

# Office Spirometry in Primary Care Pediatrics: A Pilot Study

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**ABSTRACT.** *Objective.* The aim of this study was to investigate the validity of office spirometry in primary care pediatric practices.

*Methods.* Ten primary care pediatricians undertook a spirometry training program that was led by 2 pediatric pulmonologists from the Pediatric Department of the University of Padova. After the pediatricians' training, children with asthma or persistent cough underwent a spirometric test in the pediatrician's office and at a pulmonary function (PF) laboratory, in the same day in random order. Both spirometric tests were performed with a portable turbine flow sensor spirometer. We assessed the quality of the spirometric tests and compared a range of PF parameters obtained in the pediatricians' offices and in the PF laboratory according to the Bland and Altman method.

*Results.* A total of 109 children (mean age: 10.4 years; range: 6–15) were included in the study. Eighty-five (78%) of the spirometric tests that were performed in the pediatricians' offices met all of the acceptability and reproducibility criteria. The 24 unacceptable test results were attributable largely to a slow start and failure to satisfy end-of-test criteria. Only the 85 acceptable spirometric tests were considered for analysis. The agreement between the spirometric tests that were performed in the pediatrician's office and in the PF laboratory was good for the key parameters (forced vital capacity, forced expiratory volume in 1 second, and forced expiratory flow between 25% and 75%). The repeatability coefficient was 0.26 L for forced expiratory volume in 1 second (83 of 85 values fall within this range), 0.30 L for forced vital capacity (81 values fall within this range), and 0.58 L/s for forced expiratory flow between 25% and 75% (82 values fall within this range). In 79% of cases, the primary care pediatricians interpreted the spirometric tests correctly.

*Conclusions.* It seems justifiable to perform spirometry in pediatric primary care, but an integrated approach involving both the primary care pediatrician and certified pediatric respiratory medicine centers is recommended because effective training and quality assurance are vital prerequisites for successful spirometry. *Pediatrics* 2005;116:e792–e797. URL: [www.pediatrics.org/cgi/doi/10.1542/peds.2005-0487](http://www.pediatrics.org/cgi/doi/10.1542/peds.2005-0487); *office spirometry, primary care pediatrics, asthma, children.*

ABBREVIATIONS. PF, pulmonary function; FEV<sub>1</sub>, forced expiratory volume in 1 second; ATS, American Thoracic Society; FVC, forced vital capacity; FET, forced expiratory time; FEF<sub>25–75</sub>, forced expiratory flow between 25% and 75% of expired FVC; ICC, intraclass correlation coefficient; GP, general practitioner.

Pulmonary function (PF) tests are useful in both the diagnosis and the monitoring of lung disease. The international guidelines for asthma management have endorsed the use of objective lung function measures for assigning a severity rating to patients with asthma and guide asthma therapy.<sup>1</sup> Although children's and their parents' reporting of asthma symptoms is important in staging and managing pediatric asthma, many children and parents do not perceive asthma symptoms adequately, and children with long-standing airway obstruction are less likely to report dyspnea than children with acute-onset airway obstruction.<sup>2–4</sup> In addition, physical findings seem to be inadequate for assessing obstruction that may be present despite a normal physical examination.<sup>5</sup>

Despite a large body of evidence showing that airway obstruction in children with asthma is associated with ongoing respiratory morbidity<sup>6,7</sup> and a reduced forced expiratory volume in 1 second (FEV<sub>1</sub>) in adulthood,<sup>8–10</sup> spirometry is not routinely performed by physicians who treat children with asthma as an objective measure of airway obstruction. According to the Asthma Insights and Reality Europe Study (a survey that assesses the current level of asthma control in Western Europe), a large proportion of children with asthma are treated without lung function measurements, and physicians base their treatment decisions on symptom reports and auscultation.<sup>11</sup>

Ideally, spirometry should be available on-site in primary care practices. However, despite the increasing use of spirometric tests in primary health care, little is known about their validity.<sup>12–17</sup> Spirometry is often regarded as a simple, noninvasive screening test, but careful consideration clearly needs to be given to a number of aspects, including optimal test performance, adherence to standard acceptability and repeatability criteria, and accurate, well-informed interpretation of the results.

