

Quality of Pulmonary Function Testing in 3 Large Primary Care Pediatric Clinics in Rural North Carolina

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BACKGROUND Pulmonary function testing (eg, spirometry) is recommended by the National Heart, Lung, and Blood Institute as part of basic asthma management. Previous research has shown that spirometry is feasible in primary care settings.

OBJECTIVES In this retrospective study, we sought to describe the proportion of spirometries meeting American Thoracic Society (ATS) and European Respiratory Society (ERS) quality criteria in children with asthma evaluated in North Carolina primary care pediatric clinics and to characterize predictors of spirometry that meets ATS/ERS quality criteria.

METHODS Medical records and spirometries from January 1, 2001, to August 1, 2009, were reviewed and analyzed from children enrolled in a larger asthma study that focused on communication between physicians, children, and caregivers. Children were eligible for the larger study if they were between the ages of 8 and 16 years and had received a previous diagnosis of persistent asthma. Children were enrolled from primary care pediatric practices.

RESULTS Spirometry was not acceptable, on the basis of ATS/ERS criteria, in 75% of cases. Approximately 19% of spirometries used incorrect or outdated predictive sets.

CONCLUSIONS More than three-quarters of spirometries in these primary care pediatric clinics were unacceptable. Changes or lack of changes in asthma management may be based on unacceptable spirometry. Additional education and training regarding accurate spirometry and interpretation are warranted.

Asthma currently affects approximately 9 million children in the United States and 7.9%-8.5% of children in North Carolina [1, 2]. The National Heart, Lung, and Blood Institute (NHLBI) recommends that all medical professionals who treat asthma patients have access to pulmonary function testing (eg, spirometry) [3]. Children as young as 4 years are able to complete spirometry in accordance with American Thoracic Society (ATS) and European Respiratory Society (ERS) guidelines, when trained and enthusiastic technicians perform the test [4]. However, very little is known about the quality of spirometry in primary care settings overall, and even less is known about spirometry quality in primary care pediatric clinics. Most children receive asthma care at generalist clinics, so it is important to assess the quality of spirometry in this setting [5].

Spirometry is a screening test of general respiratory health that provides important objective data to clinicians that assist diagnosis. The presence or absence of symptoms has not been shown to directly correlate with pulmonary function measures. The NHLBI recommends using multiple measures of asthma severity, such as symptoms, the need for short-acting beta-agonists, and spirometry results, in the initial diagnosis and subsequent management of asthma [3]. Spirometry that is technically incorrect may lead to substantial misclassification (due to false-positive or false-negative findings) of the child's pulmonary function and to unwarranted therapies or undertreatment.

There is evidence of a disparity in spirometry quality and

interpretation skills between office staff and hospital staff [6, 7]. There are also differences in performance between groups who have been trained intensively on spirometry and groups who have not been trained [7]. Nevertheless, the consensus from researchers and the NHLBI reflects agreement that spirometry in general practices is feasible if physicians and staff receive proper training [4].

The ATS and ERS have issued joint statements to reduce the variability in and improve the quality of spirometry. However, these guidelines may be too stringent for young children, and new acceptability criteria are now being proposed for this age group [8-12]. Table 1 highlights the criteria for performing spirometry on children, as defined by the ATS and ERS guidelines.

Additionally, there is published evidence that spirometry results affect treatment decisions and severity classifications for children who received abnormal spirometry results, but that investigation was performed in an outpatient pulmonary office [5]. To our knowledge, there are no data on the acceptability of spirometry results in a subspecialty clinic. However, given that respiratory therapists may receive

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TABLE 1.
Components of Acceptable Spirometry Among Children

Component	Definition
Demographic variables	Correct height and weight must be obtained before spirometry
Predictive set	For children <8 years, use the set from Wang et al. [13]; for those aged ≥8 years, use the set from NHANES III [13]
Maximal exhalation duration	Children <13 years of age must exhale maximally for at least 3 seconds; those aged ≥13 years must exhale maximally for ≥6 seconds
Reproducibility	Values from the final 3 FVC and FEV ₁ measurements must be within 10% of each other
Note. FEV ₁ , forced expiratory volume in 1 second; FVC, forced vital capacity; NHANES, National Health and Nutrition Examination Survey.	

