Should We Keep Pushing for a Spirometer in Every Doctor's Office?

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Professional societies have encouraged primary care providers to conduct spirometry testing for the detection of chronic obstructive pulmonary disease (COPD). In spite of this effort, the success rate is unacceptably low. Simple flow-sensing spirometers have technical flaws that can cause misreadings, and they are rarely checked for accuracy. When spirometry is performed by an experienced technologist, and when payment is made on the criterion of quality, the success rate for adults and school-aged children can be as high as 90%. But testing remains a challenge for younger children and the elderly. Regular feedback for the technologist about their testing results is essential. Even with an accurate spirometer, an able patient, and a skilled technologist, the ordering physician may wrongly interpret the data. Use of spirometry in primary care will continue to be problematic unless high quality testing is tied to reimbursement. Using FEV_1 or peak flow measurements to rule out airway abnormality in the majority of patients, followed by referral for more sophisticated studies in those remaining, may be the best approach. Respiratory therapists should engage in this effort.
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Introduction

During the past decade, the American Association for Respiratory Care was a sponsor of the National Lung Health Education Program (NLHEP), a non-profit organization developed by Petty. The primary purpose of the NLHEP was to encourage primary care practitioners to purchase and use spirometers in their office for the early detection of COPD. Office spirometry guidelines were published by NLHEP in RESPIRATORY CARE and *Chest*.[1,2] Guidelines for the purchase of office spirometers were then developed by NLHEP, and a group of respiratory therapists (RTs) with considerable experience with spirometers checked several office spirometer models to determine if they met these new guidelines.[3]

Also during the past decade, the lung division of the National Institutes of Health National Heart, Lung, and Blood Institute shifted their primary emphasis from asthma to COPD. In parallel, the Global Initiative for Chronic

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Obstructive Lung Disease (GOLD) guidelines for the diagnosis and treatment of COPD were developed and adopted worldwide.[4] These guidelines defined COPD as post-bronchodilator airway obstruction, and since the majority of patients with risk factors for COPD are seen by primary care providers, considerable funding has been directed toward encouraging them to find cases of COPD in their practice. Large direct to consumer (DTC) campaigns in the United States urge smokers with respiratory symptoms to ask their doctor for a spirometry test and to determine if they might benefit from a daily COPD inhaler. The worldwide market for these inhalers now exceeds 5 billion dollars per year, and will continue to grow.

What have we learned from the studies of spirometry in primary care? The one essential indication for spirometry is to confirm the "O" in COPD before starting treatment.[5,6] On average in the United States, only about 1 in 4 smokers with a new diagnosis of COPD has had a spirometry test that may have been used to confirm airway obstruction.[7–9] In contrast, the rate of spirometry testing for confirming COPD in The Netherlands, Australia, and the United Kingdom is much higher.[10,11] These countries provide extra financial incentives for general practitioners who perform spirometry, but there has been adequate reimbursement for spirometry testing in the United States for decades.

Clinical practice guidelines for COPD also recommend spirometry for current and former smokers over age 40 at increased risk for the disease.[12] The proportion of patients in this category who have had spirometry testing done (even once) by their primary care provider is very low. Multiple barriers have been identified, which have dampened the widespread uptake of case-finding for COPD,[13] despite efforts by pulmonary specialists and drug companies to promote it. In an attempt to make up for this deficit, the American Association for Respiratory Care has partnered with the United States COPD Foundation to test the potential of free screening for COPD at community-based health fairs and sporting events.[14] The American Thoracic Society has developed online spirometry courses and quality mentoring for primary care providers.[15]

Other methods of delivering spirometry testing to adult smokers have been tried in various countries, including itinerant nurses,[16] programs that give office spirometers or pocket spirometers to every general practitioner in the country who will accept one,[17–19] and training pharmacists to use office spirometers in local pharmacies.[20] However, within 12 months of the initial training, a majority of the primary care practices stop using the spirometer.[17,21] Of those who continue testing, the average rate is about one spirometry test per week (pre-bronchodilator only).

