Original Article

Impact of a Pharmacist-driven Spirometry Clinic Service within a Community Family Health Center: A 5-year Retrospective Review

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ABSTRACT

Objective: This study was designed to describe the impact of a trained pharmacist in performing quality spirometry testing within a community family health center. **Methods:** This was a retrospective, cohort study of 150 physician-referred patients who attended their scheduled spirometry office appointment between November 2008 and December 2013. Information obtained included type of the disease (patients with obstructive or restrictive pulmonary disease), calculated lung age decline due to smoking history, quality of spirometry testing, and percentage of patients requiring pulmonary drug regimen alterations due to spirometry results. Pearson correlation and descriptive statistics were used to address study objectives. **Findings:** Spirometry testing performed by a pharmacist resulted in 87% of tests meeting guidelines for quality. Testing identified patients with reversible airway disease (39%), chronic obstructive pulmonary disease (21%), restrictive (11%), and mixed obstructive/restrictive (11%) lung defect. Patients with abnormal spirometry demonstrated a greater smoking pack-year history and calculated lung age than patients with normal spirometry (29.1 pack-years vs. 17 pack-years; $P = 0.024$ and 76.3 years vs. 54.6 years; $P < 0.001$, respectively). A weak correlation was found between a 29.1 smoking pack-year history and forced vital capacity ($r = -0.3593$, $P = 0.018$). The pharmacist assisted in modifying pulmonary drug regimens in 69% of patients based on evidence-based guidelines. **Conclusion:** A pharmacist-driven spirometry service was associated with quality testing results, identified respiratory disease abnormalities, and helped modifications of pulmonary drug regimens based on evidence-based guidelines. Future direction of this service may include collaborative practice agreements with physicians to expand services of pharmacists to include spirometry testing.

Keywords: *Pharmacists, residence characteristics, respiratory function testing, spirometry*

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Introduction

Spirometry is a pulmonary function test that requires the patient to maximally inhale and then forcefully exhale into a handheld monitoring device. The testing is invaluable for clinicians and indicated for diagnosis and monitoring of respiratory diseases, disability/impairment evaluations, and public health epidemiological survey evaluations.[1-4] However, its use in asymptomatic patients is not advised since it may potentially lead to unnecessary testing, increased costs, resource utilization, and unnecessary disease labeling.[5]

Spirometry has evolved from testing performed in a pulmonary function laboratory under the direction of a pulmonologist to testing performed in primary care or outpatient settings including community pharmacies.[6,7] This paradigm shift in outpatient testing has primarily occurred due to advances in spirometry technology. Spirometry technology has advanced to include portable handheld devices requiring minimal calibration or

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quality control to perform accurate testing. Due to these advances, a major concern is that the quality of testing performed outside of a pulmonary function laboratory may be substandard and not meet rigorous standards set forth by international clinical practice guidelines.[5] Traditionally, primary care physicians utilize office staff including medical assistants or registered nurses to perform office testing.[8] Inadequate training or limited time in performing testing by the office staff may result in suboptimal quality testing. Testing of poor quality can lead to false-positive interpretations and prescription of unnecessary respiratory medications, which may lead to serious adverse effects.[9]

The practice and scope of pharmacy services may vary internationally. In the United States, the scope of practice is established by state legislatures and regulated by each state board of pharmacy. At present, 47 states and the District of Columbia (Washigton, D.C.), pharmacists are authorized into collaborative practice agreements with a physician or designated prescriber, which results in the expanding of clinical services. However, since there are no restrictions on who can perform spirometry, pharmacists have an opportunity to expand this service and incorporate this into collaborative practice agreements with physicians.

Pharmacists have demonstrated their value in optimizing pharmaceutical care for patients with respiratory diseases including chronic obstructive pulmonary disease (COPD) and asthma. Data have shown that pharmacists improve medication adherence, knowledge of disease, and reduction in hospital admission rates, and patients were more satisfied with the quality of their care.[10-12] In addition, pharmacists have also introduced spirometry testing as a service in a limited number of clinical studies in the care of COPD and asthma patients.[13-21] Pharmacists trained in performing quality spirometry can offer a number of advantages including better convenience for the patient, early identification of airflow limitations, expedite physician prescribing inhaled respiratory medications, and teaching patients the proper use of respiratory delivery devices.[13] Pharmacists working in collaboration with the prescribing physician can perform spirometry testing within the community pharmacy or within the physician's office.[14] Due to the novelty of these services, pharmacists may not be aware of the potential opportunity to provide physicians' another option in spirometry testing or training opportunities to gain the skills necessary to offer a quality service. A more comprehensive description of the use of spirometry by pharmacists to expand direct patient care services is beyond the scope of this article but can be found elsewhere.[22]

The objective of this study was to describe the impact of a trained pharmacist in performing quality spirometry testing within a community family health center including identification of obstructive or restrictive lung defects, calculated lung age decline due to smoking history, and pulmonary drug regimen modifications.

