Comprehensive Quality Control for Pulmonary Function Testing: It's Time to Face the Music

> Criticism may not be agreeable, but it is necessary. It fulfils the same function as pain in the human body. It calls attention to an unhealthy state of things.
> —Winston Churchill

Every day in pulmonary function laboratories and clinics around the world, efforts to ensure the quality of spirometry testing begin, and all too often end, with a few strokes of a 3-liter calibration syringe. Of course, validating a spirometer's accuracy and precision is a universal practice and is described in great detail in the American Thoracic Society/European Respiratory Society (ATS/ERS) spirometry guidelines.[1] However, having a finely-tuned instrument, be it a spirometer or a violin, doesn't ensure a virtuoso performance once the curtain is raised. Indeed, musicians require years of training and practice to achieve virtuoso status. Even after the violinist has mastered his instrument, there is feedback on the performance. Feedback and criticism, whether desired or not, come from the orchestra conductor, peers, and, of course, those in the audience with a keen ear and the unwillingness to bestow effusive applause for a less than sublime performance. Indeed, the criticism a musician receives, when used properly, accelerates learning and ascension to elite levels of performance. The positive influence of feedback and criticism on performance also holds true for pulmonary function technicians and others who conduct spirometry. Coincidently, John Hutchinson, who invented a water spirometer and introduced the term "vital capacity," was an accomplished violinist.[2]

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As mentioned above, in far too many pulmonary function laboratories, quality control begins and ends with verification of the accuracy and precision of equipment. However, the ATS/ERS lung function testing guidelines[3] recommend that laboratories also verify the accuracy and precision of technicians on an ongoing basis. Table 1 outlines ATS/ERS recommendations for composing a technician feedback program to improve quality control. Much of the evidence supporting the practice of technician feedback comes from epidemiologic studies, which, as pointed out by Stoller[4] in a 2008 editorial in RESPIRATORY CARE, require high-quality data and also pose a greater challenge in terms of assuring quality spirometry because of multicenter testing and large numbers of inexperienced data gatherers. Yet despite the challenges of large multicenter studies, high-quality spirometry has been repeatedly reported when comprehensive quality-control measures are utilized.

The Salute Respiratoria Nell'Anziano (SARA [Respiratory Health in the Elderly]) study was conducted in 24 Italian geriatric and pulmonary centers to investigate the natural history of chronic obstructive pulmonary disease in patients $\geq$ 65 years of age.[5] The subjects' ages ranged from 65 to 100 years—not generally considered an easy group to test. Forty-eight technicians were trained to perform spirometry for the study, only 10 of whom had prior training in pulmonary function testing. In addition to initial training and daily equipment calibration, technician performance was monitored by a coordinating center, and technician-performance reports were regularly sent to all centers. The coordinating center communicated deficient spirometry quality to participating centers via telephone, and made site visits for repeat training and troubleshooting as needed. Spirometry was attempted in 1,622 subjects, and even when accounting for the 91 subjects who could not perform spirometry at all, 77% of all the subjects had 3 acceptable spirometry efforts.

Another challenging endeavor was undertaken by the investigators in the Projeto Latino-Americano de Investigação em Obstrução Pulmonar (PLATINO) study,[6] which assessed the prevalence of chronic obstructive pulmonary disease in 5 cities: São Paulo, Brazil; México City, México; Montevideo, Uruguay; Santiago, Chile; and Caracas,

Table 1. American Thoracic Society/European Respiratory Society Recommended Performance Feedback for Spirometry Technicians[3]

Information concerning the nature and extent of unacceptable maneuvers and non-reproducible tests
Corrective action that the technician can take to improve the quality and number of acceptable maneuvers
Positive feedback to technicians for good performance
Comments regarding system set-up and reporting results

Venezuela. The study was designed to perform spirometry in 800 subjects per city, by making house calls with handheld spirometers. In addition to the difficult testing conditions, 73% of the data gatherers had no prior training in pulmonary function testing, and on average the study population had less than 8 years of formal schooling.

