Quality of Spirometry Performed by 13,599 Participants in the World Trade Center Worker and Volunteer Medical Screening Program

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OBJECTIVE: To determine the ability of spirometry technicians in the World Trade Center Worker and Volunteer Medical Screening Program to meet American Thoracic Society spirometry quality goals. METHODS: Spirometry technicians were trained centrally and performed spirometry sessions at 6 sites in the greater New York City area. We reviewed and graded the spirometry results for quality every month. RESULTS: About 80% (range 70–88%) of the spirometry sessions met the American Thoracic Society spirometry goals. In general, the spirometry technicians with the most experience were more successful in meeting the quality goals. Participant characteristics explained very little of the quality variability. CONCLUSIONS: The overall spirometry quality in this multicenter program was very good. Efforts to improve spirometry quality should focus on the performance of individual spirometry technicians. *Key words: spirometry; quality control; World Trade Center.* [Respir Care 2010;55(3):303–309. © 2010 Daedalus Enterprises]

Introduction

Due to concerns about possible health effects from exposures sustained by persons involved in the rescue and recovery response to the World Trade Center attack of September 11, 2001, the United States Congress authorized funding, through the Centers for Disease Control National Institute of Occupational Safety and Health, for a program to evaluate for health effects. Respiratory disease was considered an important possible health effect, because there was reportedly a high prevalence of chronic cough, so spirometry became part of the standardized examination. Firefighters from the Fire Department of New York were examined at the Fire Department of New York, separately from other workers and volunteers, but with a very similar examination protocol.

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In pulmonary health screening and surveillance programs it is important to minimize misclassification of pulmonary function tests, so a strict spirometry quality assurance program was established. This paper reports on the accuracy of the spirometry program and the correlates of good quality spirometry.

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This study was supported by the Centers for Disease Control, National Institute for Occupational Safety and Health, under contract 200-2002-0038 and grant 5U1O 0H008232.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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Table 1. Quality-Control Messages From the EasyOne Handheld Spirometer

Condition	Message Displayed by Spirometer
Back-extrapolated volume was high	"Don't hesitate"
Time to peak expiratory flow was > 120 ms	"Blast out faster"
End-of-test volume was high or forced expiratory time was less than 5 s for an adult	"Blow out longer"
Grade of A or B after 3 or 4 maneuvers, or C or better after > 4 maneuvers	"Session complete. Good job"

Table 2. Spirometry Grades

Grade	Acceptable Forced Expiratory Maneuvers (*n*)	And/Or Other Required Conditions
A	≥ 3	And best 2 FEV_1 and FVC matched within 150 mL
B	≥ 3	And best 2 FEV_1 and FVC matched within 200 mL
C	≥ 2	And best 2 FEV_1 and FVC matched within 250 mL
D	1	Or best 2 FEV_1 or FVC did not match within 250 mL
F	Zero	None

Methods

Before the program started, the spirometry technicians were trained by 2 pulmonary physicians (GSS and PLE) who have considerable experience in spirometry. The quality of all the spirometry sessions was reviewed each month by GSS, and quality reports were returned to the technicians and program physicians at each participating site, as in the Lung Health Study.[1]

The program purchased new spirometers for each site. The spirometer model (EasyOne Diagnostic, ndd Medizintechnik, Zurich, Switzerland) was chosen carefully to retain accuracy for prolonged periods of time,[2] to minimize the risk of cross-contamination during the expiratory and inspiratory forced vital capacity (FVC) maneuvers, to provide automated quality-control messages (Table 1), and to store the results for transfer to a personal computer database. Spirometer calibrations were done with a 3.00-L calibration syringe and special gray adapter, at a single speed every day of testing, and once a month at 3 speeds (to check linearity), per the American Thoracic Society (ATS) guidelines.[3]

The spirometry technicians were instructed to coach the participants to vigorously perform up to 8 FVC maneuvers, with the goal of obtaining a quality grade of A or B (meeting or exceeding ATS criteria for 3 acceptable and 2 repeatable maneuvers) (Table 2). The inspiratory FVC maneuver was performed immediately following the expiratory FVC maneuver, to obtain a flow-volume loop. The spirometer stored the best 3 FVC maneuvers.

