

The reliability and utility of spirometry performed on people with asthma in community pharmacies

Deborah Lei Burton, BSc (Hons), PhD, Kate S LeMay, B.Pharm M.A, Bandana Saini, B.Pharm, M.Pharm, M.B.A, PhD, Grad Cert Ed Studies (Higher Ed), Lorraine Smith, B.A.(Hons), PhD, Sinthia Bosnic-Anticevich, B.Pharm(Hons), PhD, Phillipa Southwell, B.MedSc (Hons), Julie Cooke, BSc (Hons), PhD, Lynne Emmerton, B.Pharm(Hons), PhD, Kay Stewart, B.Pharm(Hons), PhD, Ines Krass, B.Pharm, Dip Hosp Pharm, Grad Dip Ed Studies (Health Ed), PhD, Carol Armour, B.Pharm(Hons), PhD

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Abstract

Objective

To investigate the reliability and utility of spirometry generated by community pharmacists participating in two large asthma intervention trials of 892 people.

Methods

The Pharmacy Asthma Care Program (PACP) and the Pharmacy Asthma Management Service (PAMS) involved up to 4 visits to the pharmacy over 6 months **for counseling and goal setting**. Pharmacists performed spirometry according to ATS/ERS guidelines **to inform management**. The proportion of A-E, F quality tests, as per EasyOne™ QC grades, were recorded. Lung function results between visits and for participants referred/not referred to their general practitioner on the basis of spirometry were compared.

Results

Complete data from 2593 spirometry sessions were recorded, 68.5% of spirometry sessions achieved 3 acceptable tests with between-test repeatability of 150 mL or less (A or B quality), 96% of spirometry sessions included at least one test that met ATS/ERS acceptability criteria. 39.1% of participants had FEV₁/FVC values below the lower limit of normal (LNN), indicating a respiratory obstruction. As a result of the service, there was a significant increase in FEV₁ and FEV₁/FVC and asthma control. **Lung function values were significantly poorer for participants referred to their general practitioner, compared to those not referred, on the basis of spirometry.**

Conclusions

Community pharmacists are able to reliably achieve spirometry results meeting ATS/ERS **guidelines** in people with asthma. Significant improvements in airway obstruction were demonstrated with the pharmacy services. Pharmacists interpreted lung function results to identify airway obstruction for referral, making this a useful technique for review of people with asthma in the community.

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Author Information:

Adjunct A/Prof Deborah Lei Burton,
Charles Sturt University, Orange, NSW, Australia
(BSc (Hons), PhD)

Mrs Kate S LeMay, Faculty of Pharmacy, Woolcock Institute of Medical Research, the
University of Sydney, Sydney, Australia
(B.Pharm M.A.)

Dr Bandana Saini, Faculty of Pharmacy, The University of Sydney, Sydney, Australia
(B.Pharm, M.Pharm, M.B.A, PhD, Grad Cert Ed Studies (Higher Ed))

Dr Lorraine Smith, Faculty of Pharmacy, The University of Sydney, Sydney, Australia
(B.A.(Hons), PhD)

A/Prof Sinthia Bosnic-Anticevich, Faculty of Pharmacy, The University of Sydney, Sydney,
Australia
(B.Pharm(Hons), PhD)

Ms Phillipa Southwell, Charles Sturt University, Orange, NSW, Australia
B.MedSc (Hons)

Dr Julie Cooke, University of Canberra, ACT, Australia
BSc (Hons), PhD

A/Prof Lynne Emmerton, School of Pharmacy, Faculty of Health Sciences, Curtin
University, Perth, Australia
(B.Pharm(Hons), PhD)

A/Prof Kay Stewart, Centre for Medicine Use and Safety, Monash University, VIC, Australia
(B.Pharm(Hons), PhD)

Prof Ines Krass, Faculty of Pharmacy, The University of Sydney, Sydney, Australia
(B.Pharm, Dip Hosp Pharm, Grad Dip Ed Studies (Health Ed), PhD)

Prof Carol Armour, Woolcock Institute of Medical Research and Faculty of Medicine, The
University of Sydney, Sydney, Australia
(B.Pharm(Hons), PhD)

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Asthma, forced expiratory volume, pharmacy, program evaluation, spirometry

JUST ACCEPTED

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JUST ACCEPTED

Introduction

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Asthma affects approximately 10% of adults **in Australia**, placing a large burden on health services.^[1] **Data from** community surveys of asthma **confirm the** significant symptom burden **and additionally**, a low implementation of recommended evidence-based therapies.^[2,3] **This** sub-optimal quality of asthma care^[3] suggests the need for development of innovative models to address the needs of people with asthma in the community. **Expanding the role of a wider range of primary care health professionals in asthma management is one suggested model.**

Within the area of asthma management, there is an increasing awareness of the underutilization of community pharmacists as a powerful resource.^[4] Studies have shown that people with asthma are happy to consult pharmacists as a first point of contact for asthma management advice, and value services provided by pharmacists.^[5,6] Moreover, pharmacy-based asthma care interventions have also been shown to affect outcomes with improvements in asthma control,^[4,7] self-management,^[8] asthma knowledge^[9] and quality of life.^[4,7] Screening of lung function in pharmacies may be a useful addition to these services by engaging people with asthma in counseling discussions with their pharmacist.