more-intense training and clinic staff (ie, nurses) may have more experience conducting the test, spirometry performed in subspecialty clinics may differ in quality from spirometry performed in a primary care pediatric setting. Currently, there are certifications available from the National Institute for Occupational Safety and Health (NIOSH) on how to properly conduct spirometry [14, 15]. There are also certifications through Kettering National Seminars for individuals who wish to become registered pulmonary function technicians; these seminars are also accredited for continuing nursing education [15]. However, we are not aware of any studies that have evaluated this training and have examined the quality of spirometry in primary care pediatric settings. The ATS/ERS guidelines endorse that technicians in the United States should be certified through NIOSH, to ensure that they can correctly administer spirometry. The ATS/ERS guidelines also recommend that technicians undergo refresher training every 3-5 years, so they can learn new skills in spirometry [12].

To our knowledge, no studies have investigated the quality of spirometry in primary care pediatric clinics in North Carolina or other US states. There also has been no formal assessment of the impact of unacceptable spirometry on treatment decisions. Therefore, the aims of this study were to determine the proportion of spirometries that accorded with ATS/ERS guidelines (ie, "acceptable spirometry") among children evaluated in North Carolina primary care pediatric clinics and to characterize predictors of acceptable spirometry.

Methods

Participants. This study was approved by the University of North Carolina-Chapel Hill Institutional Review Board, and the sample was drawn from a larger pediatric asthma study. In the larger study, children and their caregivers were recruited between 2006 and 2009 at rural primary care pediatric practices in North Carolina. Children were eligible for the larger study if they were 8-16 years of age, were able to speak English, could read the assent form, had been seen at the clinic at least once before, were present at the visit with an adult caregiver (parent or legal guardian) who could read and speak English and who was at least 18 years of age,

and were categorized as having mild or moderate/severe persistent asthma.

Subjects were eligible for the present study if at least 1 clinic visit before enrollment in the larger asthma study included spirometry. The subject's entire medical chart was required and was reviewed by C.M.G.

Procedures. We performed a retrospective analysis of spirometries and clinical characteristics of a subset of pediatric subjects currently participating in a larger asthma research study. For eligible children, medical records and spirometry data from January 1, 2001, to August 1, 2009, were reviewed and analyzed. Twenty-one pediatric medical providers and 100 of their subjects were enrolled into the present study. After initial analysis, we calculated the 25th and 75th percentiles of the dispersion of spirometries per subject, to determine subjects with an outlying number of spirometries. The number of spirometries per subject ranged from 1 to 7 (interquartile range, 1.75-5.25 spirometries/subject) during the study period. Three subjects underwent more than 5 spirometries and were classified as outliers and excluded from analysis.

After enrollment, data on all spirometries and patient clinical characteristics from each medical visit were abstracted from the medical charts. Each spirometry was then rated by a pediatric pulmonologist (C.E.L.) as acceptable or not acceptable, with stated reasons if not acceptable. Data from a random sample of 10% of the children were then analyzed by a second pediatric pulmonologist (S.D.D.), to verify concordance in the assessment of spirometry acceptability. Concordance between the 2 pediatric pulmonologists was 100%. Acceptability was based on ATS/ERS quality criteria [16].

Measurement. Age at each spirometry was measured as a continuous variable. Correct height and weight were measured as dichotomous variables. Child race was measured as white, African American, American Indian, Hispanic, or other. Asthma severity was classified as either mild persistent or moderate/severe persistent. Subjects were classified as having mild, persistent asthma if at least 1 asthma-control medication was being taken on the day of enrollment and/or asthma symptoms were experienced more than 2 times per week, but not every day, during the year before enrollment.

Subjects were classified as having moderate/severe persistent asthma if at least 2 controller medications were being taken on the day of enrollment and/or asthma symptoms were experienced on a daily basis during the year before enrollment [17]. Child sex was measured as a dichotomous variable.