To assess the overall quality of spirometry performance by the subjects and the technicians, we calculated descriptive statistics for the maneuver acceptability variables (back-extrapolated volume, time to peak flow (PEF), end-of-test volume, and forced expiratory time) for the single best maneuver from each spirometry session. We also calculated the differences between each subject's best and second-best FVC, forced expiratory volume in the first second (FEV_1), FEV in the first 6 seconds (FEV_6), and PEF values. We refer to those differences as the reproducibility variables (eg, ΔFVC is the difference between a subject's best and second-best FVC). Because many spirometry sessions are done without post-bronchodilator testing (and to simplify this report), in this paper we report only the results from pre-bronchodilator spirometry sessions. The overall quality of the post-bronchodilator spirometry sessions was slightly better than the pre-bronchodilator sessions.

To identify significant influences on spirometry performance, we performed multiple regression analyses on each performance-quality variable. The initial regressions included age, height, sex, and obesity (defined as a body mass index > 30 kg/m^2). Pulmonary obstruction was defined as an FEV_1/FVC below the 5th percentile *and* FEV_1 below the 5th percentile, using the National Health and Nutrition Examination Survey III reference equations.[4] Pulmonary restriction was defined as FVC below the 5th percentile, and a normal FEV_1/FVC.

Results

From July 16, 2002, through August 6, 2004, a total of 13,599 participants performed spirometry at one of 6 sites in the greater New York City area. The majority of the participants were men (86%), and their self-described ethnic groups were white 63%, Hispanic 23%, African-American 11%, Asian 1%, and other 2%. Asthma was reported by 9%, and possible asthma by 2%. Table 3 describes the participants.

Sixteen of the spirometry technicians performed > 100 spirometry sessions. Each spirometry session included both pre-bronchodilator and post-bronchodilator spirometry, but we report only the pre-bronchodilator results here. The overall success rate in meeting the ATS spirometry quality goals (quality grade A or B) was about 80% (range 70–88%) (Table 4). One technician who worked full-time at the site where over 80% of the participants went for the examinations performed over 4,000 spirometry sessions.

Table 3. Characteristics of the 13,599 Spirometry* Subjects

	Women		Men	
	(mean)	(5th–95th percentile)	(mean)	(5th–95th percentile)
Age (y)	41.4	27.0–57.0	42.1	29–58
Height (cm)	161	150–175	176	162–188
Weight (kg)	72	52–104	92	68–123
BMI (kg/m^2)	27.7	20.5–38.0	29.7	23.1–38.5
FEV_1 (L)	2.62	1.80–3.45	3.60	2.48–4.72
FVC (L)	3.25	2.31–4.26	4.54	3.21–5.91
FEV_1/FVC (%)	81	70–90	79	67–88
FVC (% predicted)	93	70–117	91	70–112
FEV_1/FVC (% predicted)	98	84–108	99	85–110

* Pre-bronchodilator spirometry

Table 4. Technicians' Spirometry Success

Spirometry Technician*	Spirometry Sessions (*n*)	Success (%)†	Time Period
A	4,121	82	8/2002 to 10/2004
B	1,960	87	1/2004 to 11/2006
C	1,633	75	8/2002 to 5/2003
D	1,201	76	11/2002 to 1/2005
E	846	88	9/2004 to 9/2006
F	751	74	3/2003 to 2/2007
G	494	73	9/2002 to 10/2004
H	373	74	10/2001 to 12/2006
I	323	84	5/2003 to 12/2006
J	310	85	4/2003 to 12/2006
K	204	86	12/2006 to 04/2007
L	166	80	9/2002 to 1/2003
M	150	75	12/2002 to 9/2006
N	132	76	3/2003 to 7/2004
O	127	82	9/2005 to 8/2006
P	104	75	3/2003 to 2/2005
Q	704	71	7/2002 to 3/2007

* The results from the 16 spirometry technicians who performed > 100 tests are listed in order of the number of tests they performed. The technicians who performed < 100 tests are grouped together under Q.
† Spirometry quality grade A or B.