Why Is Good Quality Spirometry So Difficult to Obtain?

A common problem in most programs that have provided spirometers to primary care providers is a relatively low rate of good quality test sessions. Poor quality tests increase the likelihood of misclassification of spirometry interpretations (false positive and false negative diagnoses of restriction or obstruction). The quality goals for spirometry tests for adults (and children) have been established by an American Thoracic Society (ATS) committee for decades, and were updated in 2005 by a combined ATS/European Respiratory Society (ERS) task force.[22] The NLHEP office spirometry guidelines provided a quality grading system where A or B indicates that ATS guidelines were met; C indicates that 2 acceptable tests were done, but the FEV_1 or FVC values did not match closely (within 150 mL); D indicates that only one acceptable maneuver was obtained; and F indicates that no acceptable maneuvers were performed.[1] A simpler (and less strict) method defines a good quality test session as one with an A, B, or C quality grade. Studies of thousands of spirometry tests done by hundreds of primary care providers show that the success rates for obtaining good quality spirometry tests range from 35–60%, even when using spirometers with quality checks, messages, and grades.[18,23] That is not good.

What Is the Most Common Cause of Poor Quality Results: The Equipment, the Patient, the Technologist, or the Interpreter?

The Equipment

The FDA has made it difficult for a manufacturer or distributor to sell spirometers that are grossly inaccurate in the United States. Most experts agree that, in general, volume-sensing spirometers are inherently more accurate and remain accurate for longer periods of time than flow-sensing spirometers. However, very few volume-sensing spirometers remain in the marketplace, and they are rarely used in primary care settings, probably because, when compared to flow-sensing spirometers, they are much larger, cost more to manufacture and buy, and are more difficult to sanitize.

The majority of office spirometers sold in the United States during the past decade either measure the pressure created when the patient blows through a tube against a disposable fiber or metal screen sensor (such as those formerly made by Puritan-Bennett) or use an ultrasonic flow sensor (such as those made by ndd Medical Technologies). Disadvantages of the screen-type pneumotachometers is the potential for clogging by exhaled secretions, condensation of exhaled moisture on the screen, or partial block-

age of the screen by the patient's fingers, all of which cause falsely high FEV_1 and FVC results.[24] Clogging is not a problem with ultrasonic flow-sensing spirometers, where the patient blows through an empty tube, but errors may occur if the patient bites down on the mouthpiece, and the FVC may be falsely elevated if zero flow is not set properly (the sensor is moved during the zero flow setting, despite instructions to the contrary).[25]

Despite ATS recommendations that the accuracy of all spirometers be checked at least every day of use, fewer than 10% of office spirometers are sold with a 3.00-L calibration syringe, so it is likely that the ATS recommendation is rarely followed outside hospital-based pulmonary function testing (PFT) labs. Factors that reduce the use of calibration checks in primary care settings include the roughly $300 cost of the syringe; claims by sales people that the spirometer remains accurate without calibration checks; the fact that calibration syringes are usually larger than the spirometer itself; adding a calibration check may double the testing time (often only one patient per day), and calibration checks may double the cost of disposable supplies (since the calibration check is not done using the flow sensor used by the patient).

The NLHEP office spirometry guidelines suggested that studies be conducted and published to demonstrate the long-term accuracy of each spirometer model. If daily calibration checks showed better than 3.0% FVC accuracy for more than 95% of the time for 12 months, perhaps the spirometer did not need daily calibration checks. Such studies have been published for one model of an ultrasonic flow-sensing spirometer,[26,27] but not for the many other office spirometer models currently being sold without calibration syringes. The low rate of spirometer calibration checks in primary care settings will probably continue unless Medicare or other insurers change reimbursement policies to require them. An additional source of spirometer error is that older spirometers may not have been programmed to provide the NHANES III reference equations,[28] as recommended for use throughout North America by the ATS/ERS 2005 guidelines.[29]

The Patient

The ATS/ERS spirometry quality goals were set by studies that showed that 90% of school-aged children and 90% of adults referred to a PFT lab could meet them when tested by experienced technologists. While subsequent studies of adults in primary care settings have shown much lower success rates, a large study of World Trade Center responders showed a mean 80% success rate, with some experienced technologists obtaining better than 90% success rates.[30] Results from a related project (unpublished data) revealed mean success rates of 60%, which improved to over 95% in the same adults when payment was made only for good quality tests.