The following variables were abstracted from the medical record for each clinical visit subjects had from January 1, 2001, to August 1, 2009: prescribed medication, defined as all medications to treat asthma (eg, short-acting beta-agonists and inhaled corticosteroids); frequency of use of all prescribed asthma medications (ie, controller and/or rescue inhaler/nebulizer) reported at the clinic visit at which spirometry was performed; performance of spirometry (at least 1 effort for a given test); height and weight, as noted on printed spirometry results; correctness of the predictive set, defined as the National Health and Nutrition Examination Survey (NHANES) III set [13], for children aged 8 years or older, and as the set by Wang and colleagues [13], for children younger than 8 years; presence of asthma symptoms on the day of the visit, as noted in the medical chart; and change in the prescribed asthma-control medication on the same day of the visit, defined dichotomously as “yes” or “no,” where “yes” was assigned if the physician (a) increased or decreased the dose for the current asthma medication and/or (b) added an asthma-control medication or had the child discontinue an asthma-control medication.

Statistical analyses. All analyses were conducted using SAS, version 9.2 (SAS Institute). First, a descriptive analysis of demographic variables and clinical characteristics was performed. Child race was recoded as a dichotomous variable (ie, “white” or “nonwhite”) for all analyses. Next, race and sex differences were analyzed for the total number of acceptable spirometries, as well as for the total number of spirometries, using independent sample *t* tests.

Zero-inflated Poisson regression was used to evaluate the relationship between the total number of acceptable spirometries and demographic variables (ie, asthma severity, race, and sex) [18]. There was also interest in evaluating the relationship between the number of excessive zeros in the outcome variable, the total number of acceptable spirometries, and the child’s age at the time of first spirometry. We hypothesized that age at first spirometry would be significant in the model because children who are older at their first spirometry would have fewer problems following the specific instructions that are required for technically acceptable spirometry. If we did not account for the excess of zeros in our outcome variable by using zero-inflated Poisson regression, it would have led to biased parameter estimates and incorrect inferences [19].

Multivariate logistic regression was used to examine the relationship between each spirometry and demographic variables (ie, asthma severity, race, sex, and age). We used Spearman’s rank correlation coefficient to determine whether there was a bivariate relationship between

the number of spirometries and acceptable spirometry for the sample. Finally, multiple logistic regression was used to examine whether a physician’s change to the child’s asthma-control medication was associated with subject age, asthma severity, presence of asthma symptoms, and acceptable spirometry (for the first 2 visits).

Results

Table 2 shows the demographic characteristics of our sample. One hundred subjects were enrolled, and 97 were included for analysis. We analyzed 196 spirometries for the 97 subjects. The mean age ($\pm$ SD) of subjects at first spirometry was 10.6 ± 2.3 years, with a range of 5 to 15 years. All subjects had received a previous diagnosis of asthma and met NHLBI guidelines for diagnosis. Seventy-two percent of children were classified as having moderate/severe persistent asthma by a clinical pharmacist with experience in asthma (D.M.W.) and by a pediatric pulmonologist (S.D.D.). The mean number of spirometries ($\pm$ SD) per child was 2.0 ± 1.1 . There were no statistically significant differences between races and sexes in the total number of spirometries. Additionally, there were no significant demographic differences in the total number of acceptable spirometries (data not shown).

In total, 50 (25%) of spirometries were acceptable on the basis of ATS/ERS criteria. Figure 1 shows the most prevalent reasons why spirometry was not acceptable. Each category is not mutually exclusive. The most prevalent reasons for unacceptable spirometry were reproducibility and nonmaximal efforts. Spearman’s rank correlation coefficient suggested that the relationship between the number of spirometries and the total number of acceptable spirometries was not statistically significant ($\rho = 0.17$; $P = .09$).