Overall, about 80% of the spirometry sessions had a quality grade of A or B (Fig. 1). Overall, 82% of the best spirometry maneuvers had an acceptably rapid start of test, as indicated by a back-extrapolated volume < 150 mL. Table 5 shows the percentile distributions for each performance variable. An end-of-test volume of < 50 mL was seen in 90% of the best maneuvers. The 5th, 10th, 25th, and 50th percentiles for the forced expiratory time from the best maneuvers were 3.4, 4.0, 5.1, and 6.4 seconds, respectively.

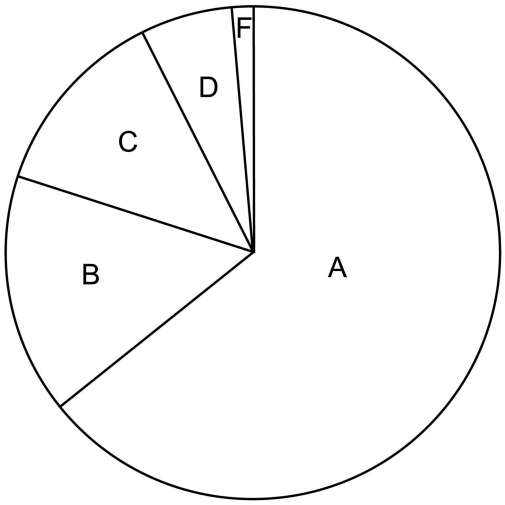

Fig. 1. Distribution of all the spirometry quality grades. (See Table 2 for grade system.)

Table 5. Percentile Distributions of Spirometry Performance Variables in 13,599 Spirometry Sessions*

	Percentile			
	50th	75th	90th	95th
Back-extrapolated volume (%FVC)	2.5	3.2	3.9	4.3
Back-extrapolated volume (mL)	108	138	169	189
Time to PEF (ms)	80	90	110	120
End-of-test volume (mL)	23	35	50	65
Forced expiratory time (s)	6.4	7.5	8.9	10.3
ΔFVC (%)	1.9	3.3	4.9	6.1
ΔFVC (mL)	81	143	201	258
ΔFEV_6 (%)	1.8	3.2	4.8	6.4
ΔFEV_6 (mL)	76	136	199	263
ΔFEV_1 (%)	2.0	3.6	5.6	7.6
ΔFEV_1 (mL)	68	124	186	241
ΔPEF (%)	4.3	8.2	13.4	18.0
ΔPEF (L/s)	0.39	0.75	1.23	1.68
ΔFEV_1/FVC (%)	1.7	3.3	5.7	7.8
$\Delta FEV_1/FEV_6$ (%)	1.5	2.9	5.0	6.9

* The back-extrapolated volume, time to peak expiratory flow (PEF), end-of-test volume, and forced expiratory time are from the best single maneuver (an acceptable maneuver with the largest sum of forced vital capacity [FVC] and forced expiratory volume in the first second [FEV_1]). The differences (Δ) in PEF, FEV_1, FEV in the first 6 s (FEV_6), and FVC are the highest minus the second highest value from the best 3 maneuvers. Lower values indicate better quality for all the variables. The absolute differences for FEV_1/FVC and FEV_1/FEV_6 are from the best maneuver (an acceptable maneuver with the highest sum of FEV_1 plus FVC) and the second-best maneuver in that spirometry session. The FEV_1/FVC from the second-best maneuver could be higher or lower.

