with spirometric evidence of mild to moderate air flow limitation reduces morbidity, improves quality of life.[56–58]

Spirometry Testing Probably Enhances Smoking Cessation Rates

Previous studies of lung function testing in the general population have had mixed results, with some showing no effect[19] and others suggesting that knowledge of an abnormal lung function test doubled the likelihood of quitting smoking, even when no other interventions were applied.[59–62] A recent review[63] concluded that spirometry meets all the criteria for a test for the early detection of COPD, except that there is no conclusive evidence that spirometry adds to the efficacy of standard smoking cessation advice, which is based on current clinical practice guidelines.[45] Two randomized clinical trials that address this issue have been performed. The first study of 923 Italian smokers found a 1-year quitting rate of 6.5% in those who received counseling with spirometry, 5.5% in those with counseling alone, and 4.5% in those who received only brief physician advice.[64] These rates did not differ significantly, but only half of the study participants who were asked to visit a laboratory for spirometry testing ever did so, and there was no evidence that the spirometry results even were discussed with those who performed the test; therefore, the study probably had inadequate power to show a difference (a type II error). The second study was population based and identified 2,610 young men who were current smokers, age 30 to 45 years, had low FEV_1 values, and were from 34 cities in Norway.[65] A random half of the men were mailed a personalized letter from a physician stating that they should quit smoking because they were at increased risk for smoking-related lung disease because of their low lung function. A 15-page smoking cessation pamphlet that emphasized behavioral

modification was included in the letter. The self-reported 12-month sustained smoking cessation rates were 5.6% in the minimalist intervention group vs 3.5% in the control group (who were not informed of their spirometry results). After adjusting for age of smoking onset, cigarettes smoked per day, and history of asbestos exposure, the letter describing the abnormal spirometry results was responsible for a 50% improvement in the smoking cessation rates ($p < 0.01$). Even a 1 to 2% improvement in smoking cessation rates would result in a very large absolute number of lives saved each year in the United States.[66]

The Relationship Between Spirometry and COPD

Various studies have determined COPD risk factors. COPD occurs predominantly in current and former cigarette smokers, and there is a dose-response relationship. The risk of COPD is strongly associated with the intensity and duration of smoking.[42,67,68] Other factors that also increase COPD risk, but less commonly or to a lesser degree, include occupational dust exposure,[69] environmental tobacco smoke,[68] exposure to environmental air pollution,[70] a rare genetic deficiency of α_1-antitrypsin,[71] a history of childhood respiratory infections,[72] and the presence of airway hyperresponsiveness, as measured by spirometry.[73,74] Even moderate COPD cannot be detected reliably by a medical history or physical examination.[75–77]

Abnormal spirometry (ie, limitation of expiratory air flow, airways obstruction, or a low FEV_1/FVC ratio) is a strong predictor for rapid progression of COPD.[28] The degree of airways obstruction correlates closely with pathologic changes in the lungs of smokers and patients with COPD.[78] Spirometry results are also a strong independent predictor of morbidity and mortality due to COPD,[79,80] mortality due to cardiovascular disease,[81] lung cancer,[82,83] as well as all-cause mortality.[84,85]

A Feasible Testing Strategy Is Available That Minimizes the Rates of False-Positive and False-Negative Results

The accuracy of a test for the early detection of disease is measured in terms of two indexes: sensitivity and specificity.[5] A test with poor sensitivity will miss cases (true positive results), producing false-negative results, while a test with poor specificity will result in healthy persons being told that they have the disease, producing false-positive results.

An accepted reference standard (a "gold standard") must be available to provide the means for distinguishing between true positive and false-positive results from the new test. The traditional "gold standard" for the diagnosis of COPD is the pathologic examination of lung tissue,[78] but this confirmation of the disease is inappropriate in routine

practice due to the invasive nature of a lung biopsy. The finding of abnormally low lung densities on a high-resolution computed tomography lung scan in adult smokers is very highly correlated with the pathologic grading of emphysema[86] and, therefore, may soon be considered a secondary reference for COPD, but high-resolution computed tomography lung scans are infrequently performed clinically due to their high cost. COPD, as determined by high-resolution computed tomography lung scans, is moderately correlated with lung function testing (FEV_1/FVC ratio and diffusing capacity of the lung for carbon monoxide) in adult smokers,[87] but emphysema (lung tissue destruction accompanied by lung hyperinflation) is only one component of COPD and may not be an important predictor of morbidity and mortality, independent of air flow obstruction. The widely accepted definition of COPD progression is an abnormal rate of decline in lung function.[54,80] The normal annual decline in FEV_1 in healthy, never-smoking adults who are 35 to 65 years old has been determined by several longitudinal studies to be a mean of 30 mL/yr with an upper limit of the normal range of 50mL/yr, which may be used to define "rapid fallers."[88]

It is important that a high proportion of those who test positive actually have disease (positive predictive power). This proportion is higher when the prevalence of disease is high. The best estimates of the prevalence of air flow obstruction and COPD in the United States population are now available from NHANES III (conducted from 1988 to 1994). In NHANES III, spirometry was measured in a sample of > 16,000 adults who represented the noninstitutionalized population of the United States. About 29% of all the adult participants reported current smoking, and 24% were former smokers. Normal reference values of several spirometry variables were developed from the "healthy" subset of the nonsmoking men and women who were free of respiratory symptoms and diseases. Lower limit of normal (LLN) values, which were specific for age, sex, and height, were set at the fifth percentile of the reference population values.[27] For this report, prevalence rates of low lung function in the United States population were estimated by defining low lung function as an FEV_1/FEV_6 ratio less than the LLN and an FEV_1 value less than the LLN. See Table 1 for the results.