TABLE 2.
Demographic Characteristics of Study Participants

Characteristic	Subjects, no. (%) (N = 97)
Sex	
Male	55 (56.7)
Female	42 (43.3)
Race	
White	58 (59.8)
Black	29 (29.9)
Hispanic ^a	3 (3.1)
Other ^b	7 (7.2)
Asthma severity ^c	
Mild, persistent	26 (26.8)
Moderate/severe persistent	70 (72.2)
No data	1 (1.0)

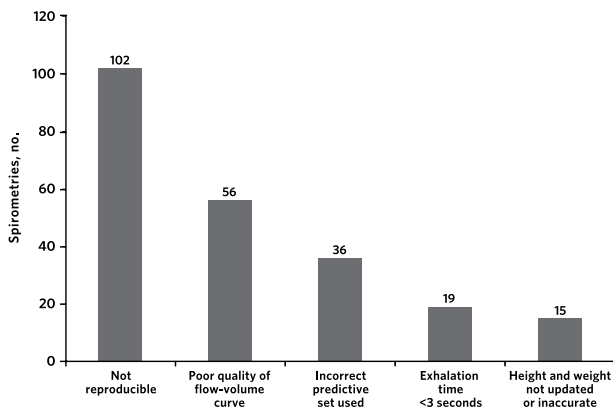
Note. The mean age ($\pm$ standard deviation) at first spirometry was 10.6 ± 2.3 years, with a range of 5 to 15 years.

^aIncludes Mexican Americans.

^bIncludes subjects with mixed race.

^cSee Methods for definitions of asthma severity.

FIGURE 1.
Reasons for Unacceptability of Spirometry



Note. Data are for 147 spirometries considered to be unacceptable on the basis of American Thoracic Society and European Respiratory Society guidelines. Individual spirometries can appear in >1 category.

The zero-inflated Poisson regression results showed no significant associations between the total number of acceptable spirometries and demographic variables (data not shown). Multiple logistic regression results showed no significant predictors of acceptable spirometry, after control for each individual spirometry (data not shown). Thirty-eight spirometries (19%) were done using outdated or incorrect predictive sets, with the first session having the greatest concentration of outdated or incorrect predictive sets (almost 31%).

Asthma-control medication was changed in association with 22 unacceptable spirometries (15%), with no clinical symptoms documented in the medical chart to explain the change. Conversely, asthma-control medication was not changed in association with 48 unacceptable spirometries (33%), with clinical symptoms noted in the medical chart that may have prompted a change in medication otherwise. Multiple logistic regression analysis showed no statistically significant associations between changes to prescribed asthma medications and either demographic variables or clinical aspects of the visit, such as the presence of asthma symptoms (data not shown).

Discussion

Our results show that the quality of spirometry for children in these primary care pediatric clinics was poor, with only 1 in 4 tests being acceptable, as defined by ATS/ERS guidelines. The most common problems with spirometry among these patients were reproducibility and submaximal efforts. For our study, a child was included even if only 1 spirometric maneuver had been attempted. Therefore, it is likely that issues with reproducibility could be even greater than what this study reports. This has important treatment implications because exhalations that are not performed maximally by the patient can lead to important misclas-

sifications that may result in suboptimal or unnecessary therapies.

The technical quality of spirometry is extremely important for validity and reproducibility. Failure to meet the quality standards for 1 component of the test can influence the interpretation of the results. For example, an exhalation that is not done at maximal inspiratory capacity may not detect an obstructive component. Failure to obtain 3 measurements with values that are within 10% of each other suggests poor reproducibility of FEV₁ (forced expiratory volume in 1 second) results. An inadequate duration of measurement can also affect the results. The FVC (forced vital capacity) is dependent on an adequate measurement period. If the duration of measurement is too short, the FVC will be underestimated, which affects the FEV₁/FVC ratio. Technicians who conduct spirometry on children should be trained thoroughly so that they can help young patients attain maximal effort, which is crucial to the correct interpretation of spirometry results. The courses taught by NIOSH should be able to help technicians obtain the best efforts from children.

There were no statistically significant predictors of acceptable spirometry in our data set. This is extremely important because one hypothesis is that the prevalence of acceptable spirometries is greater among children who have undergone more spirometries. However, this association was not detected in our study. Although we did not analyze the association between individual technicians and the prevalence of acceptable spirometries, past research has shown that proper training of both physicians and nurses results in high-quality spirometry [5]. We chose not to analyze individual technicians because the technician's name was not updated in the computer each time spirometry was attempted. This makes it impossible to tell which technician was actually performing the spirometry.

Physicians changed decisions about medication management in association with approximately 15% of unacceptable spirometries, with no asthma symptoms documented in the medical chart to explain the change. Previous studies have found that spirometry results prompt pediatric pulmonologists to change medication, but further research would need to replicate the study by Nair and colleagues [5] in primary care pediatric offices, to determine the role of spirometry in medication-management decisions made by general pediatricians.

