Spirometry Quality-Control Strategies in a Multinational Study of the Prevalence of Chronic Obstructive Pulmonary Disease

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We report the characteristics of a centralized spirometry quality-control program developed for a population-based survey of the prevalence of chronic obstructive pulmonary disease in 5 cities: São Paulo, Brazil; México City, México; Montevideo, Uruguay; Santiago, Chile; and Caracas, Venezuela (the Latin American Project for the Investigation of Obstructive Lung Diseases [PLATINO]). METHODS: We developed and used a 3-level quality-control system. Level 1: The spirometer used in the survey (EasyOne), gives quality-control messages to the user/clinician. All the spirometry technicians were trained by the same team, with the aim of meeting what became the 2005 spirometry quality criteria of the American Thoracic Society/European Respiratory Society (ATS/ERS). Level 2: In each of the 5 cities a local supervisor identified poor-quality spirometries that needed to be repeated. Level 3: Once a week during the survey, all spirometry results were sent via e-mail to the study's quality-control center in México City for review and feedback. RESULTS: In the overall totals at the end of the study, 94% of the 5,315 subjects had spirometries that met the 1994 ATS quality criteria, and 89% met the 2005 ATS/ERS criteria. In their overall totals at the end of the study, 90% of the 64 spirometry technicians were successful in getting 86% of their subjects to meet the 1994 ATS criteria, and got 75% of their subjects to meet the 2005 ATS/ERS criteria. In the first 10 subjects they tested, 90% of the 64 spirometry technicians were successful in getting 70% of their subjects to meet the 1994 ATS criteria, and got 60% of their subjects to meet the 2005 ATS/ERS criteria. CONCLUSIONS: Standardization of equipment, training, and supervision of spirometry is essential in a multinational spirometry survey. Centralized quality control can be done via e-mail with good reliability and low cost. *Key words: chronic obstructive pulmonary disease, COPD, spirometry, quality control, pulmonary function tests, Latin America.* [Respir Care 2008;53(8): 1019–1026. © 2008 Daedalus Enterprises]

Introduction

The Latin American Project for the Investigation of Obstructive Lung Diseases (PLATINO) was launched in 2002, to measure the prevalence of chronic obstructive pulmonary disease (COPD) in 5 Latin American cities. Spirometry was the main diagnosis method.

A multinational study faces great challenges in quality control and quality assurance. For these types of trials a centralized quality-control system that uses sophisticated communications systems is usually implemented. Though spirometry results can be uploaded onto a Web page, this may be costly or unreliable in some countries, whereas regular mail is usually very slow, and courier services prohibitively expensive.

The American Thoracic Society (ATS) has issued recommendations on spirometry equipment, procedures, interpretation, and quality-control strategies,[1-4] but those documents offer no specific recommendations for large-scale multicenter surveys. Strict quality control was maintained in large-scale North American trials such as the third United States National Health and Nutrition Examination Survey (NHANES III),[5] which surveyed an open population, and the Lung Health Study,[6] which surveyed patients with COPD and who had experience with spirometry. Both those studies used expensive, large spirometers not suitable for a house-by-house survey. In this paper we describe the spirometry quality-control strategies we used in the PLATINO study.

Methods

Approval was obtained from the ethics committees of the institutions involved in the study. Written, informed consent was provided by all subjects. The sampling and testing methods of the PLATINO study have been described previously,[7] as has the prevalence of COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria,[8] spirometer performance,[9] and impact of bronchodilator use in the diagnosis of COPD.[10] Briefly, a multi-stage cluster sampling was used, with a similar design in all 5 cities. We selected 68 census tracts in each city that were representative of the metropolitan area, including suburbs, and aimed for a minimum sample of 800 non-institutionalized subjects per city, visited house-by-house.