The repeatability (ie, highest minus second highest value within a spirometry session) of key variables was also very good (see Table 5). In 83% of the spirometry sessions the highest and second highest FEV_1 values matched within 150 mL, and 77% of the highest and second highest FVC values matched within 150 mL. The FEV_6 values matched

slightly more closely than the FVC values. The PEF values matched within 1.0 L/s in 85% of the sessions. The repeatability of the FEV_1/FVC was better than 5.7% in 90% of the sessions. The repeatability of the FEV_1/FEV_6 was slightly better: 5.0% in 90% of the spirometry sessions.

The overall success rates in meeting each quality goal differed among the individual technicians (Figs. 2–5). Table 6 shows the correlates of the 4 performance variables from the single best maneuver, as determined by linear regression models. Indicator variables for at least one of the 16 technicians were statistically significant in each of the models, indicating that their performance was significantly better or worse than the average. Table 7 shows the correlates of FEV_1, FVC, and PEF repeatability.

Because the number of spirometry sessions was very large, and multiple comparisons were done, only predictors with P values of $< .001$ are shown in Tables 6 and 7. Despite identifying highly significant relationships, only a small fraction of the overall variability in spirometry quality was explained by each model (as shown by r^2 values of 3–18%).

Discussion

The overall spirometry quality of the participants in this program compared favorably with previously published results.[5,6] The thresholds specified in the ATS/European Respiratory Society 2005 standards[3] were set near the 90th percentile, so that about 10% of patients (both children and adults) failed to meet each criterion when tested by an experienced technician using a diagnostic quality spirometer.[5] The overall success rates for each technician in this project ranged from $< 70\%$, in those who performed fewer than 100 spirometry sessions, to 88%, by a technician who performed > 800 spirometry sessions over 24 months. Thus, we found a 90% success rate achievable in adults, and we recommend remedial attention to technicians whose mean success rate falls below 8 of every 10 subjects tested.

The spirometry maneuver may be divided into 3 steps (or phases), each of which requires a different type of effort: (1) "take a deep breath" (maximal inhalation),

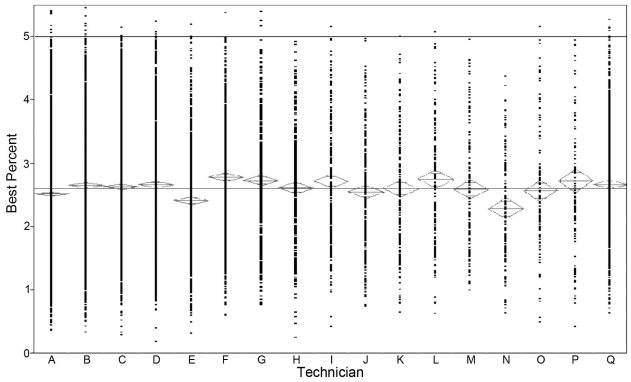

Fig. 2. Each black dot represents an individual back-extrapolated-volume percent value from a subject's single best forced-vital-capacity (FVC) maneuver. The overall mean back-extrapolated volume percent for the project was 2.6% (the thin gray horizontal line). Each trapezoid indicates the 25th percentile (bottom point of the trapezoid), the 75th percentile (top point of the trapezoid), and the mean (horizontal line that bifurcates the trapezoid) of that spirometry technician's back-extrapolated-volume percent values. A back-extrapolated volume percent value above the 5% American Thoracic Society threshold indicates a slow start (phase 2 of the FVC maneuver), which makes the maneuver unacceptable. A few outliers above 5.5% are not shown on the graph. See Table 4 for the total spirometry sessions done by each technician.