Portable, lightweight spirometry instruments that can be wired into a computer are now available, making spirometry technically feasible at the primary care level. Advantages of the newly proposed category of office spirometers include lower instru-

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ment cost, small size, and an improved quality-assurance program.<sup>16,18</sup>

No previous studies have formally assessed spirometry performance in primary care pediatric practice. We aimed to determine the quality of the spirometric tests that are performed in primary care pediatric practice after formal training for the pediatrician was provided. For this purpose, spirometric tests that were performed by primary care pediatricians were assessed for acceptability and reproducibility, and the resulting spirometric data were compared with those obtained at a PF laboratory using the same portable spirometer. The primary care pediatrician's interpretation of the spirometric data were also assessed. Finally, to validate the portable spirometer, the data that it produced in the laboratory were compared with those that were obtained with a gold-standard laboratory-based volume spirometer.

## METHODS

The study was a repeated, cross-sectional, within-subject comparison of spirometric tests in a PF laboratory and in primary care pediatricians' offices. The study involved 10 primary care pediatricians from northeast Italy and 2 pediatric pulmonologists at the Pediatric Allergy and Pulmonology Unit of the University of Padova, which is a certified European Respiratory Society center<sup>19</sup> for pediatric respiratory medicine training.

Children who had a diagnosis of asthma<sup>1</sup> or cough persisting for >15 days and were aged 6 to 15 years were selected for the study (Table 1). They were recruited during routine visits to the pediatricians' offices. All parents gave their written informed consent.

### Training

A spirometry training program that consisted of two 5-hour sessions separated by an interval of 12 weeks was arranged for the primary care pediatricians.<sup>15,20</sup> During each session, 2 pediatric pulmonologists (S.Z. and E.B.) reviewed respiratory system physiology, general aspects of asthma, indications for spirometry, basic spirometry test performance issues and the interpretation of spirometric indices, and flow-volume and volume-time curves. The practical part included a demonstration of the Microloop turbine flow sensor spirometer (Micro Medical Limited, Rochester, UK) and Spida 5 software (Micro Medical Limited) that was to be used for the study, individual practice with spirometry testing, and interpretation. During the 12-week interval between the first and second sessions, the participants were required to perform at least 30 spirometric tests and could share their experience and problems encountered using spirometry in their practice with the 2 pediatric pulmonologists. In addition, they were assisted in their offices for technical problems. During the first training session, participants were given a manual on the theoretical and practical aspects of spirometry, paying particular attention to acceptability and reproducibility criteria and test interpretation.

**TABLE 1.** Patient Characteristics and Lung Function Data

Characteristic	Value
N (male)	109 (74)
Age, y; mean (range)	10.4 (6–15)
FVC, % predicted	100 (93–105)*
FEV <sub>1</sub> , % predicted	98 (81–107)*
FEF <sub>25–75</sub> , % predicted	81 (67–92)*
FEV <sub>1</sub> /FVC, %	84 (79–88)*

\* Data are expressed as median and interquartile range (IQR) of the spirometric results. The 85 acceptable spirometric tests that were performed in primary care pediatric offices were considered for analysis.

## Spirometry Tests

Data collection started after the second training session and lasted for 1 month. The pediatricians' offices and laboratory all were equipped with the same portable spirometer (Microloop) and spirometry computer software (Spida 5). The spirometer uses a turbine flow sensor. The unit is provided with built-in quality assurance features, based on American Thoracic Society (ATS) criteria.<sup>21</sup> The spirometry software displays real-time flow-volume and volume-time curves and produces built-in quality assurance prompts, which are displayed after each unacceptable blow (eg, slow start, abrupt end, short blow) and to indicate the variability between the 2 highest FEV<sub>1</sub> and forced vital capacity (FVC) values. Spirometers were checked for reading errors by a technician before the study began, using a certified 3-L syringe. All spirometers had a deviation of <3% in the volume reading.

Patients were instructed to abstain from short-acting bronchodilators for 8 hours and long-acting bronchodilators for 12 hours before taking the test. Each patient underwent 2 spirometric tests (forced expiratory maneuvers) in random order in the same day. One test was performed at the pediatrician's office; the other was performed at the PF laboratory by 1 of the pulmonologists. Both the pediatricians and the pulmonologists were unaware of the results of the other spirometric test. All spirometric tests were conducted with the patient standing and wearing a nose clip. Patients were instructed to inhale completely before inserting the mouthpiece while holding their breath, then exhale forcefully into the spirometer for as long as they could. At least 3 acceptable and 2 reproducible forced expiratory maneuvers were required for each test. Table 2 shows the acceptability and reproducibility criteria. According to ATS recommendations, a forced expiratory time (FET) of <6 seconds is acceptable in children,<sup>21</sup> and we considered a FET ≥2 seconds as acceptable.<sup>22</sup> The expiratory spirometric indices (including FEV<sub>1</sub> and FVC) of the maneuver with the highest sum of FEV<sub>1</sub> + FVC were saved and used for analysis. Flow-volume and volume-time curves and spirometric parameters results were printed.