Spirometry is an important component in both the diagnosis and monitoring of asthma, **with** the National Asthma Council (NAC) recommending that “all doctors managing asthma should have access to and use a spirometer for this purpose”.^[10] Despite these recommendations, only 6% of general practice encounters for asthma in adults include lung function assessment.^[11] Recognized barriers to **lung function measurement** include **limited access to spirometers**, limited time **to perform spirometry** and lack of confidence in measurement and interpretation.^[12] **In order to remove these barriers** increased education and shared responsibility for lung function measurement via

multidisciplinary care models **is required**.^[13] Spirometry in primary care management of COPD, a related obstructive respiratory disease state, has been demonstrated to be reliable^[14] and to support patient education.^[15]

In two community pharmacy studies which focused on improving asthma control, the Pharmacy Asthma Care Project (PACP)^[4] and Pharmacy Asthma Management Service (PAMS)^[7,16], specialized training was provided to pharmacists by respiratory scientists, pharmacologists, research pharmacists and respiratory physicians. It was known from a pilot study that pharmacists were able to produce high quality spirometry data.^[17]

Research studies combining spirometric measurement of lung function by pharmacists integrated with pharmaceutical respiratory care have demonstrated good results in both spirometric quality and respiratory outcomes in small patient groups^[18,19]. Therefore it seemed important to investigate whether reliable spirometry data could be obtained and then incorporated as a useful component of an overall pharmacy asthma service in a large scale implementation project.

Methods

The aim of the study was to assess the quality and reliability of spirometry measurement by community pharmacists involved in two community pharmacy asthma studies and the utility of this measurement in the management and referral of the person with asthma. Approval for the studies was given by the Human Research Ethics Committees of The University of Sydney, The University of Queensland, Charles Sturt University and Monash University. Written informed consent was obtained from all pharmacists and participants.

The PACP and PAMS were multi-site studies evaluating a pharmacist-led asthma disease state management program, where community pharmacists recruited

participants with diagnosed asthma for a series of visits over a six-month period to monitor the effect of interventions on self-management of asthma.^[4,7,16] The PACP **compared randomly allocated control and intervention groups in a repeated-measures study.**^[4] Participants from both groups attended the pharmacy for baseline and six-month visits. Intervention group participants also attended at one month, and optionally at three months, post-baseline. The PAMS was an implementation study in primary care, pharmacists were randomized to deliver either three or four in-pharmacy patient consultations over 6 months, with follow-up at 12 months to assess the sustainability of patient health outcomes.^[7,16] Proportional representation from urban and rural sites was used to sample pharmacies in New South Wales, Queensland, the Australian Capital Territory and Victoria in both studies. Pharmacists were asked to recruit up to 10 participants at risk of poor asthma outcomes, as determined by the Revised Jones' Morbidity Index^[20] or no asthma review in the previous 6 months.^[16] The training was similar in both studies. Pharmacists were issued with a manual of peer-reviewed resources for pre-reading and received face-to-face training on risk assessment, pathophysiology of asthma, asthma medications, asthma guidelines,^[10] adherence assessment, patient education, goal setting, spirometry, and the service protocol during a 2-day workshop. At the end of the training, pharmacists completed an accreditation assessment administered by an external body (**Australian Association of Consultant Pharmacy**), including a skills based assessment for spirometry (Appendix 1). The training for spirometry included one hour of theoretical and two hours of 'hands-on' practical training, using EasyOne™ Spirometers (nidd Medizintechnik AG Technoparkstrasse, Switzerland) **within the 2-day training workshop.** Pharmacists were trained by respiratory scientists; the respiratory scientist-to-pharmacist ratio was

1:5. Spirometry measurement conformed to the 2005 American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines.^[21] **Prior to spirometry measurement Pharmacists screened participants for contraindications to performing spirometry.** Each pharmacist was provided with an EasyOne™ spirometer interfaced to their computer and at any stage during the study period pharmacists were able to access telephone support for interpretation/troubleshooting.

At the initial visit for both studies, pharmacists recorded participant demographics, including asthma and smoking history. **Participants were not required to withhold beta agonists prior to spirometry testing.** Spirometry was performed at each visit with pharmacists assessing the acceptability of each test attempt on the computer screen in real-time and then reviewing the automated test quality scores. Pharmacists aimed for 3 acceptable tests with A or B session quality but ceased testing after a maximum of 8 attempts. The results were used in conjunction with other measurements (e.g. asthma control, adherence) to guide changes in management over time. At all stages the opportunity for referral to the physician was available.

Reliability measurement

The EasyOne™ spirometer has an inbuilt test quality grading system (A-D, F) that provides feedback to the operator on test acceptability and repeatability. The percentage of tests meeting each quality grade **at the baseline visit and of tests with a quality rating of A (PACP/PAMS) or B (PAMS) on repeat visits is reported.** Only spirometry data with a quality rating of A or B were included in analysis of lung function. This corresponded to 3 acceptable tests with between-test repeatability of 150 mL or less, as per ATS/ERS criteria.

