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Potential conflicts of interest

During the past 3 years, Paul Enright has been paid by Pfizer to review the quality of spirometry tests for a worldwide clinical trial of varenicline for smoking cessation in patients with COPD. Pfizer also co-markets tiotropium, a long-acting bronchodilator for patients with severe COPD. Increased detection of moderate-to-severe COPD, as recommended by this article, would benefit Pfizer. Paul Enright has no conflicts of interest with any spirometer manufacturer.

OVER 90% OF SMOKERS DON'T NEED AN EXPENSIVE INHALER. PROVE IT BY USING A POCKET SPIROMETER.

P. Enright

ABSTRACT

Many patients with a chronic smokers cough have been prescribed an inhaler for “chronic obstructive pulmonary disease” (COPD) which costs €100–200 per month but have never had a spirometry test to show that they have the O in COPD. On the other hand, many smokers with moderate-to-severe, undiagnosed COPD have never seen a doctor to enquire about the cause of their dyspnoea.

The use of a €100 pocket spirometer would efficiently show, after one or two short blows, that 90% of smokers have a normal forced expiratory volume in 1 s (FEV1), ruling out COPD in the range

where an inhaler might be considered. They should be urged and helped to quit smoking. The pocket spirometer would show that a few smokers have an FEV1 below 60% predicted, and should be referred for accurate pre- and post-bronchodilator spirometry to confirm airway obstruction, followed by appropriate interventions.

WHAT IS A POCKET SPIROMETER?

Starting about five years ago, a new breed of inexpensive “pocket” spirometers became available. Unlike mechanical peak flow meters which can only measure peak expiratory flow (PEF), these ▶

battery-powered spirometers can accurately measure FEV₁ (when effort is good). Pocket spirometers cannot replace more expensive, diagnostic-quality, office spirometers because they have no quality checks: no flow–volume or volume–time graphs, no checks or messages about slow starts, and no checks for poor FEV₁ repeatability (which often detects submaximal inhalation before the 1-s blast out effort). Some pocket spirometers were designed to replace mechanical peak flow meters for home monitoring by patients with asthma, so they prominently display PEF and indicate asthma control using the green/yellow/red traffic light colours. Currently, only two pocket spirometers calculate and display predicted and % pred FEV₁ values.

SCREENING FOR COPD IN A VIENNA PUBLIC SQUARE

For the past five years, screening spirometry has been performed in public settings on weekends during the European Respiratory Society (ERS) Annual Congress. Following newspaper, radio or television advertising each year, thousands of people come for a free spirometry test. This COPD awareness programme is being repeated at the 2009 ERS Annual Congress in Vienna. FEV₁ and forced vital capacity (FVC) are measured several times for each participant by a technologist using an office spirometer. It takes ~5 min to meet American Thoracic Society (ATS)/ERS goals for a good quality pre-bronchodilator spirometry test and the disposable flow sensors cost about €2 each.

With public screening programmes, the vast majority of “cases” of COPD are Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage I or II [1, 2], but only a small fraction of those with an FEV₁ above 70% pred actually have a progressive airway disease. According to extensive literature reviews and the

Agency for Healthcare Research and Quality, such programmes are not justified [3, 4].

Prompting smoking cessation is not a valid rationale for promoting screening spirometry. Smokers are not more likely to successfully quit smoking when faced with abnormal spirometry results [5, 6]. All smokers, regardless of spirometry results, should be helped by primary care practitioners to quit smoking; including the prescription of bupropion or varenicline for those who have failed less expensive interventions [7]. If you need a “stage prop” (abnormal test result) to convince a smoker to allow you to help them to quit smoking permanently, use a carbon monoxide (CO) breath analyser. Almost everyone who has smoked during the 4 h prior to the test will have a high exhaled CO level.

COPD CASE-FINDING BY GENERAL PRACTITIONERS

Spirometry performed in medical care settings for patients with chronic respiratory symptoms (at high risk for lung disease) is called “case finding,” in contrast to screening spirometry, which is performed outside of a physician’s office or hospital, often for anyone who is interested in the test (and thus at low risk for lung disease) [8, 9]. Screening spirometry projects are often said to be done to “increase awareness” of COPD but considerable harm can occur when the person is inappropriately told that the results are abnormal [10, 11]. Misclassification of spirometry results commonly occurs due to poor coaching, poor inspiratory or expiratory effort, an inaccurate spirometer or an inappropriate interpretation scheme; such as using a fixed ratio, <0.70, to detect obstruction.