On the other hand, patients at the extremes of age (pre-school and over age 85) are less than 90% likely to meet the ATS/ERS spirometry quality goals, even when tested by skilled and experienced technologists.[31,32] The FVC requires 3 unusual breathing maneuvers, all performed in sequence.[33] Communication, comprehension, and motor skills are all needed to perform this maneuver correctly 3 times within a few minutes, but these skills are not yet established in some pre-school children and have decreased in some older people. Most healthy pre-school children cannot exhale for 6 seconds. An ERS task force that includes experts in testing pre-school children will soon provide more realistic end-of-test goals for this age group. Older patients can easily exhale for more than 6 seconds, but it is difficult for many of them to provide the continued effort to reach a volume-time plateau (low end-of-test volume). Many experts have concluded that allowing older adults to stop after 6 seconds, followed by use of NHANES III reference equations for the FEV_1/FEV_6, does not reduce the sensitivity of spirometry for detecting airway obstruction, when compared to the traditional measurement of FVC from more prolonged maneuvers.[32,34,35]

The Technologist

It is widely recognized that the skills, patience, and dedication of the technologist are the primary factors influencing the quality of spirometry tests. Multiple studies have shown a wide range in spirometry quality between the individuals administering the tests.[30,36,37] The methods (textbook, webinar, hands-on workshop) and the duration of the initial spirometry training (1 h to 16 h) are less important for long-term success in meeting quality goals, when compared to regular feedback (weekly to monthly) regarding the quality of tests done by that technologist.[16] Some people simply do not possess the necessary interpersonal communication skills to obtain good quality, which rely heavily on the use of body language for coaching and observing the patient.

The Interpreter

Even if an accurate spirometer is used by a skilled technologist to test a patient who provides good quality FVC maneuvers, the physician who ordered the test may poorly interpret the results and may then make inappropriate decisions regarding the diagnosis and treatment.[38–42] Current GOLD guidelines for COPD recommend the use of a fixed FEV_1/FVC ratio < 0.70 to detect airway obstruction and a mild-to-moderate severity threshold of 80% predicted FEV_1,[4] which causes a high misclassification rate for interpretations, when compared to using the fifth percentile

lower limits of the normal range.[43] Pre-bronchodilator (instead of post-bronchodilator) results may be used to define COPD in adult cigarette smokers, but about one-third of these patients have normal post-bronchodilator spirometry,[44] making asthma more likely than COPD as a cause for their respiratory symptoms.

In the absence of airway obstruction, using 80% predicted as the threshold for interpreting restriction causes a high false positive rate in older adults.[43] About half of such adult patients have a normal total lung capacity.[44] Abdominal obesity is a common cause of spirometric restriction,[45] but waist circumference is currently rarely considered when interpreting spirometry results. Spirometric restriction occurs in 5–20% of adult patients, and predicts morbidity and mortality,[46,47] but the clinical correlates of this pattern are poorly described[48] and the optimal work-up for this finding in patients with dyspnea—perhaps including a chest x-ray and D_{LCO} test[49]—has not been studied.

What Roles Should Spirometry Play in Prompting Smoking Cessation Efforts?