Prevalence rates of low lung function increase with age and are highest in current smokers, intermediate in former smokers, and lowest in never smokers. Rates are similar in men and women. Compared with rates in never smokers, rates are more than five times as high in current smokers at $\geq$ 45 years old and are more than three times as high in former smokers $\geq$ 55 years old. Prevalence rates also were compared in men and women who reported any respiratory condition or symptom with those who did not. A report of any of the following placed the individual in the symptomatic group: a doctor's diagnosis of asthma, chronic bronchitis, or emphysema; cough or phlegm on most days for $\geq$ 3 consecutive months during the year; shortness of breath on mild exertion; or chest wheezing or whistling apart from colds. Rates of low lung function were consistently three or more times higher in symptomatic men and women than in those who were asymptomatic.

We recommend that all patients $\geq$ 45 years old who are current smokers, as well as those with respiratory symptoms, perform office spirometry or diagnostic spirometry. Based on the NHANES III study, the numbers of patients eligible for spirometry under these recommendations, and the expected yield of abnormal spirometry tests are given in Table 2. About one quarter of current cigarette smokers with a respiratory symptom, a total of 9 million persons in the United States, can be expected to have low lung function (airway obstruction). Smokers $\geq$ 45 years old without respiratory symptoms also have a relatively high abnormality rate: about 9% of men and 14% of women. On the other hand, current and former smokers < 45 years old have spirometry abnormality rates that are similar to those of healthy never smokers (about 5%), reducing the value of spirometry testing of young adult smokers. Asymptom-

Table 1.   Prevalence of Low Lung Function in the National Health and Nutrition Examination Survey III of the Adult United States Population

Age Group (y)	Current Smoker (%)		Former Smoker (%)		Never Smoker (%)	
	Men	Women	Men	Women	Men	Women
17–24	5.9	2.2	1.5	0.0	2.9	3.0
25–34	5.3	3.3	0.3	3.0	2.6	2.0
35–44	5.2	6.7	2.6	2.2	2.3	2.3
45–54	13.1	19.2	4.1	4.0	2.8	1.8
55–64	21.3	28.4	8.8	10.5	3.3	3.5
65–74	30.9	20.9	13.6	14.6	2.9	3.0
75–89	24.8	15.4	13.8	12.8	9.1	2.7
Totals*	9.6	9.6	6.5	6.7	2.9	2.5

*Values given as abnormality rate for all age groups.

Table 2.   Number of Men and Women Eligible for Spirometry Testing in the United States and the Prevalence of Low Lung Function*

Population Data	Number of Persons Eligible in United States		Prevalence of Low Lung Function (%)	
	Men	Women	Men	Women
Smokers, age ≥ 45 y	7,620,000	6,670,000	19.0	22.4
Symptomatic	4,770,000	4,100,000	25.1	27.5
Asymptomatic	2,850,000	2,560,000	8.9	14.4
Symptomatic, age ≥ 25 y	19,000,000	25,200,000	11.1	7.2
Never smokers and former smokers	13,000,000	19,000,000	12.3	7.7
Current smokers, age 25–44	6,000,000	6,200,000	8.6	5.5

*Estimated from the National Health and Nutrition Examination Survey III.
See text for definitions of symptomatic and asymptomatic.

atic former smokers ages ≥ 55 years also have a spirometry abnormality rate of 5%.

Office Spirometry Is Relatively Simple and Affordable

Spirometry is a relatively simple, noninvasive test. Office spirometry takes only a few minutes of the patient's and technician's time and includes a few athletic type breathing maneuvers of 6-second duration. The economic costs of a spirometry test include the cost of the instrument and the cost of personnel time (both training and testing). Diagnostic spirometers currently cost about $2,000, and about $10 of time per test is spent in testing (including training time) and disposable supplies. Office spirometers will cost < $800 and require even less testing time than diagnostic spirometers. Adding a post-bronchodilator spirometry test for asthma adds about 15 minutes to the test time (but is not needed for COPD evaluations).

Spirometry Safety

Any medical test has both tangible and intangible costs. Adverse effects may occur (1) due to the procedure itself, (2) due to the investigation of abnormal results, or (3) due to the treatment of detected abnormalities or diseases.[33,34] There are no adverse side effects from spirometry testing, other than occasional minor discomfort. However, investigation and confirmation of abnormal spirometry results in some patients will cost both time and money and may result in psychological and social harm in some patients. The cost of diagnostic spirometry to confirm air flow obstruction when performed in a hospital-based pulmonary function (PF) laboratory ranges from $20 to $60. The estimated travel time, waiting time, and testing time spent by the patient ranges from 1 to 3 hours. The possible psychological impact of being labeled as "ill" by self and others

related to false-positive or even true positive test results could lead to alterations in lifestyle and work and to seeking medical attention. Another potential adverse effect is the unmeasured risk of reinforcing the smoking habit in some of the four of five adult smokers who are told that they have normal results for spirometry testing. However, the clinician should counteract this possibility by taking the opportunity to tell the patient that normal results for spirometry testing do not mean that the patient's high risk of dying from a heart attack, lung cancer, or other smoking-related diseases is substantially reduced; therefore, smoking cessation remains very important.

Finally, the risk of an adverse effect caused by the intervention for COPD (smoking cessation) is very small. The side effects of over-the-counter nicotine replacement are minimal. Successful smoking cessation leads to a small average increase in body weight,[89] but the slight increase in medical risk from minor weight gain is far exceeded by the benefits due to reduced morbidity and mortality and the economic savings in cigarette and cleaning costs.