A NORMAL FEV₁ OR PEF RULES OUT COPD?

Lower false-positive rates will be obtained, at no loss of sensitivity ►

for smokers who may benefit from a COPD inhaler, if inexpensive pocket spirometers [12] or mechanical PEF meters are used to exclude substantial airway obstruction in primary care settings. A ground-breaking report from the PLATINO (*Proyecto Latinoamericano de Investigación en Obstrucción Pulmonar*) and BOLD studies demonstrates the utility of measuring a normal PEF to confidently exclude smoking adults from GOLD stage III or more severe COPD [13]. This stepped approach is efficient because only those with a low PEF or low FEV1 need a referral to a specialty service for good quality pre- and post-bronchodilator spirometry to confirm post-bronchodilator airway obstruction.

The optimal threshold for referral for diagnostic spirometry will depend on many factors, including the pre-test probability of lung disease, the accuracy of the pocket spirometer or peak flow meter, the match of the reference equations to the population being tested, and a thoughtful comparison of the consequences of false-negative versus false-positive results.

EFFICIENCY SEEN IN NEW COPD SCREENING PROGRAMMES

A National Institutes of Health (National Heart Lung and Blood Institute, USA) sponsored task-force meeting in June, 2008 in Washington DC (USA), concluded that two-stage COPD screening programmes should be evaluated. Since then, a programme, sponsored by the US COPD Foundation, has been using a Vitalograph (Maids Moreton, UK) pocket spirometer to screen thousands of adults at events around the USA [14]. Those with low values are offered pre-bronchodilator spirometry testing by a certified respiratory therapist using an EasyOne™ (ndd, Zurich, Switzerland) spirometer. For

example, in 3 days at a convention of retired people, 460 attendees were screened for COPD; 90% had at least one COPD risk factor; 95% had a normal PEF; and about 4% (18 older adults) had moderate or severe airway obstruction confirmed by spirometry.

Another programme using a two-stage COPD case-finding approach has been conducted in pharmacies in Hawaii (USA) [15]. If the client's FEV1 was <70% pred according to the copd-6 pocket spirometer (Vitalograph) used in the front of the store, they were offered spirometry to confirm airway obstruction in a quiet medical education room, performed by a skilled nurse or respiratory therapist. All smokers were urged to quit using motivational interviewing techniques. Those who were ready to quit were given a book about smoking cessation and referred to local resources. Pharmacists in Barcelona (Spain) conducted a COPD screening program in April and May, 2007, testing 161 customers at 13 community pharmacies [16]. However, their efficiency could have been much higher if they had used a two-stage programme, starting with pocket spirometry.

FALSE-POSITIVE RATES FOR "MILD COPD" ARE VERY HIGH

Somehow, COPD guidelines published by pulmonary specialists during the past decade have become biased towards increasing prescriptions for expensive inhalers. Patients with a normal FEV1 were classified as having mild COPD (GOLD stage I) if their FEV1/FVC was <0.70 [17, 18]. However, the FEV1/FVC decreases with aging in healthy never-smokers, so the false-positive rate for airway obstruction (and thus COPD), as defined by several pulmonary professional societies, increases above age 50 yrs and is very high above age 70 yrs ►

[19–21]. The fifth percentile from spirometry reference equations, derived from a healthy population sample, should be used to determine the lower limit of the normal range (LLN) for both the FEV1/FVC and for the FEV1 itself [22]. The age and gender-corrected LLNs are calculated automatically by the majority of commercially available spirometers [23], so there is no need to use the faulty 0.70 ratio in practice.

There is no need to detect COPD “early” because there is no evidence that GOLD stage I is a disease or a risk factor [24, 25]. The risk of a subsequent rapid decline in lung function in a smoker with airway obstruction is substantially increased only after their FEV1 has fallen to below ~65% pred [26].