Another major rationale for encouraging primary care providers to perform office spirometry is to increase smoking cessation rates. Some smokers, when confronted with an abnormal breathing test (airway obstruction suggesting COPD), are prompted to quit.[50] However, a well designed randomized clinical trial found that the addition of spirometry to approved smoking cessation techniques did not further increase smoking cessation rates.[51] As a more easily understood concept to help the medical provider with the discussion, some spirometers calculate a "lung age" from the spirometry results.[52] Smoking cessation rates were doubled when lung age was discussed with smoking patients, according to a recent study in Great Britain,[53] but the study design was not optimal,[54] and the results not duplicated in a study of younger smokers.[55] In addition, estimates of lung age are often highly inaccurate.[56] Reviews conclude that spirometry is not worthwhile for the sole purpose of trying to prompt smokers to quit.[57,58] The limited time available during primary care visits of smoking patients is more effectively spent discussing why the patient enjoys smoking (motivational interviewing), and then providing pharmaceutical support when they want help in quitting.

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I would say, "No."[59] In the United States, spirometer ownership rates by primary care providers have probably reached a plateau. Rates for confirming airway obstruction before making a COPD diagnosis will probably not improve unless payments for prescriptions for COPD inhalers are denied when post-bronchodilator spirometry has not confirmed COPD. Likewise, the quality of spirometry tests done by primary care providers will probably not improve unless reimbursement is limited to good quality tests. Meanwhile, COPD case-finding can be much more efficient using a 2-stage program where clinically important COPD is ruled out in 80% of adult smokers who have a normal peak flow or FEV_1 using an inexpensive pocket spirometer,[60] and referral for good quality pre- and post-bronchodilator spirometry for the 20% of patients with low values.[61] RTs should develop spirometry services that visit primary care providers in their community once per month to provide high quality pre- and post-bronchodilator spirometry with valid interpretations for patients who have been scheduled for testing. RTs who provide these services should first obtain a CPFT credential or the new "spirometry driver's license."[62] Success rates for meeting spirometry quality goals should be proven to remain above 80%.

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Discussion

Ruppel: What makes you think that measuring peak flow will allow us to adequately screen for patients with COPD?

Enright: Glad you asked. Go ahead, Steve.

Nelson:* It's funny you should ask. As it turns out, we use peak flow based on what PLATINO[1] [Latin American Project for Investigation of Obstructive Lung Disease] and BOLD[2] [Burden of Obstructive Lung Disease] had found in their preliminary results. We used a 70% cutoff. Anybody who had a peak flow 70% or higher, we said, "You probably don't have any disease." If they had 70% or lower you go on to get diagnostic spirometry done. This was based on a study of 5,638 people and had a 93.3% positive predictive value and 68.2% negative predictive value for substantial COPD, so if the peak flow was low, you probably had lung disease. On the other hand, if the peak flow was above 70%, you probably didn't have lung disease. Based on our population of the general public attending health fairs and other large public events, we calculated the probability of having COPD as 8.7%.

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Ruppel: Were those peak flows done correctly with equipment that measured it accurately?

Enright: Well-trained RTs coached the PEF [peak expiratory flow] tests using electronic pocket spirometers that met ATS standards[1] for accuracy. Each day they measured their own PEF and FEV_1 as a biologic control for the devices. However, these factors are often not present in primary care settings. If peak flows are done poorly (a submaximal inhalation or a poor blast effort), you almost always get lower values when compared to a truly maximal effort. So the false positive rate doesn't increase, but a larger number of more expensive diagnostic-quality spirometry tests is needed (the second stage).

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Kaminsky: I wanted to make a comment about lung age and using it as a motivator to quit smoking. You mentioned the Parkes study[1] in your references. That was the study published in Britain showing you could double smoking cessation rates by sharing lung age with smokers in a primary care setting.

We just finished a pilot study in the PFT lab,[2] which is why I bring it up to this group. We used the lab as the setting for this. That is to say, people referred to the lab for lung function testing, so by definition there's some concern about their breathing.It's pilot only because of the small sample size, but we found that the lung age did enhance the quit attempt rate one month later. The flip side was very interesting, because if the lung age was normal, it *de*motivated them to make

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a quit attempt one month later. This has been discussed a lot in the literature, but nobody has ever looked at it; there are a few indirect data to support this. We think we've found that kind of a signal and that's very important, because if we're going to use lung age, we have to use it in the right population, that is to say the people who have an abnormal lung age only. Or think of some other clever strategy to apply it.