The Action Plan

Even when test quality seems good, diagnostic spirometry is highly recommended to confirm abnormal office spirometry findings prior to initiating an expensive workup or an intervention with negative economic consequences (such as a recommendation to change jobs or to prescribe a medication).

The key focus of the NLHEP program is prevention and early intervention. Validated abnormal test results in a smoker should lead to a more detailed history and examination for pulmonary disease and cardiovascular risk factors (including hypertension, diabetes mellitus, obesity, hypercholesterolemia, etc). Consideration should be given to the presence of pulmonary diseases other than COPD, including asthma, restrictive lung and chest wall diseases, neuromuscular diseases, and cardiac disease.

When airway obstruction is identified in a smoker, the primary intervention is smoking cessation. In the event that a patient with airway obstruction continues to smoke cigarettes, a renewed or increased effort to assist with smoking cessation is essential. Future research may determine that other interventions, such as anti-inflammatory therapy, are effective in selected patients with airway obstruction. Referral to a subspecialist for further diagnostic testing should be considered in some patients, such as those in whom bronchiectasis or other lung diseases are suspected. Pre- and post-bronchodilator diagnostic spirometry is indicated if asthma is suspected.

Recommendation

Primary-care physicians should perform an office spirometry test in patients with respiratory symptoms such as chronic cough, sputum production, wheezing, or dyspnea on exertion in order to detect asthma or COPD.

Rationale: Analyses of data from a population sample of 25–75-year-old white men in Tucson, Arizona, found that spirometry abnormality rates increased in those who reported respiratory symptoms, after excluding those who reported a physician diagnosis of asthma, chronic bronchitis, or asthma.[90] Abnormal spirometry was defined as an FEV_1 below the LLN, using the reference equations from the study by Crapo et al,[91] which reported spirometry reference values very similar to the NHANES III values. The comparison subjects, never smokers without respiratory symptoms, had a 3.8% spirometry abnormality rate, while asymptomatic former smokers and current smokers had abnormality rates of 9.2% and 11%, respectively. Former smokers and current smokers with any of three respiratory symptoms (chronic cough and sputum, dyspnea walking on level ground, or attacks of dyspnea with wheezing) had abnormality rates of 25.6% and 14.1%, respectively. These abnormality rates, and those from NHANES III (see Tables 1 and 2), demonstrate that the presence of respiratory symptoms in a former or current cigarette smoker substantially increases their pretest probability (risk) of having air flow obstruction (low lung function) or COPD.

The National Health Interview Survey (conducted from 1993 to 1995) estimated that 4 million adults (4.5% of those age 35 to 65 years) have asthma (by self-report) and that 630,000 emergency department visits for asthma occur each year in this age group.[92] A survey of 59 primary-care practices with 14,000 patients in Wisconsin reported an asthma prevalence of 6.2% in adults ($\geq$ 20 years old), half of whom reported adult onset of the disease.[93] An additional 3.3% of the patients without a diagnosis of asthma reported attacks of wheezing with dyspnea during the previous year, suggesting, along with other investigations,

that asthma is underdiagnosed in adults.[17] Spirometry is recommended by current clinical guidelines for patients with symptoms that suggest asthma, in order to help confirm the diagnosis.[94]

Recommendation

Primary-care physicians may perform an office spirometry test for patients who desire a global health assessment (risk assessment).

Rationale: Lung function testing is now recognized as a measure of global health, predicting all-cause mortality and morbidity in adults.[85,95–97] In addition, lung function test results and changes in lung function over time have been shown to identify patients at high risk for lung cancer,[82,83] and at increased risk for coronary artery disease,[98] congestive heart failure,[99] stroke and other heart and blood vessel disaeses,[100] and altered mental function in later years of life.[101] Early identification and recognition of increased global health risks also may allow for evaluation and for prevention and early intervention in other risk areas appropriate to each of these nonpulmonary disease categories. Office spirometry also may identify patients with subclinical asthma or restrictive lung processes in both adults and children, leading to the institution of appropriate evaluations and treatments. Although prophylactic interventions such as vaccination are recommended for patients with respiratory illnesses, only a small percentage of them receive influenza and pneumococcal vaccines.[102]

In adults, early intervention following early identification of lung function abnormalities can lead to improved smoking cessation, to occupational, avocational, or environmental changes, and to increased awareness and attention to cancer, cardiac, and other nonpulmonary health issues associated with abnormal lung function. Early identification of lung function abnormalities in relatively asymptomatic patients may provide "teachable moments" or specified times for a given patient when there is an increased awareness and response to medical education and intervention. Such moments may lead to an increased responsiveness to smoking cessation and to enhanced opportunities for other preventive therapies or modification of identifiable risk factors.

Why Not Use Peak Flow?

Assuming that lung function testing of selected individuals is a useful part of health care, it is essential that the test chosen is the best available. First, it must be able to detect mild disease. Although many lung function tests are available, previous studies examining the value of these tests have shown that most of them are unacceptable or ineffective as tools for the early detection of COPD.[19,20]

The exceptions are peak expiratory flow (PEF) and spirometry. PEF measurements are recommended for asthma management by current clinical practice guidelines, but spirometry is recommended to help make the diagnosis of asthma.[94] Likewise, we do not recommend the use of PEF to evaluate patients for COPD. The advantages of PEF tests are the following: measurements within a minute (three short blows) using simple, safe, hand-held devices that, typically, cost < $20. On the other hand, the disadvantages of using PEF when compared to spirometry are as follows: PEF is relatively insensitive to obstruction of the small airways (mild or early obstruction); PEF is very dependent on patient effort; PEF has about twice the intersubject and intrasubject variability;[103] and mechanical PEF meters are much less accurate than spirometers.[13]

Tracking Changes in Lung Function

Tracking of lung function over time has potential advantages over a single test.[104] However, there are no published data demonstrating that when the results of the first spirometry test are normal in a high-risk patient the measurement of annual changes in lung function (tracking) in the primary-care setting is better than simply repeating office spirometry at 3-year to 5-year intervals, which we recommend.