Methods

This retrospective cohort study was an analysis of patients who attended the spirometry clinic within the community family health center from November 2008 to December 2013 incorporating 150 patients. The study was approved as exempt by the University of the Sciences and Crozer-Keystone Health System's Institutional Review Boards. The requirements for written informed consent were waived due to the retrospective nature of the study.

The electronic medical records of all patients who received spirometry testing were evaluated. Demographic and clinical data including age, gender, height, weight, body mass index, lung age, and smoking pack-year history were recorded for all patients. Inclusion criteria for study participants included all patients >18 years of age with pulmonary symptoms including history of chronic cough, shortness of breath, pleuritic chest pain or previous diagnosis of asthma, COPD, or other pulmonary disease warranting spirometry testing. Patients were excluded who had contraindications for performing testing including elevated blood pressure (systolic >200 mmHg or diastolic >110 mmHg), recent myocardial infarction or stroke (within 3 months), recent cataract or increased ophthalmic pressure, chest or abdominal surgery (within 3 weeks), history of angina, hemoptysis, pneumothorax, nausea and vomiting, and thoracic or abdominal or cerebral aneurysms.[23] In addition, patients were excluded if they self-administered prescribed respiratory medications (short- and long-acting beta-agonists, anticholinergic agents, corticosteroids, leukotriene modifiers, or theophylline) <24 h before the scheduled spirometry testing procedure to maintain baseline pulmonary function values not influenced by respiratory medications.

Before patient testing, the spirometer and flow transducer were checked and calibrated at the beginning of each day utilizing a 3 L single stroke calibrated syringe. Both devices were to meet the American Thoracic Society/European Respiratory Society (ATS/ERS) reproducibility for syringe volume which was defined as maintaining a calculated syringe volume reproducibility <3% of predicted values. ATS/ERS reproducibility criteria were based on the 1998 National Health and Nutrition Examination Survey-III criteria for patient age, sex, race, height, and weight. Calculated lung age was also determined by calculation from Fletcher and Peto.[24] Calculated lung age uses linear regression

equations to calculate how smoking accelerates age-related decline in lung function.

Initiation of spirometry testing included the pharmacist explaining and demonstrating the procedure to the patient. The patient was instructed to perform a minimum of three pre- and three postbronchodilator maneuvers. Prebronchodilator testing continued until the patient achieved the ATS/ERS guidelines of a forced vital capacity (FVC) in liters or forced expiratory volume in one second (FEV_1) in liters until the value was within 0.150 L or 150 ml of the next largest value.[1] A maximum of eight efforts would be attempted. If the patient was not able to achieve adequate quality for either the pre- or postbronchodilator test, further testing was terminated. Once a prebronchodilator test was of adequate quality, the pharmacist would administer a bronchodilator (2.5 mg albuterol sulfate [synonym: salbutamol]) through nebulizer. 15–20 min after bronchodilator administration, the patient would then perform three postbronchodilator maneuvers. Once testing was complete and of adequate quality (both three pre- and three postmaneuvers), the pharmacist would proceed to discuss the quality of the test, interpretation of test results, and pharmacological intervention (if warranted) with the physician. After a therapeutic plan was agreed to between the physician and pharmacist, the pharmacist would then educate the patient on the prescribed drug, drug dosing, respiratory delivery device operation, and other education initiatives (i.e., smoking cessation) if warranted.