1. Parkes G Greenhalgh T, Griffin M, Dent R. Effect on smoking quit rate of telling patients their lung age: the Step2Quit randomised controlled trial. BMJ 2008; 336(7644):598-600.
2. Kaminsky DA, Marcy T, Dorwaldt A, Pinckney R, Desarno M, Solomon L, Hughes JR. Motivating smokers in the hospital pulmonary function laboratory to quit smoking by use of the lung age concept. Nicotine Tob Res 2011 May 6 [Epub ahead of print].

Enright: I agree that we need more studies in different settings to verify that performing spirometry and then discussing lung age (or the abnormal results) really increases smoking cessation rates and offsets the cost of performing the tests.

Haynes: I find the peak flow idea actually very attractive, because I think part of the problem is not just having the offices do the spirometry correctly. But the primary care physician also has to be able interpret the data. I can tell you that many times when I do spirometries and hand the report to the non-pulmonary physician, I observe the blank stare expression, which is shortly followed by "How does it look?" So in addition to being an easier technique to do, it's also the easier for primary care physicians to interpret the single number. When they can interpret the number and make sense of it, they may be more likely to actually do it.

Enright: The biggest worry that I have with this new 2 stage process[1] of COPD case-finding is that many doctors will see a red peak flow reading (low PEF) and start treating the patient for COPD without ordering diagnostic quality spirometry to verify clinically important COPD (a low FEV_1/FVC and post-bronchodilator FEV_1 below 60% predicted).

1. Qaseem A, Wilt TJ, Weinberger SE, Hanania NA, Criner G, van der Molen T, et al. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. Ann Intern Med 2011;155(3): 179-191.

Haynes: The other side of it is no testing at all, just diagnosing COPD on the basis of a cough and a smoking history. When I hear people say that COPD is the 4th leading cause of death,[1] I sometimes wonder if that's because people are dying from it who don't have it. Many physicians do no testing at all, and it's just assumed that 90% of long-term smokers have COPD. We know that that's not true.

1. United States Department of Health and Human Services; National Institutes of Health; National Heart, Lung, and Blood Institute. Survey: awareness of COPD—the nation's fourth leading cause of death—is rising, but understanding is still low. Smokers and those at risk are far less likely to talk to their doctor about symptoms. NIH News; November 9, 2009. http://www.nih.gov/news/health/nov2009/nhlbi-02.htm. *Accessed September 28, 2011.*

Miller: Just some validation of the peak flow, which I was not overly impressed with, until we compared peak flow with FEV_1 first in a population of asthmatics because of the recommendation that you monitor asthmatics with peak flow. We found[1] a very good correlation, and then did the same thing in COPD patients and found an even better correlation; you could predict the FEV_1 from the peak flow fairly well. It is pretty robust and, let's face it, a very simple and available measurement: peak flows done by knowledgeable people on various gadgets.

1. Patel MC, Mehta KB, Miller A. Peak flow in COPD: to define the relationship between FEV_1 and PF in patients with COPD and compare it with that seen in asthma patients. Chest 1999;118(Suppl):200S.

McCormack: I worry a lot about providing pocket spirometers to general practitioners to rule out COPD for smokers over 40. I don't really see how that is going to be much better than putting regular spirometry in primary care offices. Although I think that pocket spirometers are valuable in tracking lung function over time, and I use them in clinical research in COPD and in childhood asthma, they are a step away from the quality of typical portable office spirometry. While I understand the point about using it to rule out rather than rule in disease, once you have the device in the primary care office, it's not just going to be used to rule out obstruction. Then a practitioner will have checked the box that they have done some kind of spirometry on someone who might have COPD. Seems to me that this could be opening up a big can of worms.

In my practice I see referred patients with COPD who clearly have disease, are on treatment, and now they're here for some new problem, yet they still have never had spirometry at a referral lab. I would shift more towards trying to get the message out to get patients to a setting where they can get good quality testing versus the pocket.