In occupational medicine, diagnostic-quality spirometry tests often are performed regularly for the surveillance of employees at high risk.[104,105] Annual tests increase the likelihood of detecting changes in lung function earlier, when compared to less frequent testing intervals. Infrequent testing (eg, every 5 years) may delay identification of lung function abnormality, reducing the benefits of identification, prevention, and early intervention in lung disease. However, when testing is performed more frequently, and when a less-than-optimal spirometry quality-assurance program is used, the false-positive rate increases. Office spirometry may be indicated for patients who report workplace exposures to chemicals, dusts, or fumes that are known to cause lung disease; however, a discussion of testing for occupational lung disease is beyond the scope of this document.

Technical Requirements for Office Spirometers

Recommendation

A new category of spirometers, office spirometers, should be available for use in the primary-care setting. Each new model must successfully pass a validation study (see Appendix 1).

Rationale: Traditionally, spirometry has been used as a diagnostic test, with the usefulness and accuracy of spirometry measurements depending on both the equipment and proper test performance. Although simple to learn, spirometry is an effort-dependent test that requires a cooperative patient and a trained person capable of administering the test. Specific recommendations have been developed by the ATS and other professional organizations to ensure accurate and reproducible measurements when using diagnostic spirometers.[13,106–109] In many cases, a diagnostic spirometer that meets ATS standards will be the preferred choice for a hospital, outpatient clinic, or doctor's office since it permits diagnostic and follow-up testing (tracking) of lung function. Currently available diagnostic spirometers also may be used in the primary-care setting to evaluate smokers for COPD. However, some characteristics of diagnostic spirometers create a barrier to their widespread use for this purpose. Advantages of the newly proposed category of office spirometers for this purpose include lower instrument cost, smaller size, less effort to perform the test, improved ease of calibration checks, and an improved quality-assurance program. Office spirometers should not be utilized for diagnostic testing, surveillance for occupational lung disease, disability evaluations, or research purposes.

Current ATS recommendations for diagnostic spirometry[1] must be followed for office spirometry, except for the following seven factors.

1. Office Spirometers Must Only Report Values for FEV_1, FEV_6, and the FEV_1/FEV_6 Ratio

The reported FEV_1 and FEV_6 values should be rounded to the nearest 0.1 L and the percent of predicted as an integer (for instance, 72%); and the FEV_1/FEV_6 ratio should be calculated as a fraction with only two decimal places (for instance, 0.65). An indication should be made next to the reported value (an asterisk for instance) when the patient's values fall below the LLN range for the variable. The false-positive rate increases when additional variables (for instance, the midexpiratory phase of forced expiratory flow) are used to define abnormality.[110]

Rationale: Spirometry is a simple test that measures the volume of air expelled from fully inflated lungs as a function of time.[111] Following inspiration to a maximal lung volume, the patient is instructed to exhale as fast and hard as possible. Many lung function indexes may be derived from spirometry; however, the most valuable indexes are the total volume of exhaled air and the FEV_1.[1]

2. The ATS End-of-Test Criteria Should Be Modified for Office Spirometry

Rationale: The measurement of FVC should be replaced by that of FEV_6 so that each maneuver need last for only

6 seconds. The advantages of using FEV_6 for office spirometry are the following: (1) it is easier for the patient and the technician when maneuvers last only 6 seconds; (2) technical problems with flow sensors related to accurately measuring very low flows over several seconds of time (resolution and zero drift) are minimized; (3) the FEV_6 is more reproducible than the FVC in patients with airways obstruction; (4) using the FEV_6 reduces the overall time to perform a test; and (5) shorter maneuvers reduce the risk of syncope. The FEV_6 has long been proposed as a surrogate measurement for FVC;[112] however, reference values for FEV_6 and the FEV_1/FEV_6 ratio have only recently become available.[27] The validity of using FEV_6 as a surrogate for FVC is now being established. For example, unpublished data from the LHS suggest that the FEV_1/FEV_6 ratio is as good as the FEV_1/FVC ratio in predicting the decline in FEV_1 over the subsequent 5 years in adult smokers. Some healthy children and some young adults empty their lungs before 6 seconds has elapsed; in those cases, their FVC and FEV_6 values should be considered equivalent if their end-of-test volume is not too high (suggesting that their FEV_6 has been underestimated).

3. Airway Obstruction Will Be Interpreted When the FEV_1/FEV_6 Ratio and the FEV_1 Percent of Predicted Are Both Below Their LLNs

The FEV_1 percent of predicted may optionally be used to categorize the severity of the abnormality (Table 3). Report FEV_1 as a percent of predicted to patients. This is "the number" the patient should remember.

Table 3.   Interpretation of Office Spirometry Results

1. First ensure that test quality is good (see Table 4).
2. Use the NHANES III reference values to calculate predicted values and LLNs for the FEV_1, FEV_6, and FEV_1/FEV_6 ratio (this should be done automatically by the spirometer).
3. If the FEV_1/FEV_6 ratio and the FEV_1 are both below the LLN in a test with good quality, airways obstruction is present. Report the FEV_1 percent of predicted to the patient. Optionally, the severity of the obstruction may be graded using the FEV_1 percent of predicted as follows:
   FEV_1 LLN to 60% of predicted FEV_1 = "mild obstruction"
   40–59% of predicted FEV_1 = "moderate obstruction"
   < 40% of predicted FEV_1 = "severe obstruction"
4. If FEV_1/FEV_6 ratio is above the LLN but the FEV_6 is below the LLN, the patient has a low vital capacity, perhaps due to restriction of lung volumes.