In the survey we used the EasyOne hand-held spirometer (ndd Medical Technologies, Zürich, Switzerland), which measures gas flow on the principle of ultrasound-measured transit-time. In each city the spirometers were set to the same options except altitude, which was set to the city's mean altitude. We used the NHANES III reference values for European Americans,[5] which are included in the spirometer and which showed good agreement with our independently derived reference values.[11,12] Calibration was verified daily with a 3-L syringe (Hans Rudolph, Shawnee, Kansas) before field use.[9]

The subjects performed up to 15 forced expiratory maneuvers per session (the maximum accepted by the spirometer) to attempt to obtain grade A quality tests (3 acceptable maneuvers, according to ATS criteria, with the 2 best forced expiratory volume in the first second [FEV_1] and forced vital capacity [FVC] values within 150 mL, which was better than required by the 1994 ATS criteria (3 acceptable maneuvers and the 2 best FEV_1 and FVC within 200 mL)[1] that were current at the time of the study, and equivalent to the 2005 ATS/European Respiratory Society [ERS] guidelines.[2] The technician observed the flow-volume curve on the spirometer's screen after each maneuver and was able to reject it independently of the spirometer's assessment. The EasyOne spirometer has a smaller screen than is recommended by the ATS/ERS and lacks a volume-time curve for immediate check, but the shape of the flow-volume curve can be easily identified.

An inhaled bronchodilator (albuterol 200 μg) was then administered via a 500-mL spacer, and the spirometry was repeated 15 min later. All spirometries were carried out with the subject seated, using a nose clip and a disposable mouthpiece. The technician was allowed to conduct a repeat spirometry session on the same day or a different day, to try for better spirometry quality. Usually the quality level achieved by 90% of the tested population is selected as the standard.[13] We also obtained criteria for the quality level achieved by 90% of the technicians, and thus studied variability and differences in the technicians' performance. We analyzed their performance after their first 10 spirometries and their overall performance during the entire study.

Exclusion Criteria

We excluded subjects who reported having had thoracic or abdominal surgery, heart attack, eye surgery (or retinal detachment), hospitalization for heart problems, current treatment for tuberculosis, pregnancy in the last 3 months, or a pulse rate above 120 beats/min.

Spirometry Quality Control

We planned 3 levels of quality control. First, at all sites we used the same equipment and methods. The database included calibration checks and quality-control measures. All the spirometry technicians were trained and certified by the same team, at a 2-day basic spirometry training program, based on the National Institute for Occupational Safety and Health course. They then practiced in local pulmonary laboratories and during the pilot phase of field

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Table 1. Spirometry Grading and Scoring System

Grade	Criteria Met	Points
A	2005 ATS/ERS spirometry quality criteria:	5
	3 acceptable maneuvers	
	2 highest FEV_1 and FVC within 150 mL	
B	1994 ATS criteria	4
	3 acceptable maneuvers	
	2 highest FEV_1 and FVC within 200 mL	
C	2 or 3 acceptable maneuvers reproducible within 200–250 mL	3
D	2 or 3 acceptable maneuvers but no reproducibility within 250 mL	2
E	One acceptable maneuver	1
F	No acceptable maneuvers	0

ATS = American Thoracic Society
ERS = European Respiratory Society
FEV_1 = forced expiratory volume in the first second
FVC = forced vital capacity

Table 2. Characteristics of the Study Population[*]

Age (mean $\pm$ SD y)	56.6 ± 11.9
Education (mean $\pm$ SD y of school)	7.5 ± 4.8
Male (%)	40.8
Current smokers (%)	29.2
Current or past smokers (%)	56.6
Pack years of smoking in the whole population (mean $\pm$ SD)	4.9 ± 15.2

* 5,315 pre-bronchodilator spirometries in non-institutionalized subjects $\geq$ 40 y old.

testing. Each spirometry maneuver was evaluated by the technician, with the goal of obtaining grade A spirometries (ie, that met the 2005 ATS/ERS criteria).

The second level of spirometry quality control was the responsibility of local supervisors, who checked all the printed spirometry results and visually identified poorly-done spirometries (flow-volume curves that showed inadequate patient effort or artifacts), regardless of the quality grade assigned by the spirometer. All such spirometries had to be repeated. The same spirometry supervisor oversaw the spirometry in Montevideo, Santiago, and Caracas.