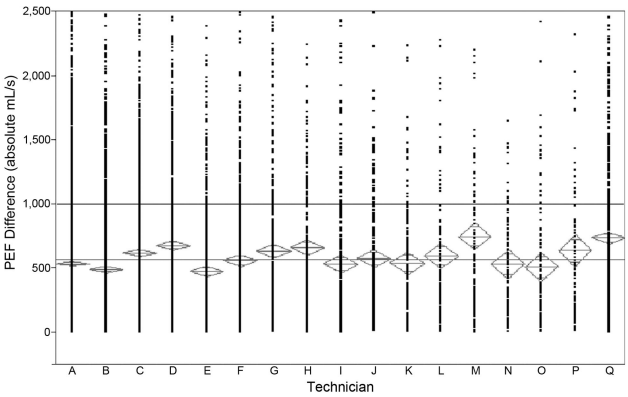

Fig. 3. The distribution of the differences in peak expiratory flow (PEF) for the 16 spirometry technicians who performed > 100 spirometry sessions. Technicians who performed < 100 spirometry sessions are grouped under Q. The overall mean PEF difference for the project is indicated by the thin gray horizontal line. Each trapezoid indicates the 25th percentile (bottom point of the trapezoid), the 75th percentile (top point of the trapezoid), and the mean (horizontal line that bifurcates the trapezoid) PEF difference for that technician.

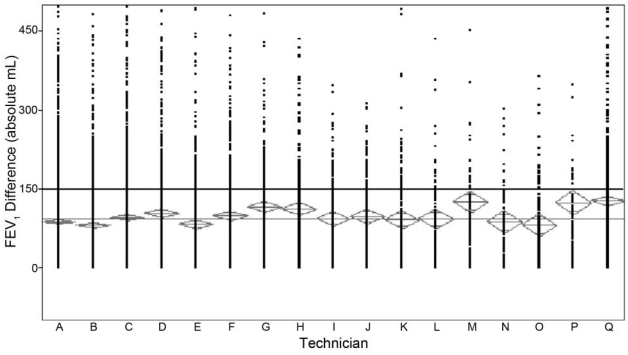

Fig. 4. The distribution of repeatability of forced expiratory volume in the first second (FEV_1) for the 16 spirometry technicians who performed > 100 spirometry sessions. Technicians who performed < 100 spirometry sessions are grouped under Q. The overall mean FEV_1 difference for the project is indicated by the thin gray horizontal line. Each trapezoid indicates the 25th percentile (bottom point of the trapezoid), the 75th percentile (top point of the trapezoid), and the mean (horizontal line that bifurcates the trapezoid) FEV_1 difference for that technician. The American Thoracic Society goal is 150 mL.

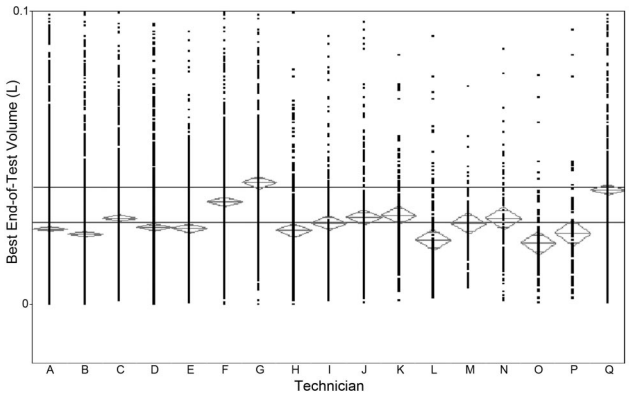

Fig. 5. Distribution of end-of-test volume (volume during the final second of the forced-vital-capacity maneuver) for the 16 spirometry technicians who performed > 100 spirometry sessions. Technicians who performed < 100 spirometry sessions are grouped under Q. Each trapezoid indicates the 25th percentile (bottom point of the trapezoid), the 75th percentile (top point of the trapezoid), and the mean (horizontal line that bifurcates the trapezoid) end-of-test volume for that technician. The overall mean end-of-test volume was 28 mL (lower horizontal line). An end-of-test volume > 40 mL (upper horizontal line) indicates incomplete exhalation (the volume-time graph did not end in a flat plateau). Note that the mean value for technician G was above the 40 mL threshold, and the mean value for the technicians who performed < 100 spirometry sessions (Q) was near the threshold, indicating that about half of the time they did not coach the patients to exhale completely.