About one-third of adult smokers with airway obstruction, found during screening spirometry using the current GOLD guidelines, will not have airway obstruction 10 min after inhaling a fast-acting bronchodilator (post-bronchodilator, after salbutamol) [27]. By definition, COPD is then ruled out. This finding increases the probability of asthma in those with asthma-like symptoms. Up to half of adults with asthma in some countries are current smokers [28, 29] and their asthma will be more easily controlled if they successfully quit smoking [30]. Primary care practitioners rarely have the time to repeat spirometry, so it follows that they should not make a diagnosis of COPD in a patient with mild-to-moderate airway obstruction without referring these patients for post-bronchodilator spirometry [31]. Differentiating asthma from COPD is important because asthma infrequently responds to the anticholinergic inhalers often prescribed for COPD.

MILD RESTRICTION IS NOT EARLY COPD

“Mild restriction” is a nonspecific, nondiagnostic, spirometry result. It

is often due to poor inspiratory or expiratory efforts, not measuring height (since men exaggerate their height), the use of an inappropriate reference equation (such as that for Caucasian when testing a black patient) or using an interpretation scheme which is not evidence-based. A low FVC without a low FEV1/FVC is often interpreted as restriction but at least half of such patients have normal lung volumes when referred to a pulmonary function laboratory and tested in a body plethysmograph [32]. Clinical research is needed to determine the clinical correlates of this nonspecific spirometry pattern, much of which is probably due to obesity or poor efforts. There is no evidence that mild “spirometric restriction” is due to “air trapping” secondary to “small airways disease” or early COPD in patients who would benefit from treatment with inhalers [33]. It wastes resources to use spirometric “restriction” for medical decision making, or as an indication for referring the patient for complete pulmonary function testing, unless the FVC is repeatedly <60% pred, or the patient has an abnormal chest radiograph, or has dyspnoea on exertion but is not obese.

In order to minimise misclassification of spirometry interpretations, we should learn to accept uncertainty when the results are near the LLN (*i.e.* borderline abnormal), the quality of the test was poor (due to sub-maximal efforts) and when post-bronchodilator results are unavailable [9].

YET SPIROMETRY IS GREATLY UNDER-UTILISED

The majority of people in the USA who report a doctor’s diagnosis of COPD had never had spirometry testing to confirm COPD [34–36]. This practice is akin to prescribing antihypertensive medications without measuring blood pressure. While they may be smokers with ►

a chronic cough and perhaps some dyspnoea, due to poor conditioning, many of these patients do not have obstruction [37].

SHOULD GPs BUY A SPIROMETER OR SIMPLY ORDER SPIROMETRY TESTS?

A minority of primary care practitioners have purchased a spirometer; and few have actually used it during the past month [38–41]. Some GPs use a spirometer several times a month but many of the tests fail the standard goals for good quality [42]. In the USA, a nurse or technologist performs the spirometry tests (not the doctor) but the majority of these staff have not been trained to properly perform spirometry tests and post-bronchodilator spirometry is almost never done (due to time constraints) [43].

A few GPs purchase a spirometer and use it for the majority of their patients who have an indication for spirometry; smokers over age 40 yrs with dyspnoea or patients with poorly controlled asthma. These “early adopters” report that the spirometry results often assist medical decision making [44–46]. However, the majority of GPs, who are given a spirometer and training, do not use it after the first few months [47].

For many GPs, the best solution may be to use a pocket spirometer to rule-out COPD, referring the small fraction of patients with an FEV1 <60–70% pred to a third-party expert to perform the necessary spirometry tests to confirm airway obstruction [48–51]. In the USA, about half of the spirometry tests performed around the time of the initial diagnosis of COPD are performed in a traditional PFT laboratory [35] but this approach is greatly under-utilised, perhaps due to long delays, inconvenience or excessive cost. Regularly scheduled “free clinics” in convenient ►