The third quality-control level was the quality-control center in México City, which received all the spirometry results weekly via e-mail, which we found to be an inexpensive and highly reliable method of communication. A few hours after each week's data were received, the quality-control center returned automated quality reports about the spirometry results to each study city and each technician. The automated quality report assessed several criteria of intra-test reproducibility, results of calibration checks, technician performance, and each center's overall score during the survey. The spirometry database included several quality indicators (back-extrapolated volume, forced expiratory time, peak expiratory flow time, end-of-test volume, and the change in volume during the last second of the forced expiratory maneuver), which we analyzed in addition to the quality-control messages and assessments produced automatically by the spirometer's software.

Each technician received a quality grade based on the number of spirometries that satisfied ATS criteria and the average quality of the spirometries, which were scored from 0 to 5 (Table 1).

The technician-performance reports presented the means of the quality scores from all the spirometries, in original units (ie, from 0 to 5) and as percentages of the spirometries that met the 1994 ATS criteria or the 2005 ATS/ERS criteria. The results were given to each spirometry technician each week, and those who performed below the rest (below the 10th percentile) were supervised more closely and encouraged to improve. Any doubts or issues were discussed with the quality-control center in México City, via e-mail.

The sampling strategy was taken into account during analysis, using the "survey" commands in the statistics software (Stata, StataCorp, College Station, Texas).[14] In addition, the variance in the spirometry measurements was separated into that explained by differences between the cities and that explained by differences between the technicians, using mixed or multilevel models.[15]

Results

Five-thousand three-hundred fifteen subjects completed the pre-bronchodilator spirometry, and 5,183 completed the post-bronhodilator spirometry (Table 2). Eighty-nine percent had not undergone previous spirometry. The results of the calibration checks have been reported.[9]

One-thousand two-hundred one (22.6%) subjects had more than one spirometry session; 895 of the repeat sessions were on the same day (usually immediately after the first, and using the same spirometer), and 306 of them were on different days (Table 3). On average, the quality improved considerably in the repeat spirometry, regardless of whether it was done on the same day or a different day. Among the spirometries repeated on different days, 277 of 306 were requested by the local supervisor.

Figure 1 shows that the quality of spirometries, center-by-center, during the entire survey was very stable and sustained, as assessed by the fraction that satisfied the 1994 ATS criteria. Quality was slightly better in Montevideo, Santiago and Caracas, where the same field supervisor oversaw the testing. The highest quality was in Montevideo, where all the technicians had previous spirometry experience. Overall, 89% of all the subjects in the study achieved grade A spirometry (ie, met the 2005 ATS/ERS criteria), and 94% satisfied the 1994 ATS criteria. Changes

Table 3. Quality of Spirometry in Repeated Test Sessions[*]

	Spirometry Repeated the Same Day ($n = 895$)		Spirometry Repeated on a Different Day ($n = 306$)	
	First Test (%)	Last Test (%)	First Test (%)	Last Test (%)
No acceptable[†] maneuvers in the pre-bronchodilator spirometry	14.7	4.1	11.8	6.2
No acceptable[†] maneuvers in the post-bronchodilator spirometry	3.4	1.6	11.8	6.2
Satisfied 2005 ATS/ERS quality criteria before bronchodilator	30.5	77.1	48.5	83.0
Satisfied 2005 ATS/ERS quality criteria after bronchodilator[‡]	40.9	85.7	65.5	93.1

