

## Quality Control for Spirometry in Large Epidemiologic Studies: “Breathing Quality” Into Our Work

Spirometry is a time-honored, invaluable measurement for assessing lung function in individuals with chronic obstructive pulmonary disease (COPD) as well as for studying populations with COPD in epidemiologic studies.<sup>1,2</sup> Indeed, the prognostic value of spirometry has been appreciated since the 1960s,<sup>3</sup> and forced expiratory volume in the first second (FEV<sub>1</sub>) was more recently included in more comprehensive, multivariate prognostic indices for COPD (eg, the BODE index [body mass index, airflow obstruction, dyspnea, and exercise capacity]<sup>4</sup>). Also, spirometry has been an early, longstanding, and key measurement in assessing the natural history of lung function in population studies. For example, in 1977 Fletcher and Peto studied FEV<sub>1</sub> changes in London transit workers to determine the impact of cigarette smoking on lung function.<sup>5</sup>

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As with any test, performing spirometry well requires careful attention to technique, as reflected by the generous attention paid to spirometry guidelines and recommendations issued by official societies such as the American Thoracic Society<sup>1</sup> and the European Respiratory Society.<sup>2</sup> Indeed, the challenge of acquiring high-quality spirometric data in large studies (eg, to assess natural history or the effect of various interventions on the lung) magnifies the challenge of making good measurements with an individual, because the aggregate results depend critically on the technical adequacy of the individual measurements and because processes must be in place for oversight and feedback to centers and to individual pulmonary function technicians regarding their performance in overall quality control. No wonder, then, that large, multicenter epidemiologic studies that have measured spirometry as a main outcome (eg, the Lung Health Study sponsored by the National Institutes of Health,<sup>6</sup> the Registry for Individuals with Severe Deficiency of Alpha-1 Antitrypsin,<sup>7</sup> and the Multiple Risk Factor Intervention Trial,<sup>8</sup> to name only a few) have paid close attention to spirometry quality control. As further evidence of the importance of the issue and the substantial attention paid to spirometry quality control, a MEDLINE search (1950 through March 2008) with the search terms “spirometry” and “quality” revealed 340 citations.

The paper by Perez-Padilla et al<sup>9</sup> in this issue of RESPIRATORY CARE adds to the available experience and knowledge regarding spirometry quality control in large epidemiologic studies of individuals with COPD. Perez-Padilla et al report the quality-control methods and outcomes of the multicenter Latin American Chronic Obstructive Pulmonary Disease Prevalence Study (PLATINO),<sup>10</sup> in which 5,315 subjects in 5 Latin American cities (in 5 countries) underwent spirometry to determine the prevalence of COPD. The practical considerations of conducting in-home spirometry in PLATINO required use of a small, commercially available spirometer (EasyOne, NDD, Switzerland) rather than laboratory-based spirometers with highly sophisticated internal quality-control software and feedback capability, as have been used in other landmark studies (eg, the Lung Health Study<sup>6</sup>). In this regard, PLATINO teaches us about more “grass roots” spirometry quality control in the context of a large, multinational study. The study employed 3 levels of spirometry quality control. Stated as directives, these 3 quality control measures offer advice and options for investigators in epidemiologic studies:

1. Use the same type of spirometer, with internal quality-control software, at all sites.
2. Use centralized training of the pulmonary function technicians (in PLATINO, 73% of the technicians had no prior spirometry experience), and oversight of the testing and rating based on established criteria.
3. Provide feedback to all study sites from a quality-control center, which receives via e-mail the results of all tests and evaluates and sends feedback on calibration checks, intra-test reliability, and technician-specific performance. Technicians with outlier performance should be counseled and supervised more closely.

Overall, though it is difficult to directly compare it with the spirometry quality-control in other studies that used more sophisticated spirometry equipment and quality-control techniques (eg, Lung Health Study<sup>6</sup>), the quality of spirometry in PLATINO was reportedly high. For example, the authors report<sup>9</sup> that 89% of subjects achieved the American Thoracic Society/European Respiratory Society standard of 3 acceptable maneuvers and reproducibility of FEV<sub>1</sub> and FVC within 150 mL.<sup>1</sup> At the same time, trends in the data suggest inter-center differences in performance,

perhaps related to greater technician experience in certain of the 5 cities. This trend reminds us yet again of the value of technician experience and training in achieving the highest quality spirometry performance.<sup>11</sup> Also, the ability to compare the quality-control results of PLATINO to earlier spirometry quality-control studies is confounded by the investigators' choice of somewhat arbitrary and confusing cut points in presenting the data (eg, in their Table 3, the "percentage of subjects who satisfied the criteria achieved by 90% of technicians at the end of the study").

Notwithstanding these shortcomings, this report from PLATINO offers important reminders and lessons for investigators, respiratory therapists, and supervisors of pulmonary function laboratories:

1. Spirometry quality control continues to be important and requires attention to achieve credible results.

2. The seemingly daunting challenge of performing spirometry in 5 cities in 5 different countries can be met with respectable quality and, it would seem (although the budget was not presented in the PLATINO report), with achievable expense.

3. Technician experience and training, and a commitment to maintaining quality are key determinants of achieving high quality in studies of spirometry.

By heeding these lessons we will advance our ongoing efforts to "breathe quality" into pulmonary population research and into our work caring for individuals with lung disease.

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