To validate the portable spirometer against a gold-standard spirometer, a group of 55 patients with asthma (38 boys; mean age: 10.2 years) performed 1 spirometric test in the PF laboratory with a 10-L bell spirometer (Biomedin, Padova, Italy) and 1 with the portable Microloop turbine spirometer. The order in which the devices were used was varied systematically. The results of the 2 tests were compared.

## Outcomes and Statistical Analysis

### Acceptability Criteria

Individual spirometry tests were judged to be "acceptable" when all of the following requirements were met: good start (as defined by a back-extrapolated volume <5% of FVC), satisfactory exhalation for ≥2 seconds, no abrupt end, and no cough during the maneuver (Table 2).

### Reproducibility Criteria

After 3 acceptable spirometry tests had been identified, the test was judged to be reproducible when the two highest FVC and FEV<sub>1</sub> values were within 5% of each other.

### Comparison Between Pediatricians' Offices and Laboratory Spirometric Tests With the Portable Spirometer

One of the primary outcomes was the within-subject difference between laboratory and primary care office spirometry test re-

**TABLE 2.** Acceptability and Reproducibility Criteria

Acceptability Criteria
Back-extrapolated volume <5% of the FVC
No abrupt ending
Duration of exhalation ≥2 s
No cough in the first second
Reproducibility criteria
Current FEV <sub>1</sub> and previous highest FEV <sub>1</sub> from an acceptable effort must differ by no more than 5%
Current FVC and previous highest FVC from an acceptable effort must differ by no more than 5%

**TABLE 3.** Spirometry Quality Assurance Data

No. of tests (total)	109
Acceptable tests	85
Unacceptable tests	24
Slow start	8
Expiratory time <2 s	7
Abrupt end	3
Tests not reproducible	6

sults in terms of  $\Delta FEV_1$ ,  $\Delta FVC$ , and forced expiratory flow between 25% and 75% of expired FVC ( $\Delta FEF_{25-75}$ ).

**Interpretation**

For each spirometric test result, the primary practice pediatrician was asked to record an interpretation, choosing from the following options: normal, mild obstruction, moderate obstruction, moderate to severe obstruction, severe obstruction, and restriction.<sup>23</sup> These records then were reviewed by the 2 pediatric pulmonologists, who marked the primary care pediatrician’s interpretations as “correct” or “incorrect.”

**Statistical Analysis**

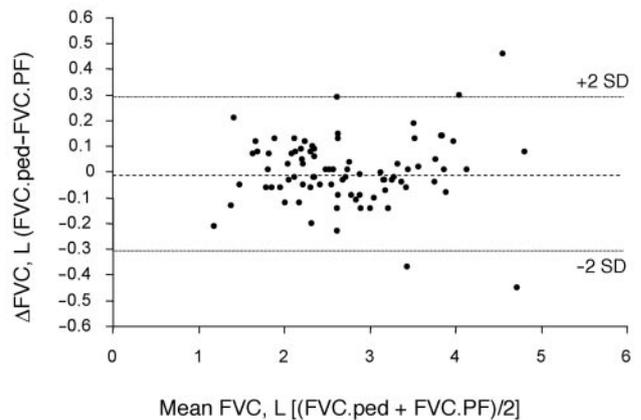
For the statistical analysis, we performed a power calculation that showed that we needed 85 patients per spirometry group to have 80.3% power to detect a 7% or greater difference in spirometric parameters between spirometry performed in the pediatric office and in the PF laboratory (with  $\alpha$  set at 5%). FVC, FEV<sub>1</sub>, and FEF<sub>25-75</sub> values are expressed as median and interquartile range. FVC, FEV<sub>1</sub>, and FEF<sub>25-75</sub> of the spirometry tests that were performed with the portable spirometers in the pediatricians’ offices and the PF laboratory were compared using an intraclass correlation coefficient (ICC). In addition, for assessing the agreement between the 2 spirometric test results, crude mean  $\Delta FVC$ ,  $\Delta FEV_1$ , and  $\Delta FEF_{25-75}$  were calculated by subtracting a patient’s laboratory value from the pediatric practice value. Mean values for these parameters with 95% confidence interval were calculated, and difference versus mean plots and accompanying limits of agreement ( $\pm 1.96$  times the SD of the differences) were produced to express the variability between laboratory and pediatric practice measurements according to the Bland and Altman method.<sup>24</sup> The Bland and Altman method was used to assess the agreement between the spirometric parameters that were obtained in the PF laboratory with the portable and the laboratory-based volume spirometers.