[*] All improvements in quality were statistically significant.
[†] Met the 2005 American Thoracic Society/European Respiratory Society (ATS/ERS) spirometry quality criteria: 3 acceptable maneuvers, and the 2 highest forced expiratory volume in the first second and forced vital capacity values within 150 mL.
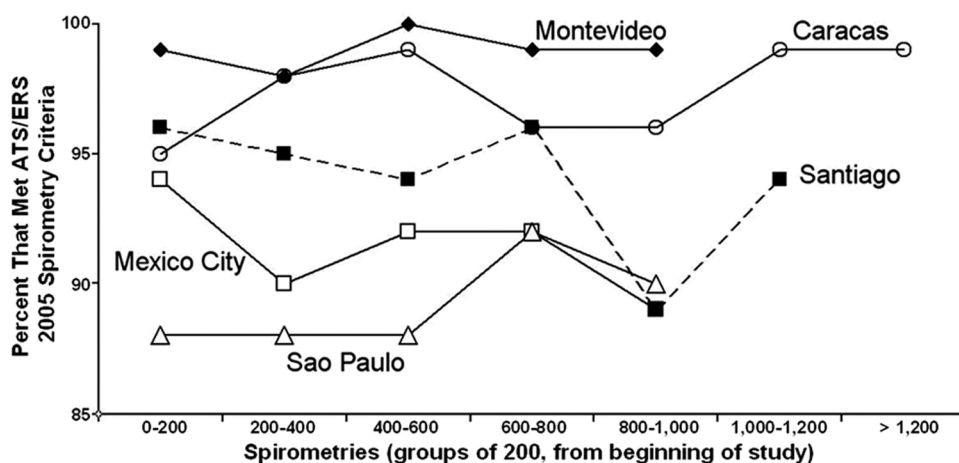[‡] 200 μg inhaled salbutamol

Fig. 1. Percentage of spirometries that met the American Thoracic Society/European Respiratory Society (ATS/ERS) 2005 spirometry performance criteria (3 acceptable maneuvers, and FEV_1 and FVC repeatable to within 150 mL) at the 5 centers in the Latin American Project for the Investigation of Obstructive Lung Diseases (PLATINO) The horizontal axis shows the sequential spirometries in groups of 200. Quality was maintained throughout the study, with small differences between the cities (see text), and very few subjects failed spirometry (ie, spirometry quality score zero).

in spirometry quality over the course of the study were statistically nonsignificant when evaluated in groups of 200 spirometries or when comparing the spirometries in the first half to those in second half of the study.

Thirty-eight subjects failed spirometry (no acceptable maneuvers). In a logistic regression model, the subjects who failed spirometry were associated with age > 70 years (odds ratio 3.0, 95% confidence interval 1.4–6.3), a higher GOLD stage (odds ratio 1.5, 95% confidence interval 1.2–2.0), female sex (odds ratio 2.7, 95% confidence interval 1.1–3.0), and zero education (odds ratio 3.8, 95% confidence interval 1.8–8.0), adjusted by city and order of spirometry.

We applied a multiple regression model to explore the relationship of spirometry quality and the magnitude of spirometry variables (FEV_1, FVC, and the ratio of FEV_1 to FVC). We adjusted the model for previous exposures (to-bacco, workplace dust, or biomass smoke), anthropometry, age, sex, self-reported diagnoses (asthma, COPD, chronic bronchitis, depression), pre-test events (recent respiratory infection, use of bronchodilator, or exercise), and scores on the health-related-quality-of-life questionnaire. In Figure 2, note that the magnitude of FEV_1 and FVC decreased significantly (with an increase in the FEV_1/FVC ratio) only in failed spirometries (ie, quality grade zero).