NHANES III = National Health and Nutrition Examination Survey III
LLN = lower limit of normal
FEV_1 = forced expiratory volume in the first second
FEV_6 = forced expiratory volume in the first 6 seconds

Rationale: The ATS recommends that the FEV_1/FVC ratio be used to diagnose airways obstruction.[13,106] The FEV_1/FEV_6 ratio is a good surrogate for the FEV_1/FVC ratio (see above). The LLN is now well defined for all ages of African Americans, Hispanic Americans, and whites, with a mean of about 73%, ranging from 70 to 76%, depending on age, gender, and race.[27]

This recommendation for using the FEV_1/FEV_6 ratio with office spirometers should not discourage clinicians from continuing to use an older diagnostic-quality spirometer that reports the FEV_1/FVC ratio and its LLN, but not the FEV_1/FEV_6 ratio. However, the FVC is defined as the maximum amount of air that the patient can exhale, and most adult patients can exhale more air after 6 seconds. Therefore, when using traditional reference equations and an interpretation of airways obstruction based on the FEV_1/FVC ratio, airway obstruction may be missed (a false-negative result) if the patient is not coached to exhale completely (usually $\geq$ 10 seconds).

In patients with COPD, the FEV_1 percent of predicted is directly proportional to their quality of life and ability to perform exercise.[113] Clinicians and patients understand the semiquantitative terms *mild*, *moderate*, and *severe* better than *percent of predicted* when discussing the relative severity of diseases. A stronger admonition and the patient's adherence to the recommended intervention may be more likely when the abnormality is reported as moderate or severe. Also, when the abnormality is moderate or severe, the likelihood that the test result is falsely positive is much lower than when the abnormality is mild. The severity category cut-points suggested in Table 3 (40% and 60%) correspond roughly to z scores of 2 and 3 in the distribution of the percent of predicted for FEV_1 in patients with COPD, and are in widespread clinical use.[106]

4. Automated Maneuver Acceptability and Reproducibility Messages Must Be Displayed and Reported

Rationale: Many performance standards essential to reliable spirometry measurements[1] already have been automated and included within spirometry devices to reduce the likelihood of poor-quality test results.[40,112,114] Additional built-in performance checks are necessary for office spirometers that do not display or print spirograms or flow-volume curves, which the technician or physician can review for acceptability and reproducibility of the maneuvers. Table 4 lists quality control (QC) criteria that must be monitored electronically along with recommended messages to be displayed when these maneuver quality errors are detected. These thresholds were designed so that > 90% of adult patients (even the elderly) can pass all the QC checks within five maneuvers if coached by a technician who has good training, motivation, and experience.

Table 4.   Recommended Automated Maneuver Quality Control
Checks, Messages, and Grades

Messages:

If the BEV is > 150 mL, display "don't hesitate."

If the PEFT is > 120 ms, display "blast out faster."

If the FET is < 6.0 s and EOTV* is > 100 mL, display "blow out
longer."

If the PEF values do not match within 1.0 L/s, display "blast out
harder."

If the FEV_6 values do not match within 150 mL, display "deeper
breath."

After two acceptable maneuvers that match, the message is "good
test session."

Quality Control Grades†

A = At least two acceptable maneuvers, with the largest two FEV_1
values matching within 100 mL and the largest two FEV_6 values
matching better 100 mL.

B = At least two acceptable maneuvers, with FEV_1 values matching
between 101 and 150 mL.

C = At least two acceptable maneuvers, with FEV_1 values matching
between 151 and 200 mL.

D = Only one acceptable maneuver, or more than one, but the FEV_1
values match > 200 mL (with no interpretation).

F = No acceptable maneuvers (with no interpretation).

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*A large EOTV indicates that a volume-time plateau was not obtained, so the FEV_6 was
probably underestimated. The appropriate PEFT and EOTV thresholds depend on several
characteristics of the spirometer, such as frequency response, sampling rates, and filtering of
the flow signal. For instance, for a given model of office spirometer, the PEFT threshold of
120 ms may be changed if based on the 95th percentile of PEFT from studies in which
experienced technicians test > 200 adults. The 95th percentile of PEFT for school-age
children and adolescents is about 160 ms.
†A quality control grade, which indicates the degree of confidence in the results, should be
calculated, displayed, and reported along with the numeric results and the interpretation
BEV = back extrapolated volume
PEFT = time to peak flow
FET = forced expiratory time
PEF = peak expiratory flow
EOTV = end-of-test volume (calculated as the change in exhaled volume during the last 0.5 s
of the maneuver).
FEV_6 = forced expiratory volume in the first 6 seconds

Devices should present the numeric spirometry results and
interpretations only if all maneuver QC criteria are met.
While we believe that these electronic quality checks will
reasonably ensure good-quality tests, studies are necessary
to validate their performance in primary-care settings.