The PLATINO investigators employed several layers of quality control. Local supervisors inspected all printed pulmonary function test reports, including the flow-volume loops, and directed technicians to repeat poor-quality spirometries. This proved to be an important feature of their methods, since 23% of subjects required repeat spirometry. In addition, monitors at the coordinating center assessed test quality and provided ongoing feedback to regional sites, including feedback on individual technician performance. Despite these difficult quality-control challenges, the investigators reported that 89% of the subjects performed spirometry that met the ATS/ERS quality standards.

Numerous other studies have shown similar success with comprehensive quality-control measures. In this issue of RESPIRATORY CARE a study by Enright and co-workers details their quality-control strategy in the World Trade Center Worker and Volunteer Medical Screening Program.[7] Of course, management of spirometry quality control in large epidemiologic studies is not new ground for Dr Enright. As a principal investigator in the Lung Health Study, Enright and his colleagues in the Lung Health Study Research Group gave us the blueprint on how to produce and sustain high-quality spirometry.[8] The Lung Health Study documented that after the initial training of mostly inexperienced technicians, spirometry quality declined over time. Technician performance improved somewhat after site visits by instructors, and was markedly improved and sustained following the implementation of a quality-assurance strategy that included performance feedback to technicians (Fig. 1).

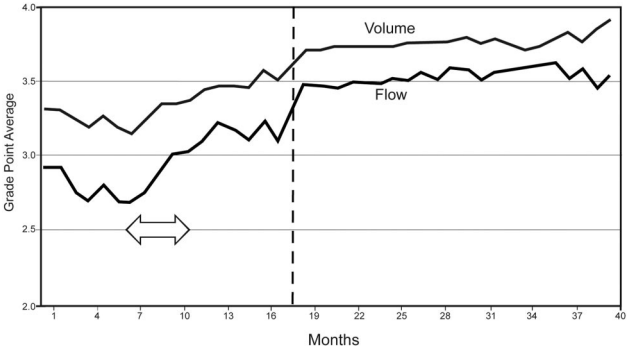

Fig. 1. Spirometry test quality, reported as a grade point average, for the pulmonary-function technicians, in the first 40 months of the Lung Health Study. The horizontal arrow indicates the time of the site visits by the spirometry instructors, for repeat training of spirometry technicians at participating centers. The dashed line indicates the inception of technician monitoring and feedback. (Data from Reference 8.)

It is not terribly remarkable that in the World Trade Center Worker and Volunteer Medical Screening Program, $>$ 80% of the spirometry tests met the acceptability and repeatability goals when using a quality-control program modeled after that in the Lung Health Study. Success with that quality-control format has been reported many times by various researchers studying different cohorts in various places around the world. What is remarkable is that this quality-control format has not been adopted by pulmonary function laboratories outside of epidemiologic studies. In preparation for writing this editorial, I conducted a small informal poll of pulmonary function personnel from around the country. I posed the following question: "Are the technicians in your laboratory regularly given statistical feedback detailing their proficiency in performing spirometry (eg, monthly or quarterly report detailing percentage of tests that met ATS guidelines)?" Only 30% of respondents answered in the affirmative.

Momentum is growing to establish accreditation of pulmonary function laboratories, which would undoubtedly require spirometry quality control to go beyond stroking a 3-liter super-syringe every morning. However, it is unacceptable to wait for the evolution of a credentialing organization to force us to follow a more comprehensive quality-control program that is supported by undisputed data published 20 years ago. Many modern pulmonary function systems make technician-performance data easily accessible. In my laboratory we found a 21% increase in the number of spirometries that met ATS/ERS acceptability and repeatability criteria after we started a program that monitors technician proficiency and provides monthly individualized technician feedback, which is shared among the group (unpublished data).

High-quality spirometry data are essential for epidemiologic studies to identify differences within a population; however, we must insist on the same quality for individual patient diagnostics. Big-impact decisions, such as suitability for surgery, need for expensive medications (possibly with important adverse effects), and employment eligibility, can hinge on spirometry data. Centralized monitoring of spirometry quality, coupled with technician feedback, improves spirometry quality. If your laboratory does not have central spirometry monitoring and technician feedback, can you really assert that your spirometry testing is done in accordance with the ATS/ERS guidelines?

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