**RESULTS**

A total of 109 patients (74 boys) were included in the study (Table 1). Their mean age was 10.4 years (range: 6–15 years). Thirty-four (31%) patients had never had a spirometric test before. Ninety-eight children had bronchial asthma, 11 had cough persisting for >15 days. In 75 cases, the diagnosis of asthma was made on the basis of recurrent wheeze and reversible airflow limitation, as measured by spirometry; in 23 cases, the diagnosis of asthma was made on the history of recurrent wheeze. Fifty-two children were randomly assigned to have the first spirometry at the primary care office and the second at the PF laboratory; 57 had the tests in reverse order.

**TABLE 4.** FVC, FEV<sub>1</sub>, and FEF<sub>25-75</sub> Values (Median and IQR) Measured in the Pediatric Practices and in the Laboratory and ICCs Calculated Between the Two Measurements

Spirometric Parameter	Pediatrician’s Office	PF Laboratory	ICC
FVC, L	2.59 (2.19–3.24)	2.58 (2.17–3.29)	0.98
FEV <sub>1</sub> , L/s	2.10 (1.81–2.62)	2.06 (1.79–2.65)	0.98
FEF <sub>25-75</sub> , L/s	2.19 (1.64–2.83)	2.22 (1.62–2.68)	0.94



**Fig 1.** Differences in FEV<sub>1</sub> between pediatrician’s office (ped) and PF laboratory spirometry plotted against mean FEV<sub>1</sub> values. The dashed horizontal lines indicate the limits of agreement (mean difference  $\pm 1.96$  times the SD of the differences).

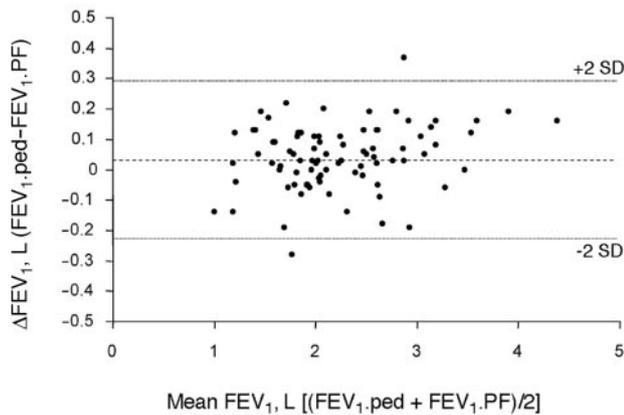
Each pediatrician performed at least 9 spirometric tests.

**Spirometric Test Quality**

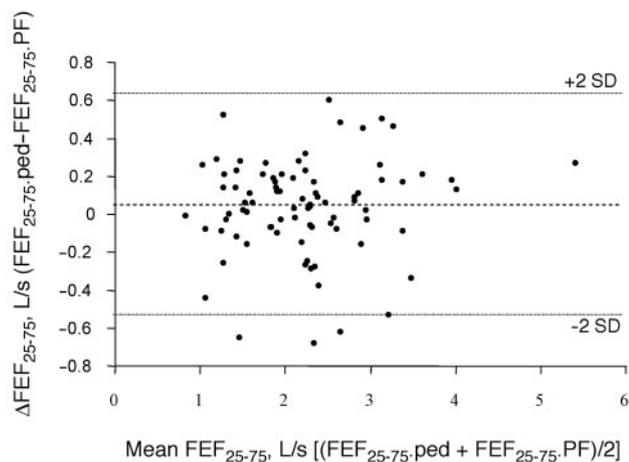
All of the spirometric test results were checked by the 2 pediatric pulmonologists. The analysis of the tests that were performed by the pediatricians in primary care practice revealed that 85 (78%) of 109 tests met all of the acceptability and reproducibility criteria (at least 3 acceptable and 2 reproducible curves). Most of the unacceptable blows were so judged on the grounds of an inadequate duration of exhalation or slow start (Table 3). In 6 cases, the spirometric test results were not reproducible. Twelve of the 24 unacceptable spirometry tests had been performed by children who were  $\leq 8$  years of age. In 11 of 24 cases, the children were performing their first spirometry.