Sixty-four spirometry technicians participated in the study. Of those, 47 had no spirometry experience before the survey. The technicians tested a mean $\pm$ SD of 90 $\pm$ 53 subjects, with a mean $\pm$ SD of 6.0 $\pm$ 0.7 pre-bronchodilator maneuvers, and 5.6 $\pm$ 0.7 post-bronchodilator maneuvers. Table 4 summarizes the spirometry quality obtained by the participants in the study and by 90% of all technicians. If the 6 technicians with the lowest performance are excluded as outliers, then the 10th percentiles in
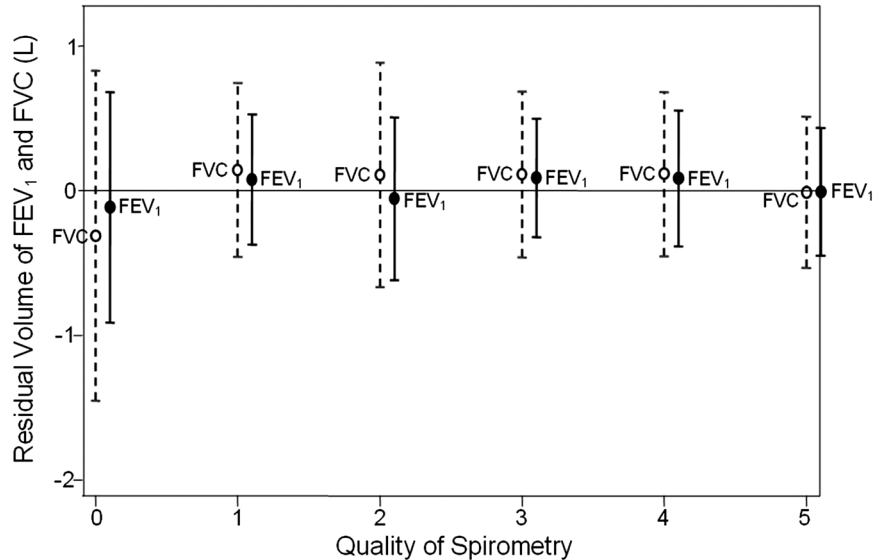
Fig. 2. Spirometry quality (0 = no acceptable maneuvers, 5= met 2005 American Thoracic Society/European Respiratory Society spirometry quality criteria [see Table 1]) versus mean residual forced expiratory volume in the first second (FEV_1) and forced vital capacity (FVC), after adjustment for other variables (see below). The bars indicate one standard deviation. Spirometries with quality 0 had a lower FVC and lower FEV_1 (the difference was marginally statistically significant) and a 6% higher ratio of FEV_1 to FVC (not shown) than the other 5 spirometry-quality categories. Adjustment was made for age, sex, height, body mass index, exposures (eg, tobacco, dust at work), self-reports of asthma or COPD, pre-spirometry events (recent respiratory infection, use of bronchodilator and strong exercise), and an indicator variable for each city. Adverse impact on overall spirometric function is then expected only for spirometries with quality grade 0 (ie, failed spirometries) with a rise of FEV_1/FVC that may interfere with the diagnosis of airflow obstruction.

Table 4. Quality of Spirometry Obtained With 90% of Subjects and by 90% of Technicians (90th Percentile) in the Pre-bronchodilator Tests

Quality Criteria	Subjects Who Satisfied the Criteria at the End of the Study % (95% CI)*	Subjects Who Satisfied the Criteria, Achieved by 90% of Technicians at the End of the Study % (95% CI)†	Subjects Whose Spirometry Complied With the Criteria Obtained by 90% of Technicians After the First 10 Subjects Tested (95% CI)‡
Tests with no acceptable maneuvers according to ATS criteria	0.7 (0.4–0.9)	1.7 (1.5–5.2)	0 (0–2.4)
Tests with 3 acceptable maneuvers according to ATS criteria	96.6 (96.2–97.1)	90.1 (88.5–91.9)	8 (7–9)
Tests with 3 acceptable maneuvers and with FVC and FEV_1 reproducible to within 200 mL§	94.2 (93.6–94.9)	86 (83–88)	7 (4–8)
Tests with 3 acceptable maneuvers and with FVC and FEV_1 reproducible to within 150 mL‖	88.7 (87.8–89.6)	75 (70–80)	6 (3–7)

* The first column cannot be used as standards after only a few subjects tested, nor for technicians, even at the end of study (in which case see the 2nd column).
† If at the end of the study, a technician had fewer tests that satisfied the criteria than shown, she/he was significantly below the 90th percentile of the group. The estimates include all 64 technicians.
‡ If after the first 10 subjects tested, a technician had fewer subjects with tests that satisfied the criteria than shown, she/he was significantly below the 90th percentile of the group and required special supervision.
§ Criteria of the 1994 American Thoracic Society (ATS) guidelines[1]
‖ Criteria of the 2005 American Thoracic Society/European Thoracic Society guidelines[2]
FVC = forced vital capacity
FEV_1 = forced expiratory volume in the first second