(2) "blast out your air" (maximal exhalation effort), and (3) "keep blowing until all your air is gone" (prolonged exhalation). Poor effort can occur during any or all of these steps, and is usually due to suboptimal interaction between the technician and the subject. A submaximal inhalation falsely reduces all of the results except for the ratios. A submaximal blast during the second phase falsely reduces the PEF, variably affects the FEV_1, and may increase the FVC. A premature termination of the exhalation falsely reduces the FVC (and the FEV_6, if the expiration ends before 6 seconds), and is detected by a high end-of-test volume.

Objective quality checks are designed to detect all of the above faults and to identify poorly performed maneuvers or spirometry sessions that could result in false positive or false negative diagnoses, or increased measurement noise/bias in epidemiologic and intervention studies. Poor inhalation effort is common but is not evident by examination of any single spirometry record (unless the inspiratory FVC, which follows the expiratory FVC, is measured and found to be larger than the FVC). Thus, poor inhalation effort can be detected in the spirometry results only by poorly reproducible FVC and FEV_1 across multiple maneuvers. Submaximal blast and premature termination can, however, be identified objectively from the recording of any single blow.

The second phase of the spirometry maneuver is to blast out the air as quickly as possible, thereby achieving a "sharp" (high) peak flow during the first tenth of a second and a high average flow during the first second of the maneuver (the FEV_1). A hesitating start creates a high back-extrapolated volume and the FEV_1 may then be underestimated or overestimated, so the ATS guidelines consider unacceptable a maneuver with a high back-extrapolated volume. A long time to reach peak flow (time to PEF) indicates a relatively slow start (ie, submaximal effort to blast out the air). It is important to use both the back-extrapolated volume and time to PEF criteria, because a patient may have a short time to PEF and high PEF following a hesitating start (large back-extrapolated volume), or, on the other hand, an acceptably low back-extrapolated volume followed by a sigh (a large time to PEF, low PEF, and falsely low FEV_1).

The ATS goal for a rapid start-of-test (back-extrapolated volume < 5% of FVC) was met in the single best maneuver in > 95% of the spirometry sessions in this project, and was no more difficult to meet when applied to 6-second maneuvers (using back-extrapolated volume < 5% of FEV_6). See Figure 2 for the distribution of back-extrapolated volume percent among the 16 technicians who conducted > 100 spirometry sessions. The goal of a back-extrapolated volume < 150 mL was somewhat more difficult to meet with a 90th percentile of about 170 mL. The goal of a time to PEF < 120 ms (which indicates a rapid exhalation effort) was met in 95% of the best maneuvers. The EasyOne software version used in this project had a low-pass filter designed to remove high-frequency flow "noise" above 10 Hz. This filter reduced the time to PEF and PEF itself somewhat for very sharp blast efforts.

The end-of-test acceptability criteria detect maneuvers that "quit too soon" and thus underestimate the true FVC. The ATS 2005 guidelines goal is a forced expiratory time of > 6 seconds for adults, and an "obvious plateau" in the volume-time curve, defined as < 40 mL volume change during the final second of the maneuver (the end-of-test volume). About 90% of the best spirometry maneuvers achieved an end-of-test volume of < 50 mL. See Figure 5 for the distribution of end-of-test volume among the 16 technicians who conducted > 100 sessions. Attaining a low end-of-test volume is easier when blowing into a volume-sensing spirometer because the exhaled air is cooling and compressing in volume throughout the FVC maneuver.

Good repeatability of the FEV_1 is a worthwhile goal in longitudinal studies because a low ΔFEV_1 is associated with better visit-to-visit reproducibility,[1] so that exposures that change the rate of FEV_1 decline are detected with more confidence. The FEV_1 was repeatable within 5.6% and within 186 mL in 90% of the spirometry sessions, although the current ATS goal is 150 mL.[3] See Figure 4 for the distribution of ΔFEV_1 values among the 16 tech-

Table 6. Correlates of American Thoracic Society Spirometry Maneuver Acceptability Criteria, Applied to the Single Best Maneuver. Reported are the coefficients for each predictor in the multiple regression analysis and the overall coefficient of variation (r^2)