5. Displays and Printouts of Spirograms and Flow-Volume Curves Will Be Optional for Office Spirometers

Rationale: Standards for diagnostic spirometry require
that graphs of the maneuvers be produced so that techni-
cians who perform the tests, physicians who interpret the
results, and those who later review the test reports may
recognize problems with maneuver quality.[13] The graphs
also assist physicians in the recognition of the character-
istic patterns of different types of abnormalities, such as
generalized airways obstruction, restriction of lung vol-

umes, and the rare upper airways obstruction.[111,115] How-
ever, a graphic display or a printer usually increases the
size, cost, and complexity of spirometers, reducing their
widespread acceptability in the primary-care setting. It is
also likely that many technicians and physicians will not
learn to recognize the patterns of unacceptable spirometry
maneuvers and that many physicians will not recognize
the patterns of abnormality. We believe that automated-
maneuver QC checks and messages are generally more
reliable now for quality-assurance purposes than are pro-
grams to teach pattern recognition of spirometry graphs,
although no published studies demonstrate this.

6. Office Spirometers Must Be Sold With Easy-to-Understand Educational Materials

These educational materials should include procedure
manuals, audiovisual instructional aids (such as a video-
tape or multimedia CD ROM), and patient handouts that
describe the potential risks and benefits of NLHEP spi-
rometry, interpretation of the results, and limitations of the
test.

Rationale: It is unlikely that many primary-care physi-
cians will spend the time and money necessary to send
their technician or nurse to a 2-day spirometry training
course.[116] Emphasis in training materials must be placed
on effective interactions between the technician and the
patient when performing spirometry tests (Table 5). In
order to minimize the number of breathing maneuvers
needed to obtain a good-quality test session, technicians
always must demonstrate the correct maneuver themselves
before instructing patients to perform them. The technician
must then enthusiastically coach and watch the patient
throughout the three phases of each maneuver: (1) maxi-
mal inhalation, (2) blast out quickly, and (3) continue ex-
halation for 6 seconds. Most maneuver errors are easily
recognized by watching the patient. When the technician
or the automated spirometer maneuver QC checks detect
poor-quality maneuvers, the technician must tell the pa-
tient what went wrong and again demonstrate how to per-
form the maneuver correctly. After eight maneuvers are
performed and the test session is of poor quality, the test
should be rescheduled for a later date.

Table 5.   Spirometry Steps

1. Measure standing height in stocking feet.
2. Record age, gender, height, and ethnicity.
3. Explain and demonstrate the correct maneuver.
4. Coach and watch the patient perform each maneuver.
5. Repeat until two acceptable and matching maneuvers are obtained.

7. Simple Inexpensive Solutions Should Be Developed to Replace the Daily Use of 3-L Calibration Syringes to Check the Accuracy of Office Spirometers

Rationale: One-liter calibration syringes may be as effective as 3-L syringes, and they are smaller and less expensive. It is also possible that precisely manufactured plastic (Mylar, 3M Corp, St. Paul, Minnesota) bags could be used to check volume accuracy on a daily basis. However, until alternative calibration methods are proven to check spirometer calibration effectively, the use of calibrated 3-L syringes on a regular basis is necessary. If a calibration syringe is not available in a primary-care setting, calibration checks using a standard 3-L calibration syringe may be performed at regular intervals by a local diagnostic PF laboratory at minimal cost. A proper interval cannot be arbitrarily set for all spirometers. Manufacturers should validate the acceptable calibration interval specified for their office spirometers that ensures that they remain accurate when used as directed in the primary-care setting. Third-party testing of the between-sensor (within-batch) accuracy of single-use flow sensors should be established.

Periodic testing of a biological control also should be used to check the long-term performance of office spirometers. The individuals chosen as biological control subjects must be > 25 years old and must not have an obstructive lung disease. Their FEV_1 and FEV_6 first must be measured on 10 days, and the average values and ranges must be calculated. The range of measurements for FEV_1 and FEV_6 (largest minus smallest) should not exceed 10% of the average value, otherwise a different biological control subject should be chosen. If disposable flow sensors are used, the biological control subject may reuse a single-flow sensor, and it should be stored with the subject's name on it. The biological control subject then should be tested on each day that patients are tested. If the control subject's measured FEV_1 or FEV_6 is $> 10\%$ from the average value, the test should be repeated. If the FEV_1 remains "out of bounds," even after replacing or cleaning the sensor, the device should not be used on patients until repaired.

The FEV_1 and FEV_6 Must Be Corrected to BTPS Conditions

The device should sense the temperature automatically if necessary for accurate body temperature, ambient temperature, and saturation with water vapor (BTPS) corrections. The technician should not be asked to enter the temperature.

Rationale: The measurement of ambient or spirometer temperature and barometric pressure may not be needed for some spirometers in which the design allows the use of a fixed BTPS correction factor.[117] Errors in measuring FEV_1 and FEV_6 must remain $< 3\%$ (according to BTPS testing methods recommended by the ATS). Manufacturers must specify the range of ambient temperatures and altitudes in which the results remain accurate.

The Current ATS Recommendations Regarding Measures to Avoid Cross-Contamination Should Be Followed by Those Using Office Spirometers

Staff performing spirometry tests must be instructed to wash their hands before and after assisting each patient with the test. If patients are only exhaling through the devices, proper use of disposable mouthpieces is all that is needed to minimize the risk of the transmission of infections. In particular, disposable in-line filters are not mandated.[13,116] All devices should be inspected and kept clean to meet good hygiene standards. Devices with completely disposable flow sensors or with mouthpieces that have one-way valves should be used if testing is to be performed in patients likely to inhale through the mouthpiece. Manufacturers should give explicit instructions about cleaning techniques and frequency of cleaning.

A New Billing Code Should Be Created for Office Spirometry Tests

Rationale: Charges should be kept as low as possible but should at least cover the real costs of the test. It seems imprudent to charge patients or third-party insurers for diagnostic-quality spirometry tests when office spirometry tests are performed, since office spirometry tests will require less expensive instruments, less technician time, and less training to interpret.