Table 4 increase slightly: the expected percentage of subjects that meet the 1994 ATS criteria rises from 86% to 88.2%, and those that meet the 2005 ATS/ERS criteria rises from 75% to 78.4%. There was no correlation between the number and quality of spirometries done by the technicians during the survey. Figure 3 shows the spirometry quality results for the individual technicians. Only 10% of the technicians scored below 75% of their subjects
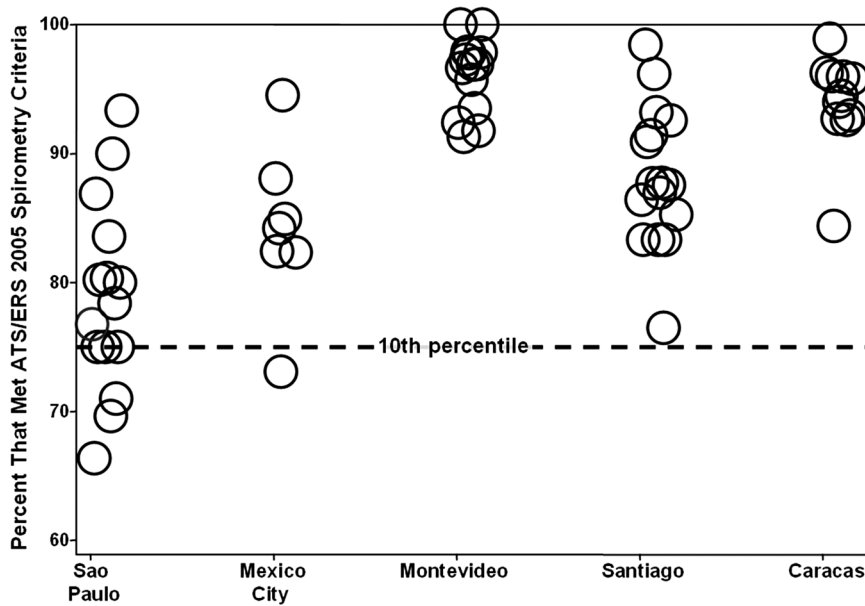
Fig. 3. Percent of spirometries that met the American Thoracic Society/European Respiratory Society (ATS/ERS) 2005 spirometry quality criteria (3 acceptable maneuvers, and FEV_1 and FVC repeatable to within 150 mL) among the 64 spirometry technicians at the 5 centers in the Latin American Project for the Investigation of Obstructive Lung Diseases (PLATINO). The overall 10th percentile was 75% at the end of the study; that is, a technician who had less than 75% of his or her subjects meet the 2005 ATS/ERS spirometry quality criteria was performing significantly below the average and required special supervision. The 10th percentile for meeting the 1994 ATS criteria was 86%. For obtaining 3 acceptable maneuvers the 10th percentile was 90%. However, the 10th percentile of the first 10 subjects a technician tested was lower; among the first 10 subjects tested, 90% of technicians had only 6 subjects meet the 2005 ATS/ERS criteria.

meeting the 2005 ATS/ERS criteria, or below 86% of the 1994 ATS criteria, or below 90% of 3 acceptable maneuvers. The post-bronchodilator spirometries had generally better quality and less variability than the pre-bronchodilator spirometries.

Discussion

Standardization of spirometry was acceptable in PLATINO, though the study was done in 5 geographically distant cities. E-mail communication with the quality-control center in México City was efficient and affordable for all 5 centers. The quality-control center provided quick (usually the same day) automatic reports that included comparisons of the centers' performance.