Data relevant for assessment included patient demographics, results of pulmonary function testing including FVC, FEV_1, FEV_1/FVC (%), forced expiratory flow 25%–75% ($FEF_{25\%–75\%}$) in liters/second, and peak expiratory flow rate (PEFR) in liters/second. In addition, other information evaluated included respiratory medication changes including discontinuation, addition, or dose adjustments; new or supporting diagnosis of reversible airway disease, COPD, restrictive lung defect, or mixed obstructive/restrictive lung defect; number of patients requiring specialty physician referral (i.e., pulmonary, cardiologist, and allergy/immunologist) or required further diagnostic testing (i.e., chest radiograph and cardiac echocardiogram); and number of patients who achieved ATS/ERS guidelines for quality of spirometry testing. A positive postbronchodilator response indicative of reversible airway disease was determined if >12% increase in FEV_1 and 200 ml increase in FVC or FEV_1 or 15%–25% increase in $FEF_{25\%–75\%}$ was obtained.[23]

Statistical analysis was performed using SPSS software, version 18.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive statistics were done for all variables. Results were presented as standard deviation, mean, and percentage. The Student's *t*-test, Chi-square test, and Pearson's correlation coefficient were used to analyze the differences and the correlation between groups. Statistical significance was assumed at $P < 0.05$.

Results

One hundred and fifty patients attended their scheduled office spirometry appointments. Thirty-one patients were excluded from the study due to age <18 years, inability to perform spirometry testing to meet acceptable ATS/ERS guidelines or administering respiratory medication <24 h before scheduled spirometry testing. One hundred and nineteen patients (57 displayed normal spirometry and 62 displayed abnormal spirometry) completed their scheduled appointments and met the inclusion criteria for study evaluation. Seventy-eight percent ($n = 93$) were Caucasian, 19% ($n = 23$) African-American, 1% ($n = 1$) Asian, and 1% ($n = 2$) Hispanic [Table 1]. Thirty-seven percent (44 male) completed spirometry testing.

The pharmacist achieved ATS/ERS guidelines of a FVC or FEV_1 within 0.150 L or 150 ml of the next largest value in 104/119 (87%) patients tested. A minimum of 714 spirometry tests were completed which included 119 patients performing both three prebronchodilator and three postbronchodilator spirometry maneuvers. The pharmacist assisted in identifying reversible airway disease in 39%, COPD in 21%, restrictive pulmonary defect in 11%, and mixed obstructive/restrictive pulmonary defect in 11% of patients. Patients with abnormal spirometry demonstrated a greater smoking pack-year history and calculated lung age than patients

Table 1: Demographic and clinical characteristics of the study patients

Characteristics	Normal spirometry (*n*=57)	Abnormal spirometry (*n*=62)	*P*
Age (years), mean (SD)	42.1 (17)	50.7 (3)	0.003
Height, mean (SD)	65 (7.5)	66.8 (2)	0.016
Weight (lbs/kg), mean (SD)	189/85.7 (3/1.3)	206.6/93.71 (20/9.1)	0.080
BMI (kg/m^2), mean (SD)	31.5 (9.5)	32.8 (2)	0.399
Lung age (years), mean (SD)	54.6 (6.5)	76.3 (4)	<0.001
Smoking pack (years), mean (SD)	17 (0)	29.1 (5)	0.024
Race, *n* (percentage of patients)			
Caucasian	41 (72)	51 (82.2)	0.52
Black	13 (22.8)	10 (16.1)	0.47
Asian	1 (1.7)	0 (0)	N/A
Hispanic	1 (1.7)	1 (1.6)	N/A

The *P* value was based on a *t*-test or χ^2, N/A=Not applicable, BMI=Body mass index, SD=Standard deviation

with normal spirometry (29.1 pack-years vs. 17 pack-years; $P = 0.024$ and 76.3 years vs. 54.6 years; $P < 0.001$, respectively) [Table 1]. Differences between pre- and postbronchodilator results of patients with normal and abnormal spirometry were also determined [Table 2]. In addition, patients with abnormal spirometry demonstrated a greater response to bronchodilator in percentage change in FEV_1 than patients with normal spirometry (11.69 L vs. 2.37 L; $P < 0.001$) [Table 3]. Correlations between smoking pack-year history and FVC were evaluated. Patients with at least a 29.1 smoking pack-year history demonstrated a worsening FVC and weak correlation based on Pearson's correlation coefficient ($r = -0.3593$, $P = 0.018$). Worsening of other pulmonary function parameters also demonstrated a weak correlation with smoking pack history. No statistical significance was identified FEV_1 ($r = -0.2689$, $P = 0.082$), $FEF_{25\%-75\%}$ ($r = -0.0947$, $P = 0.548$), and PEFR ($r = -0.080$, $P = 0.619$).