Further Research

There is insufficient published evidence related to many of the technical and procedural issues associated with the above recommendations for office spirometry. More detailed information is needed about the following issues: levels of training required to obtain results of acceptable quality; levels of inaccuracy and imprecision; reliability; durability; and the necessary frequency and type of calibration checks (see Appendix 1). Outcomes to be assessed include sensitivity of detection, frequency of false-positive test results, and the overall impact on patient care, quality of life, and cost-benefit analyses. These issues should be examined both for pulmonary diseases and as a part of total health care. Additional areas requiring research include the role of office spirometry in lower risk individuals (ie, nonsmokers, former smokers, and those without respiratory symptoms) and the prospective utility of office spirometry in the intervention and management of global

disease processes. Research in these areas is strongly encouraged in order to validate and improve the above recommendations.

ACKNOWLEDGMENTS

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Appendix 1
Office Spirometer Validation Studies

Background

The NLHEP recommends the widespread use of spirometry by primary-care physicians (PCPs) for detecting COPD in adult smokers and describes a new type of spirometer for this purpose: the office spirometer. The value of spirometry for aiding the diagnosis of COPD and asthma, when performed by trained technicians using diagnostic spirometers that meet current ATS recommendations, is widely accepted. The accuracy and precision of diagnostic-quality spirometry performed in the hospital PF laboratory, pulmonary research clinic, and occupational clinic settings by technicians who are trained and have considerable experience performing spirometry have been studied by many investigators and found to be acceptable for the purposes of detecting airways obstruction in individuals and for detecting abnormal declines in FEV_1 in groups of adults. However, the first prospective study of > 1,000 spirometry tests performed by nurses in the outpatient clinics of 30 randomly selected PCPs in New Zealand found that less than one third of the test sessions included at least two acceptable maneuvers.[118] About one third of the maneuvers had a "slow start" (peak expiratory flow time [PEFT] > 85 ms [a substantially stricter criterion than those in the NLHEP document]). About two thirds of the maneuvers lasted for < 6 seconds (forced expiratory time [FET] < 6 s), and visual inspection of the volume-time curves suggested that most of these short-duration maneuvers underestimated the FVC (did not achieve an end-of-test plateau). On the positive side, after attending a 2-hour spirometry training workshop, nurses were much more likely to obtain acceptable test sessions. These results confirm the necessity for each new office spirometry system to have a "real-world" validation study before it is marketed.

Several factors other than instrument accuracy are known to influence the real-world accuracy and repeatability of spirometry tests. These factors include the following: the technician's training, experience, number of tests performed per month, motivation, motivational skills, and patience; the patient's coordination, cooperation, strength, endurance, and motivation; maneuver and test session quality feedback (to the technician and patient); the training materials that accompany the spirometer; the type and frequency of calibration checks and actions taken to remedy equipment and sensor problems; the testing environment (space, lighting, noise, time constraints, and other stressors); and changes in these factors over the time period of measurement (eg, differing technicians, updated software, new flow sensors, etc).

Goals

The goal of an office spirometer validation study is to compare the spirometer's screening and tracking performance in adult patients in the PCP setting with that of diagnostic spirometers used by trained technicians. The following study protocol is designed to apply to any model of office spirometer. It is designed to be performed in a reasonable amount of time (6 months) and with reasonable resources (< $50, 000 if a price of < $20 per test is negotiated with the PF laboratory). In order to minimize post study criticism, the limits of acceptable outcomes have been predetermined. The manufacturer or distributor of all office spirometers that claim to meet NLHEP specifications must conduct this study for that model and include the published results of the study with each office spirometer sold.

Methods

A study coordinator with experience in clinical trials, without a conflict of interest (such as one that an

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employee of the office spirometer manufacturer or distributor would have), shall be selected. Exactly the same instrument, sensors, manuals, calibration tools, accessories, and training materials that are sold (or provided) commercially as *the spirometry system* shall be used in the validation study. The same amount of in-service training with the same type of personnel shall be used during the study that will be used for actual commercial training (for instance, 45 min with a local distributor). The setting, staff, and patients will be selected to optimize the generalizability of the results to the real world. A single, representative sample of the office spirometer shall first undergo (and pass) independent testing for FEV_1 and FEV_6 accuracy and reproducibility, which will be performed by a third party using current ATS recommendations[1] and a spirometry waveform generator, including four waveforms generated using BTPS conditions (body temperature humidified air). All disposable flow sensors used for testing shall be saved in a plastic bag, labeled with the date and patient identification number, and sent to the study coordinator at the end of the study.

Recruitment of Primary Care Physicians

Thirty PCPs shall be recruited from advertisements offering "a free spirometer and 6 months of spirometry supplies." At least two regions of the United States shall be represented. At least five PCPs (either medical doctors or doctors of osteopathy) shall be selected from each of the following specialties: family practice, general internal medicine, and general surgery. Allergists and pulmonary specialists shall be excluded. Staff who report that they have personally performed > 100 spirometry tests during the previous 5 years shall be excluded. PCPs who have used a spirometer in their office during the previous year shall be excluded. Each PCP must agree to perform spirometry testing for at least 20 adult patients per month (an average of one patient per weekday) for 6 months. The altitude of each office (within 500 feet) shall be recorded.

Recruitment of Patients

Inclusion criteria are consecutive outpatients, age 45 to 85 years, who are current cigarette smokers or who quit smoking during the previous year. Patients with asthma (according to self-report or the medical record) and those previously noted to have a significant response to inhaled bronchodilators (FEV_1 increases, > 12% and > 0.2 L) shall be excluded from the study, since their FEV_1 values have inherently high short-term variability.