**Comparison of Tests That Were Performed With the Portable Spirometer in Pediatric Practices and at the PF Laboratory**

Only acceptable spirometric tests were compared. Matched pairs of laboratory and pediatricians’ office tests were available for 85 patients. The agreement of the FEV<sub>1</sub>, FVC, and FEF<sub>25-75</sub> measurements that were obtained from each patient in the pediatric practice and in the laboratory was expressed using ICC, which is an estimate of the correlation between 2 measurements from 1 patient. We found very high values of ICC for the spirometric parameters that were measured in the pediatric practice and in the laboratory (Table 4). Figures 1, 2, and 3 show a curve-by-curve comparison of the differences between the 2 locations versus the mean for each of the key parameters (FVC, FEV<sub>1</sub>, and FEF<sub>25-75</sub>) according to the Bland and Altman method. There was a good agreement between the pediatrician’s office and the laboratory’s spirometric tests for all 3 parameters. The repeatability coefficient was 0.26 L for FEV<sub>1</sub> (with 83 of 85 values falling within this range), 0.30 L for FVC (with 81 values falling within this range), and 0.58 L/s for FEF<sub>25-75</sub> (with 82 values falling within this range). The scatter of the  $\Delta FEV_1$ ,  $\Delta FVC$ ,



**Fig 2.** Differences in FVC between pediatrician's office (ped) and PF laboratory spirometry plotted against mean FVC values. The dashed horizontal lines indicate the limits of agreement (mean difference  $\pm 1.96$  times the SD of the differences).



**Fig 3.** Differences in FEF<sub>25-75</sub> between pediatrician's office (ped) and PF laboratory spirometry plotted against mean FEF<sub>25-75</sub> values. The dashed horizontal lines indicate the limits of agreement (mean difference  $\pm 1.96$  times the SD of the differences).

and  $\Delta FEF_{25-75}$  values did not vary systematically over the range of measurements.

### Interpretation of the Spirometric Test Results

The pediatrician's interpretation was judged to be incorrect in 23 (21%) of 109 patients' tests. The interpretation errors are given in Table 5. In 15 cases, the test result was interpreted as normal, when it actually revealed mild obstruction in 11 cases and volume restriction in 4. In another 3 patients, the obstruction was underestimated, and in the last 5 cases, the obstruction was overestimated.

### Comparison Between the Spirometric Tests That Were Performed at the PF Laboratory With the Portable and the Laboratory-Based Volume Spirometers

Matched pairs of spirometric tests that were performed in the PF laboratory with the portable and the laboratory-based volume spirometers were available for 55 patients. There was good agreement between the 2 spirometers for all 3 main spirometric parameters (FVC, FEV<sub>1</sub>, and FEF<sub>25-75</sub>). The repeat-

**TABLE 5.** Spirometry Interpretation Errors

Cases, <i>n</i>	Pediatricians' Interpretation	Correct Interpretation
11	Normal	Mild obstruction
4	Normal	Restrictive
2	Mild obstruction	Moderate obstruction
1	Moderate obstruction	Moderate to severe obstruction
2	Moderate obstruction	Mild obstruction
2	Mild obstruction	Normal
1	Moderate to severe obstruction	Moderate obstruction

ability coefficient was 0.14 L for FEV<sub>1</sub> (with 53 of 55 values falling within this range), 0.18 L for FVC (with 52 values falling within this range), and 0.55 L/s for FEF<sub>25-75</sub> (with 54 values falling within this range).

### DISCUSSION

This is the first study to address formally the quality of spirometry that is performed in primary care pediatricians' offices after a training program. The results of this study indicate that, on average, the quality of spirometric tests in primary care pediatric practice is satisfactory by comparison with a spirometric test performed in a PF laboratory, but 22% of the tests that were performed by the former were unacceptable, and 21% of them were misinterpreted.