Respiratory medications required modifications after spirometry testing. The pharmacist assisted in modifying pulmonary drug regimens in 69% of patients based on evidence-based guidelines. Thirty-one out of 119 patients (26%) necessitated discontinuation of respiratory medications and 65/119 (55%) required additional therapy due to uncontrolled symptoms and/or based on classification of disease (i.e., asthma or COPD). Beta-agonists were discontinued more than any other therapeutic drug class when previously prescribed for "as needed" use. The discontinuation of beta-agonists was primarily based on the patient's medical history, physical examination, symptoms, and negative response to postbronchodilator in not achieving a >12% increase in FEV_1 and 200 mL increase in FVC or FEV_1, or 15%–25% increase in $FEF_{25\%-75\%}$. Inhaled corticosteroids and beta-agonist/corticosteroid combinations were added in patients who demonstrated a postbronchodilator response indicative of a reactive airway component, however, finding unsatisfactory response to treatment with a beta-agonist alone. Anticholinergic agents were initiated in patients with a diagnosis of COPD, and leukotriene antagonists were prescribed for patients with an allergenic respiratory component during the summer months (May–July) when environmental pollen counts were seasonably high. All patients received counseling on pulmonary drug therapy including demonstration and use of a prescribed respiratory delivery device. Patients were required to self-demonstrate efficient use of the prescribed device with 100% accuracy before leaving the spirometry clinic. Smoking cessation counseling in the form of health-care pamphlets and brochures on the harmful effects of smoking was also provided, if warranted.

Table 2: Spirometry results

Characteristic	Normal spirometry (n=57)		P
	Prebronchodilator	Postbronchodilator	
FVC (L), mean (SD)	3.4 (2.5)	3.4 (1.8)	0.80
FEV_1 (L), mean (SD)	2.8 (1.7)	2.9 (1.5)	0.50
FEV_1/FVC (%), mean (SD)	82.6 (15.5)	84.1 (3.5)	0.27
$FEF_{25\%-75\%}$ (L/s), mean (SD)	2.9 (0.7)	3.2 (1.7)	0.14
PEFR (L/s), mean (SD)	6.4 (2.4)	6.4 (1.6)	0.96
Characteristic	**Abnormal spirometry (n=62)**		**P**
	Prebronchodilator	Postbronchodilator	
FVC (L), mean (SD)	3.0 (0.6)	3.1 (0.7)	0.38
FEV_1 (L), mean (SD)	2.0 (0.3)	2.2 (0.4)	0.15
FEV_1/FVC (%), mean (SD)	69.6 (2.8)	72.2 (2.8)	0.17
$FEF_{25\%-75\%}$ (L/s), mean (SD)	1.5 (0.1)	1.8 (0.2)	0.13
PEFR (L/s), mean (SD)	5.4 (1.8)	5.8 (0.1)	0.37

The P value was based on a t-test. FVC=Forced vital capacity, FEV_1=Forced expiratory volume in 1 second, $FEF_{25\%-75\%}$=Forced expiratory flow, PEFR=Peak expiratory flow rate, SD=Standard deviation

Table 3: Spirometry results postbronchodilator

Characteristic	Normal spirometry (n=57)	Abnormal spirometry (n=62)	P
Percentage change FEV_1 (L) (postbronchodilator), mean (SD)	2.37 (11.31)	11.69 (6.3)	<0.001
Percentage change $FEF_{25\%-75\%}$ (L/s) (postbronchodilator), mean (SD)	11.62 (35.5)	21.9 (8.4)	0.09
Positive bronchodilator response, n (percentage of patients)			
FEV_1>12% and 200 mL increase in FVC or FEV_1 or $FEF_{25\%-75\%}$>15%	25 (43.8)	41 (66.1)	0.43

The P value was based on a t-test or χ^2. FVC=Forced vital capacity, FEV_1=Forced expiratory volume in 1 second, $FEF_{25\%-75\%}$=Forced expiratory flow, SD=Standard deviation

Physician consult referral or further diagnostic testing was required in 20% of patients which included pulmonary (9%), allergy (6%), immunology, otolaryngology, or cardiology (5%). Spirometry testing supported the need to perform other testing to differentiate a diagnosis. Spirometry testing identified three patients

with vocal cord anomalies based on flow volume loop inspiratory tracing results. The results were confirmed with performing a nasopharyngeal laparoscopy.