Table of Pocket Spirometers

Model**	Manufacturer	Parameters	Features	Website
copd-6™	Vitalograph™	FEV1, FEV1/FEV6	Airflow spins a turbine vane; measures FEV1, FEV6, FEV1/FEV6 and % pred (ERS 1993 or NHANES III race-specific references); quality messages for high BEV, cough, FET <3 s, and EOTV <25 mL; colour zones for COPD (based on % pred FEV1); lung age, two AAA batteries; and uses standard disposable one-way mouthpieces	www.vitalograph.com
PEF100™	microlife™	FEV1, PEF	Airflow spins a propeller; 240 numeric results stored (with date and time); colour zones for asthma; USB connector for optional computer software and optional printer; two AA batteries. This model would require an inexpensive rubber adaptor to use disposable one-way mouthpieces (not available from the manufacturer)	www.microlifeusa.com
PiKo-1™	nSpire™	FEV1, PEF	Airflow bends a vane; 96 numeric results stored (with date and time); error messages for cough and FET <1 s; colour zones for asthma; infrared connection for optional USB cradle for PC-based PiKoNET software; two type-357 button cells. A mouthpiece adaptor is available from the manufacturer for using disposable one-way mouthpieces	www.nspirehealth.com
PiKo-6™	nSpire™	FEV1, FEV6, PEF	Same features as the PiKo-1, plus measurement and display of FEV6 and FEV1/FEV6 (but not predicted or % pred)	www.nspirehealth.com
PulmoLife™	MicroMedical™	FEV1, FEV1 % pred	Airflow spins a turbine vane; measures FEV1 and FEV1 % pred (ERS 1993 or NHANES III race-specific references, or Chinese); quality messages for high BEV, cough, FET <3 s and EOTV <25 mL; colour zones for COPD (based on FEV1 % pred); lung age, a 3V lithium cell (CR-2450); uses standard disposable one-way mouthpieces. Calibration checks can be done using a 3-L syringe	www.viasyshealthcare.com

The spirometers are listed in alphabetical order. Only those selling for less than €300 are included. FEVn: forced expiratory volume in n seconds; % pred: % predicted; BEV: back extrapolated volume; FET: forced expiratory time; EOTV: end-of-test volume; COPD: chronic obstructive pulmonary disease; PEF: peak expiratory flow.



Figure 1. The Vitalograph copd-6™ pocket spirometer detects airway obstruction from six-second FVC manoeuvres using FEV1/FEV6 and FEV1 % predicted. Three manoeuvre quality checks are performed in order to reduce the risk of misclassification, due to submaximal efforts.



Figure 2. The Micro Medical PulmoLife™ pocket spirometer measures FEV1 and calculates the FEV1 % predicted and estimates “lung age” to help prompt smokers to quit. None of the pocket spirometers provides volume–time or flow–volume graphs, so vigorous coaching and observation of the patient’s “body language” is needed to detect poor efforts.



Figure 4. The MicroLife™ PF100 digital peak flow meter was designed for home monitoring of patients with asthma; however, it also measures FEV1. It could be used for COPD screening if a look-up table is used to determine 60% predicted FEV1 values and, if a rubber adaptor is used, with disposable one-way mouthpieces for multi-patient testing.



Figure 3. The nSpire PiKo-6™ is the smallest pocket spirometer, measuring FEV1, FEV6, and FEV1/FEV6 (but not predicted values) from six-second forced vital capacity manoeuvres. An optional base sends the numeric results (but not graphs) to a personal computer.



Figure 5. When pocket spirometers are used to test multiple patients, a disposable one-way mouthpiece which prevents inhalation from the device will reduce the risk of cross-contamination. Both medical personnel and patients should wash their hands before and after using spirometers of any type. The surface of pocket spirometers should also be wiped with alcohol to further reduce the risk of transmitting respiratory viruses from one patient to another.

locations (such as neighbourhood pharmacies or community centres) have successfully been used in Poland [52]. Another approach, which has proven successful in some settings, is for an itinerant nurse or certified technologist to schedule monthly visits to the GP's office to test the patients who have an indication for spirometry [42]. In total, >80% of the tests performed by certified and skillful

technologists meet ATS/ERS quality goals [53].

CHOOSING A POCKET SPIROMETER

In May 2009, only five pocket spirometers which sell for €50–300 each were commercially available (table 1) but new models should become available soon, as the

efficiency of the two-stage process for detecting moderate-to-severe COPD is verified in other settings. Valuable features include quality checks (to verify a low back-extrapolated volume and a 6-s exhalation time), internal reference equations and the use of inexpensive, disposable, one-way mouthpieces, which minimise the risk of cross-contamination. ■

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