Laboratory-based spirometry is the "gold standard" for assessing lung function in children with asthma, but the costs of the technician and equipment led to peak flowmeters' often being used instead for office and home monitoring of lung function in children. Although peak expiratory flow monitoring and asthma diaries are useful tools in selected patients, there are major limitations to their widespread use in children with asthma.<sup>25,26</sup> Portable spirometers are now available with the capability for collecting a wide range of PF parameters that are clinically and epidemiologically more useful than peak expiratory flow, because they are more sensitive to functional status changes in asthma.<sup>16,18</sup>

The validity of spirometric tests is a prerequisite for their use as a tool for the diagnosis, monitoring, and management of respiratory diseases. Little is known about the validity of spirometric tests in adult patients in the primary care setting, however, and it has been reported that at least one third of the tests that are performed by the general practitioner (GP) fail to meet the quality criteria that are applicable to PF laboratories.<sup>20,27</sup>

The validity of spirometric tests that are performed in general practice was investigated recently by Schermer et al<sup>15</sup> by comparing them with the tests that are performed in patients with chronic obstructive pulmonary disease using the same spirometer at a PF laboratory. After a spirometry training program, the authors found the validity and the quality of the spirometric tests that were conducted by the GPs satisfactory, but the consistency between the laboratory's and the GP's measurements seemed to be limited. No studies have hitherto formally addressed spirometry performance in primary care pediatric practice.

Although seemingly straightforward, spirometry is an effort-dependent test that requires a cooperative patient and a trained operator to administer the test. We used a spirometer with built-in quality assurance prompts on the assumption that this would improve the quality of the spirometry, but 22% of the tests nonetheless failed to meet the acceptability and reproducibility criteria. Most of the errors were attributable to slow start or short blow.

In our study, the children were instructed to exhale for as long as they could, and a FET  $\geq 2$  seconds was considered valid. The ATS standards recommend an expiratory time of  $\geq 6$  seconds in adult patients,<sup>21</sup> but, recognizing that children have difficulty in meeting such end-of-test criteria, they say that shorter exhalation times are acceptable in children. Assuming that the flow-volume curve shows no abrupt termination of expiratory flow and that the volume/time curve shows a plateau, it has been suggested that the minimum FET should be reduced to 2 seconds for children who are  $\geq 8$  years and to 1 second for children who are younger than 8 years.<sup>22</sup> Other researchers suggested taking 3 seconds<sup>28</sup> or 4 seconds<sup>29</sup> as the target exhalation times.

A previous study in adult patients with chronic obstructive pulmonary disease demonstrated a slight but significant difference between the spirometric indexes that were measured by the GP's staff and those that were measured at a PF laboratory, suggesting that an interchangeable use of these measurements should be avoided.<sup>15</sup> We found no difference in FVC, FEV<sub>1</sub>, and FEF<sub>25-75</sub> between the pediatrician's and the PF laboratory's results of tests that were performed with the portable spirometer. In addition, we demonstrated that the portable spirometer that we used provides an accurate and reliable measure of PF when compared with a gold-standard laboratory-based device, as shown by the consistency that emerged between the 2 spirometers across the key spirometric parameters.

Although we primarily addressed the quality of the test's performance, the pediatricians' interpretation of the results was incorrect in 21% of the cases reviewed. In many cases, this misinterpretation involved the failure to detect or an underestimation of airway obstruction, so any clinical decisions that are based on these results would compound, rather than reduce, the underdiagnosis and undertreatment of asthma. Accurate interpretation relies not only on a well-performed procedure but also on an appreciation of physiology and a thorough clinical knowledge of the patient. Of course, longer, more intensive training might have produced better results in terms of the interpretation of the findings.

Proper training for the technician/physician who performs the test is perhaps the most important factor in ensuring good-quality spirometric testing.<sup>20,30</sup> As stated in 1991 by the ATS,<sup>23</sup> the largest single source of within-subject variability is improper performance of spirometry; therefore, effective training and quality assurance are vital prerequisites for successful spirometry. After adequate training, it is also important to have continual competence assessments and to review the test results carefully. It has been

demonstrated that, even in a dedicated research setting paying meticulous attention to quality, a technician's performance declines over time, but the quality of spirometry can improve dramatically and be maintained by routinely monitoring test session quality and prompting individual feedback.<sup>31,32</sup>

In both the United States and Europe, there are accredited training centers for pediatric respiratory medicine with modules on PF testing. Because effective training and quality assurance are vital prerequisites for successful spirometry, we believe that only approved training centers for pediatric respiratory medicine should certify that a primary care pediatrician has acquired the competence for performing and interpreting a spirometric test.

In conclusion, with sufficient training for the physicians and their staff, it seems justifiable to perform spirometry in the pediatric primary care setting. This could improve asthma monitoring in children, as recommended by the international guidelines.<sup>1</sup> If spirometry is to be promoted as a screening tool in primary care practice, however, then it is important to pay careful attention to ensuring that quality standards are met. To achieve this goal, an integrated approach is recommended, involving both the primary care pediatrician and the certified pediatric respiratory medicine centers.

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