We also found that providers did not change asthma medication in association with almost 33% of unacceptable spirometries, even though the medical chart documented that the child was experiencing asthma symptoms at the visit. It is important to note that the spirometers used in these cases had interpretive software, which may by itself have influenced management decisions. There were no instances in which the spirometer's interpretive software acknowledged poor spirometry quality.

Almost one-fifth of all spirometry was performed using outdated or incorrect predictive sets. One explanation for

this finding could be that technicians in general pediatric clinics may lack important knowledge to properly select correct reference values. Another explanation for the finding could be that the spirometers used at these clinics were outdated and lacked the ability to download updates. This further points to a need for more-thorough training and education of technicians.

Accurate clinician interpretation of pulmonary function is dependent on correct performance of spirometry. However, correct performance was rare in our sample. There were instances in which technicians did not update the height and weight of patients for more than 2 months (some data had not been updated for more than 1 year), as well as instances in which the wrong age was entered into the computer (the age of one child was entered as 88 years, instead of 9 years). If a technician inputs the wrong demographic parameters, such as height and age, for a subject, then output variables, such as FVC and FEV₁, are also incorrect. Therefore, if a subject has an obstructive component in their breathing, the condition might not be detected because the variables for predicting pulmonary function are incorrect. In a case in which height was not updated for more than 1 year, the physician clearly wrote in the medical chart that spirometry results were normal. The physician then decreased the dose of asthma medication, even though the patient was experiencing symptoms that suggested that spirometry results were incorrect. Physicians rely on technicians to perform the test correctly, and good patient outcomes depend on correct test interpretations.

Spirometers are often purchased from companies that provide limited training to clinic office staff. One solution to this issue is that companies that provide spirometry equipment should provide continuing education and training on spirometry. For practices that have already purchased spirometry equipment, it is important that their technicians receive certification to conduct the test. No staff in this study were respiratory therapists, and none had a certification through Kettering or NIOSH, which, if received, could lead to improvements in quality at these clinics. The staff that received training when the spirometer was originally purchased may no longer be working at the clinic, or there may be new staff who never received proper training. It might also be more feasible for practices to have consistent personnel who are trained in acceptable spirometry and/or to have 1 trained physician dedicated to interpreting spirometry results.

Future research needs to focus on the training of clinic personnel who perform spirometry, as well as on analyzing the quality of spirometry before and after training, to determine the effect of training. It will be important to determine whether individual technicians have an effect on the ability to perform acceptable spirometry on a child. Additional studies are also needed to analyze the importance that physicians place on spirometry results in treatment decisions.

Our research should be considered in light of the limita-

tions of our study. First, we did not have direct access to each medical encounter at which spirometry was performed, and therefore we cannot directly conclude that spirometry results had a direct impact on disease management. For example, the physician may not have noted symptoms in the medical chart, but symptoms may have been discussed, leading to a change in treatment. Another limitation is that we did not directly compare individual technicians and cannot conclude that technicians are the most important factor in determining acceptable spirometry. We could not assess how many individuals have performed spirometry at each site, because of turnover of clinic staff over a 9-year period. Our subjects were not tested on the same day in a pulmonary function laboratory or by a trained technician, and therefore we cannot rule out that our population had characteristics that prevented them from undergoing acceptable and reproducible spirometry. Furthermore, since our inclusion criteria allowed children into the study who had performed only 1 spirometric maneuver instead of 3, reproducibility issues in our sample could have been even worse. Last, our data are limited to rural North Carolina and may not be generalizable to other geographic areas.

In conclusion, only 25% of spirometries in these primary care pediatric clinics were acceptable. Given that most asthmatic children receive asthma care from generalists and that spirometry is recommended as basic asthma management in national guidelines, it is not ideal that spirometry is restricted to tertiary care centers and subspecialty providers. Changes or lack of changes to the management of asthma medication may be based on results from a technically unacceptable spirometry. Further training and education is necessary to justify the continued use of the test in primary care pediatric clinics. **NCMJ**

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