Enright: Maybe I am just giving up after 2 decades of trying to do that without much success. Primary care practitioners are reimbursed very well when they perform spirometry, but they still perform it for less than 20% of the patients for whom it is indicated, and when office spirometry is done, fewer than half of the tests meet ATS quality goals.[1] Only one fourth

of patients with a diagnosis of COPD in the United States have ever had a spirometry test to verify airway obstruction.

1. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, et al; ATS/ERS Task Force. Standardisation of spirometry. Eur Respir J 2005;26(2):319-338.

Coates: The Ministry of Health in Ontario (the only payer in the province) did a pilot project[1] where they looked at communities where they could monitor emergency room visits and admissions. They provided an RT and an asthma educator to make it very easy for the primary care physicians in the community to have spirometry done and to have access to an asthma educator. What they showed was there was a dramatic decrease in the costs of emergency room visits and a dramatic decrease in the cost of admissions: fewer people seeking emergency room treatment and fewer people being admitted. Now, whether it's the spirometry that made the difference or the asthma educator (and maybe it was both), there was certainly no question that it was cost effective with asthma to have therapy guided by proper treatment plans and by proper pulmonary function measurements. Asthma may be easier to treat than COPD, but there may be a lesson here.

1. Ungar WJ, Coyte PC. Health services utilization reporting in respiratory patients. Pharmacy Medication Monitoring Advisory Board. J Clin Epidemiol 1998;51(12):1335-1342.

Pichurko: The argument I would make for office spirometry is the following. Having practiced for 2 decades in Michigan and Ohio, in my mind the alternative to office spirometry for many patients is not good quality laboratory spirometry, but often *no* spirometry. With many people unemployed and uninsured or underinsured, spirometry for the self-payer may cost $250 or more, and a full PFT $800. I don't know whether it's also a problem beyond the manufacturing Midwest states, but the idea of testing everybody in the full lab is cost-prohibitive.

The other point I would make is, while I love peak flow meters and I keep one in my pocket with a supply of disposable mouthpieces during each office session, I assign it a limited role. Specifically, it is very helpful in the longitudinal assessment of individual patients once their physiology has been defined. Otherwise I run the risk of assigning a reduced peak flow rate an etiology like asthma because it's common, rather than to a tracheal stricture associated with intubation for respiratory distress syndrome at birth.

Enright: There is another way to deliver good quality spirometry in primary care settings, apart from the 2-stage process that I just mentioned, and apart from them sending everyone who needs spirometry to a local PFT lab. I recommend setting up programs in each community where RTs come to primary care offices about once a month to test all the patients for whom the provider ordered a spirometry test. That approach has been tried in Tasmania and in a community in London, with good success. I'd like to see a study of that approach in the United States. We can't just continue to try a single approach to get good quality spirometry done for smokers; we have to try new approaches and provide general practitioners with multiple different methods of obtaining a spirometry test for their patients who need one.

Kaminsky: I'd like to add to that. In the survey we did in our community regarding barriers to doing spirometry in the office, a big one that came up was physician discomfort with what the numbers mean. I get back to what I said before: we in the medical education community unfortunately do a poor job of teaching medical students simple lung function and simple spirometry. So when they go into practice we hope that they understand the importance of making this measurement, whether it be in their office, if they can do it well, or by referring to the hospital by the system you just suggested. Just thinking of it in the first place is step one in getting it done. And, hopefully, of course, it would be done well.

Nelson: I harken back to the days when we were smoking kymographs. When I first learned how to do PFTs, it was sort of the military attitude of "see one, do one, teach one." I was probably 3 generations of training removed from the person who had come in and taught people how to do spirometry, so I was getting the flaws and laziness of the first generation, compounded by the second generation, compounded by the third generation. I don't think this is atypical with someone in a PFT lab, as a technologist is being trained to accept all the flaws that others have already introduced. It's even worse in the office where the office nebbish or whoever he is standing there, "emptying the trash today is now doing spirometry tomorrow," because he was the only guy who could figure out how to push the button. We've got to get to the point where training—and this goes back to the previous talk—we have to train these people and be consistent in that.