Predictor	Back-Extrapolated Volume (%)	Time to PEF (ms)	End-of-Test Volume (mL)	Forced Expiratory Time (s)
Age (10 y increments)	0.07	0	1.2	0.3
Height (cm)	–0.01	0	0.2	0.01
Obesity	–0.05	0	0	0
Female	0	–2	0	–0.2
Caucasian	0.8	0	0	0
Ever smoker	0	0	–0.9	0
Obstruction	0.3	4	–3	–0.7
Restriction	–0.1	0	1	0.3
Bronchodilator response	0.2	2	–2	0
Spirometry technicians A–J	A –0.1	A –3	A –3	C –1.0
	E –0.2		F 8	F –1.1
	F 0.1		G 14	G –2.0
Spirometry technicians K–Q		P 12	L –8	L 0.8
				M 0.9
		Q 3	Q 11	Q –0.6
r^2	8%	3%	5%	17%

PEF = peak expiratory flow

Table 7. Correlates of FVC, FEV_1, and PEF Repeatability. Reported are the coefficients for each predictor in the multiple regression analysis and the overall coefficient of variation (r^2)

Predictor	ΔFVC	ΔFEV_1	ΔPEF
Age (10 y increments)	6	0.4	0
Height (cm)	0.6	0	0
Female	0	0	60
Caucasian	0	0	–16
Obstruction	0	0	82
Spirometry technicians A–J	A –9	A –12	A –72
	B –21	B –18	E –92
Spirometry technicians K–Q	G +17	Q +27	Q +140
	M +73		
	Q +24		
r^2	2%	12%	2%

Δ = highest value minus lowest value
FVC = forced vital capacity
FEV_1 = forced expiratory volume in the first second
PEF = peak expiratory flow

nicians who conducted > 100 spirometry sessions. Note that technician G and the technicians who conducted < 100 spirometry sessions (grouped as Q) had higher end-of-test volumes.

The 1.0 L/s PEF repeatability goal was considered optional in the ATS guidelines.[3] Ninety percent of the participants in our project matched PEF within 1.2 L/s (and 13.4%). See Figure 3 for the distribution of ΔPEF among the 16 technicians. Note that technician M and the technicians who conducted < 100 spirometry sessions (Q) were less likely to match PEFs closely. In a recent study, ΔPEF was not associated with changes in ΔFEV_1,[7] which casts doubt on the usefulness of ΔPEF as an index of spirometry quality in settings where overall spirometry quality is relatively good.

The short-term repeatability of the FEV_1/FVC (or FEV_1/FEV_6) should be considered when screening for airway obstruction (eg, when screening smokers for COPD), but the repeatability of these ratios has not previously been reported. We found that the FEV_1/FVC varied up to 5.7% in 90% of the spirometry sessions, and there was less variability (5.0%) in the FEV_1/FEV_6. This "noise of measurement" of the FEV_1/FVC should be taken into consideration when interpreting the ratio as an indicator of airway obstruction. Results within 5% of the lower limit of the normal range for these ratios should be considered as "borderline" obstruction, because of reduced confidence that they are abnormal when compared to a ratio that is substantially below the lower limit of normal.

Conclusions

We found that ≥ 80% of our participants were successfully coached to perform pre-bronchodilator forced expiratory spirometry maneuvers that met the acceptability criteria for back-extrapolated volume, end-of-test volume, and forced expiratory time, and within-session reproducibility for FEV_1 and FVC. Factors related to the subject's

age, size, and sex can influence acceptability and repeatability, but their overall effect is small if the technician is well trained and experienced.

ACKNOWLEDGMENTS

We thank Jon Mercado, Mount Sinai School of Medicine, New York, New York, for providing the EasyWare files, and Nicole Edwards, Division of Respiratory Disease Studies, National Institute of Occupational Safety and Health, Morgantown, West Virginia, for performing descriptive statistics.

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