Follow-up Testing

At least one patient per week shall be asked by each PCP to return to their clinic within 1 month for repeat spirometry testing. A contract shall be made with a local hospital-based PF laboratory to perform follow-up diagnostic spirometry (including printed volume-time and flow-volume curves, but without a physician interpretation) on a subset of study patients. All patients with abnormal spirometry test results shall be scheduled to perform diagnostic spirometry testing at a local hospital-based PF laboratory within 2 weeks of the screening spirometry test. The cost of the diagnostic testing, and a $20 reimbursement for each patient, shall be paid for by the study. The PF lab shall send a copy of the results to the study coordinator. The results of the follow-up spirometry tests shall not be sent to the PCP until the end of the study.

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Measurements

The long-term accuracy of a random sample of five of the study spirometers shall be measured by a third party using a waveform generator at the beginning and at the end of the 6-month study. A random sample of five used flow sensors shall be obtained for the long-term accuracy testing at the end of the study.

The demographics of all patients tested shall be determined and stored for analysis. The demographics must include a unique patient identification number, age, gender, height, weight, race, smoking status, asthma status, date, and technician identification number. The following parameters shall be stored digitally for all (or the best three) spirometry maneuvers: FEV_1, FEV_6, back extrapolation volume, PEFT, PEF, FET, sequence number, and the 50-point flow-volume curve (the average flow during each 2% segment of the FEV_6). This may require modifications to the office spirometers used in the study (when compared to those that will be sold commercially). These modifications should be designed to minimize technician interaction with the recording device. A written log shall be kept by the office staff of any problems with the spirometer, any calibration checks performed, any preventative maintenance, and any repairs.

Statistical Analysis

The study coordinator shall determine the long-term accuracy of the office spirometer instruments by comparing the baseline and 6-month FEV_1 and FEV_6 measurements from the "gold standard" waveform generator and the records of repairs, updates, or replacements. The quality of all spirometry test sessions (screening, follow-up, and diagnostic) shall be graded by the study coordinator using the stored data and the criteria listed in Table 4 of this document. The rates, trends, and correlates of unacceptable-quality test sessions (QC grades, D or F) shall be determined using logistic regression.

The false-positive and false-negative rates for detecting airways obstruction (after allowing for 3% error in the measured FEV_1/FEV_6 ratio) shall be determined by comparing the office spirometry results with the valid follow-up diagnostic tests performed in the PF laboratory. Results from the diagnostic-quality spirometry tests that are determined by the study coordinator (using the printed reports from the PF lab) to be valid (QC grades, A or B) are assumed for the purposes of this study to be the "gold standard." Both the false-negative rate and the false-positive rate shall be < 5% for the office spirometry system to be considered acceptable.

The value of office spirometry for "tracking" purposes shall be determined by calculating the short-term coefficient of repeatability of FEV_1 for the subset of patients who performed repeat tests. Acceptable repeatability is for $\geq$ 95% of the patients to have repeat FEV_1 values that match within 0.30 L. The predictors of poor repeatability shall be determined by logistic regression.

Appendix 2
Participants and Committee Members

Participants in the NHLBI/ACCP Consensus Conference. August 18, 1998. Chicago, Illinois.

William Bailey MD, Gary Ferguson MD, Michael Alberts MD, A Sonia Buist MD,
Paul L Enright MD, John Hankinson PhD, Millicent Higgins MD, Deborah Shure MD,
James Stoller MD, Brian Carlin MD, Ray Masferrer RRT, Gregory Wagner MD, David Mannino MD,
Gail Weinmann MD, Robert O Crapo MD, Bettina Hilman MD, John W Georgitis MD,
James Fink MS RRT FAARC, and Edward A Oppenheimer MD. ACCP staff: Sydney Parker PhD,
David Eubanks EdD RRT, Mary Katherine Krause, and Barbi Mathesius.

Participants in the NHLBI-Sponsored NLHEP Conference. March 26, 1999, Bethesda, Maryland.

Thomas Petty MD FAARC (chair), William Bailey MD, Frank Bright MD, Bartolome Celli MD,
Catherine Gordon RN MBA, A Sonia Buist MD, James Cooper (HCFA), Dennis Doherty MD,
Paul Enright MD, Gary Ferguson MD, Millicent Higgins MD, Ray Masferrer RRT, Sreehar Nair MD,
Louise Nett RN RRT FAARC, Edward Rosenow MD, Deborah Shure MD, and Gregory Wagner MD.
NHLBI staff: Frederick Rohde, Suzanne Hurd PhD, Gregory Morosco PhD, and J Sri Ram PhD.

Members of the Spirometry Subcommittee of NLHEP

Gary T Ferguson MD (chair), William C Bailey MD, A Sonia Buist MD, Robert Crapo MD,
Dennis Doherty MD, Paul Enright MD, Millicent Higgins MD, Ray Masferrer RRT,
Louise Nett RN RRT FAARC, Stephen Rennard MD, Thomas Petty MD FAARC, James Stoller MD,
and Gail Weinmann MD.

Members of the Executive Committee of NLHEP

Thomas Petty MD FAARC (chair), William Bailey MD, John B Bass Jr (representing the American
College of Physicians), Gary Ferguson MD, Millicent Higgins MD, Leonard D Hudson MD
(representing the American Thoracic Society), Suzanne S Hurd PhD (representing the NHLBI),
Ray Masferrer RRT (representing the American Association for Respiratory Care), Sreedhar Nair MD,
Louise M Nett RN RRT FAARC, Stephen Rennard MD, Deborah Shure MD, and
Gail Weinmann MD.