The overall spirometry quality was good, similar in several variables to that of the NHANES III study, if we analyze only the subjects ≥ 40 years old (as in PLATINO). For example, PLATINO had fewer spirometries with no acceptable maneuvers than did NHANES III (0.7% vs 1.3%) and more spirometries with 3 acceptable maneuvers (96.7% vs 95.9%). However, not all the results can be compared fairly. For example, the reproducibility criteria in NHANES III were based on the 1987 ATS criteria,[16] whereas PLATINO was based on the 1994 ATS criteria. The quality achieved in a study is linked to the quality aims, which determine the quality messages from the de-

vices. Thus it is of little help to compare studies with regard to certain aims that were not shared or supported by the different spirometer software. As an example, the quality criteria in the Lung Health Study were seldom obtained in PLATINO, not only because the criteria were stricter[6] and designed for people with COPD and who were experienced in spirometry, but also because the spirometer software used in PLATINO did not have the encouragement messages required to satisfy the Lung Health Study criteria.

Although stability of spirometry quality was achieved over time, mild but statistically significant differences persisted among the different cities. As equipment performance was very similar at all sites,[9] these differences might be explained by inter-technician differences, intra-technician variations, or the interaction between the two. In our study, the Montevideo technicians had the highest quality spirometry, and they were the most experienced technicians. Though it is impossible for quality and lung function to be identical when several centers and technicians are involved, the "noise" due to differences between technicians and centers should be small relative to the differences in lung function caused by exposures, sex, age, altitude and ethnic factors (the "signal"). In our study, once the traditional determinants of lung function were taken into account in a multiple regression model, adding indicator variables for each city, technician and pre-test events

(recent smoking, use of bronchodilator, exercise, or infection) only marginally increased the explained variation: FEV_1 1.9%, FVC 2.3%, and FEV_1/FVC 5%. However, adjusting by cities, technicians, and pre-test events may be important if the strength of the effects we are interested in are mild or variable, and to reduce the misclassification of subjects with borderline lung function.

One common problem in surveys is defining to what degree one particular technician's deviation from the others is considered important. In our study, 94% of the subjects satisfied the 1994 ATS criteria, and 89% satisfied the 2005 ATS/ERS criteria. However, those are composite figures from all 5 centers and all 64 technicians at the end of the study. Not all centers and technicians, especially at the beginning of the survey, attained those quality percentages. Overall, at the end of our survey, 90% of the technicians had gotten 86% of their subjects to meet the 1994 ATS criteria, and 75% had gotten their subjects to meet the 2005 ATS/ERS criteria. However, in their first 10 subjects, 90% of the technicians got only 7 subjects to meet the 1994 ATS criteria, and got only 6 subjects to meet the 2005 ATS/ERS criteria (see Table 4). After testing his or her first 10 subjects (at the beginning of the study), if a technician got less than 6 subjects to meet the 2005 ATS/ERS criteria, the technician had deviated statistically from the 10th percentile, and special supervision and encouragement were indicated (see Fig. 3).

Subjects who failed spirometry tended to be older, to have COPD, and to have no education. In addition, subjects who complained of depression and ill health were less likely to have good-quality spirometry. Therefore, if only spirometries with good quality are selected for analysis, a bias toward healthier and younger people is imposed, as has been found previously.[17-20] Spirometry is an independent indicator of poor health and reduced survival.[17,20,21] In addition, for some purposes, even poorly-done spirometries can be sufficient to rule out, for example, substantial airflow obstruction, if the test reveals normal values.[22] Additionally, although in our study the grade 0 spirometries (ie, failed spirometries [$n = 38$]) had higher FEV_1/FVC and lower FVC ($P = .09$), but similar FEV_1, compared to higher-quality spirometries (see Fig. 2), we observed no change in the spirometry values in spirometries $\geq$ grade 1. The highest-quality tests in a study are important to properly identify subjects with mild or borderline alterations. If the number of poor tests is very low, adding or discarding them affects the study results very little.

Conclusions

A centralized quality-control center that regularly receives results via e-mail can supervise spirometry quality at geographically distant centers. Other important quality-control components include using the same instruments, having the technicians trained by the same team, and having the tests reviewed by technicians and supervisors on site.

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