Discussion

Pharmacists have proven themselves medication experts throughout the literature; however, they have also expanded technical skill-based services including anticoagulation monitoring, smoking cessation, asthma management, lipid control, diabetes management nutritional support, and immunization administration services.[25] Spirometry testing is another opportunity for pharmacists to expand patient services and improve the quality of patient care. Results of this study are similar to previously published data of 51 patients tested resulting in 75% of patients achieving acceptable spirometry quality, 80% of patients required altering respiratory drug regimens, and 27.4% of patients needing a physician referral or the need for greater diagnostic testing.[14] ATS/ERS has set that a performance threshold of >90% of patients can meet ATS/ERS benchmarks for spirometry quality if coached by a trained technician.[1] Technical adequacy of spirometry testing in >12,000 tests completed by trained nurses, pediatricians, and research personnel achieved 71%–92% adequacy.[26-30] Personnel received training including practice theory on performing spirometry, operation of spirometry device, interpretation of results, and criteria for diagnosis based on ATS/ERS guidelines. All testing results were evaluated for quality including acceptability and repeatability based on ATS/ERS guidelines. Collectively, these results determined that an achievable target range of 75%–90% is technically adequate for achieving quality spirometry in primary care testing.[20] Furthermore, Cawley and Warning performed a systematic review of the evidence of pharmacists performing quality spirometry testing. The testing included eight clinical studies in a variety of outpatient settings. Specially trained pharmacists tested approximately 4000 patients resulting in 66%–99% of the tests achieved ATS/ERS benchmarks for quality.[13] Our study results of 87% of tests meeting ATS/ERS quality equaled or exceeded these data.

Based on this comprehensive data, pharmacists can be trained to accurately perform quality spirometry testing. Pharmacists can receive training certificates in spirometry testing through workshops or from national sponsored programs.[31,32] Programs typically require 1–2 days of training. After training is complete, trainees may require further periodic training or online refresher courses to maintain testing competence. Properly trained pharmacist can provide quality spirometry testing and be an invaluable resource in the care of the pulmonary patient.

Smoking history has shown to directly impact the quality of spirometry results. The authors of this study identified that the abnormal spirometry results associated with a smoking pack-year history of 29.1 years are similar to previously published data. Data have shown that patients with a history of chronic heavy smoking >19 smoking pack-years were associated with significantly decreased values of FVC, FEV_1, FEV1/FVC, and PEFR and that pulmonary function parameters tended to decrease as the cigarette burden increased.[33-35] Furthermore, the results of this study are similar to other published data including a negative correlation between smoking pack-years and FVC ($r = -0.3593$, $P = 0.018$) and ($r = -0.072$, $P = 0.078$), respectively.[35]

This study did have multiple limitations. The study was a retrospective, single-center study, which has inherent design bias. The patient population included almost 80% of Caucasian with very limited addition of minority groups, which may not be a fair representation of the general population. Physician prescribing of respiratory pharmaceuticals may have been biased due to familiarity and repeated prescribing of specific medications and devices. The diagnosis of abnormal or normal spirometry was primary determined by the attending physician. Although the physician had extensive experience in reviewing pulmonary function testing data, he was not specialized in pulmonary medicine. A review by a board-certified pulmonologist of spirometry testing would have provided greater validity to the results. Respiratory quality of life symptoms (i.e., St. George's Respiratory Questionnaire) could have been assessed; however, patient follow-up was inconsistent primarily due to patient noncompliance with scheduled appointments.

The authors believe that the knowledge gained in this study has demonstrated the impact of a pharmacist trained in spirometry testing. Pharmacists should consider the many benefits of this service and consider this an option to incorporate into clinical practice to improve the quality of care for patients with pulmonary disease. Further research is needed on the impact of a pharmacist-driven spirometry service on economic and health-care outcomes of patients with respiratory disease including cost justification of this service, patient satisfaction surveys, physician office visit frequency, and emergency department or hospital admission rate avoidance due to exacerbation of respiratory illness.

A pharmacist-driven spirometry service was associated with providing quality spirometry testing results, identifying patients with obstructive and restrictive lung

defect, decline in lung function due to smoking exposure, and assisting the prescribing physician in modifying pulmonary drug regimens based on evidence-based guidelines. Pharmacists trained in performing quality spirometry testing can be an invaluable asset to physicians in the care of patients with respiratory disease. The future direction of this service may include collaborative practice agreements with physicians to expand services of pharmacists to include spirometry testing.

Authors' Contribution

MJC and WJW contributed to the project idea, designed, and analyzed the data and manuscript preparation. Both authors had complete access to all study data that support this publication.

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Conflicts of interest

There are no conflicts of interest.

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