The forced vital capacity (FVC), forced expiratory volume in one second (FEV₁), and FEV₁/FVC ratio were calculated automatically by the spirometer as the percentage of predicted values based on age, height and gender as defined by NHANES III.^[22] The proportion of participants with FEV₁/FVC and FEV₁ below the lower limit of normal (LLN) were calculated by computing LLN from regression equations^[22] and subtracting baseline values after retrieval of data. Spirometry quality and lung function values were compared between visits to assess the reliability and changes in results over time.

Utility measurement

Pharmacists referred participants to their general practitioners where poor asthma control indicated need for medication change, development of an asthma action plan and/or on the basis of spirometry results. Spirometry quality scores and mean values for lung function of participants referred on the basis of their spirometry were calculated and compared to those who were not referred on this basis.

Sample size calculation

Using a confidence level of 5% plus a power of 80% we estimated we would need a sample size of 619 participants to detect an improvement in FEV₁/FVC of 1.5% assuming baseline mean of 90% and standard deviation of 15%. For paired data for participants on subsequent visits we estimated we would need 199 participants to detect an improvement in FEV₁/FVC of 1.5% assuming a standard deviation of 7.5%.

Data analysis

Results were analyzed using SPSS[®] Version 20.0. Chi-squared was used to compare the proportion of A and B spirometry session quality scores across visits. Student's paired sample t-test was used to compare baseline with Visit 2 and with final spirometry values

for the same individual. Student's independent samples t-test was used to compare spirometry values of participants referred/not referred to the general practitioner on the basis of spirometry. Mean difference and 95% confidence intervals are provided. A two-tailed significance level of 0.05 was used in all analyses.

Results

As there were no significant differences between the PACP and PAMS in terms of the patient demographics and lung function, the data from both studies has been combined. Pharmacy and participant demographics and baseline lung function values are provided in Table 1. There were 351 patients with spirometry recorded in PACP and 541 in PAMS. **The majority of participants were Caucasian (93%), with 2.1% Asian, 0.2% African, 0.6% Hispanic and 4% of other ethnicity.**

Spirometry test quality

There were 2593 spirometry testing sessions recorded throughout the studies. The proportion of participants with A or B quality spirometry sessions increased with repeat testing at successive visits (Chi-square=27.8, $p=0.033$) (Table 2). ATS/ERS acceptability, and repeatability criteria within 150ml, was achieved in 1775 (68.5%) test sessions. Only these highest quality tests were included in analysis of lung function. A further 317 (12.2%) sessions had repeatability between 150-200ml. **Of the remaining spirometry sessions 402 (15.5%) had 1 or 2 acceptable, but not repeatable tests, and 99 (3.8%) demonstrated no acceptable tests.**

Lung function

At baseline, the FEV₁/FVC and FEV₁ values were below the lower limit of normal, indicating clinical airflow obstruction, in 39.1% and 53.5% of participants, respectively.

There was a significant improvement in FEV₁, FEV₁/FVC, PEF and FEF_{25-75%} between baseline and V2 for matched participants and in FEV₁/FVC and FEF_{25-75%} between baseline and the final visit (Table 3).

Referral based on spirometry

When all spirometry sessions were considered, regardless of test quality, pharmacists made 250 referrals (199 participants) to the general practitioner on the basis of spirometry. Fifty one participants who had not attended their general practitioner after being referred on the basis of spirometry were referred on subsequent visits. Sixty percent of those referred for spirometry had A or B session quality scores compared with 69% those not referred ($p = 0.03$). When only A or B session quality was considered ($n=1693$), 147 (8.7%) referrals to the general practitioner were made to 112 participants on the basis of their spirometry results. The lung function values of those, referred on the basis of spirometry, were significantly poorer than for those not referred for spirometry (Table 4).

Discussion

This **study** has demonstrated the ability of pharmacists to measure spirometry reliably, with 68.5% of test sessions having 3 acceptable tests with repeatability of FEV₁ and FVC within 150 mL, the current ATS/ERS recommendation for within-session repeatability for diagnostic spirometry.^[21] A further 12.2% of tests had the best two values for FEV₁ and FVC **between 150 and 200 mL**, results that could be interpreted, but with less certainty. **Our results demonstrating 80.7% of spirometry sessions with between-test repeatability criteria for both FEV₁ and FVC within 200 mL, compare favourably with similar primary care spirometry studies.** COPD case finding studies measuring spirometry in community pharmacy showed similar results to

those reported here, with 70% of spirometry measured being repeatable within 200 mL.^[14] In the general practice setting, 76% of tests performed for COPD case finding by trained nurses, compared with 44% of tests performed by general practitioners, met the same repeatability criteria.^[25] A comparison study between the primary care general practice environment and hospital laboratory spirometry, using the 200 mL repeatability criteria, showed the proportion of non-repeatable tests to be 18% (82% repeatable) in both settings.^[26]

Improvement in spirometry test quality on subsequent visits, with increased experience of the pharmacist and participant team, suggested a learning effect. A correlation between the number and frequency of spirometry tests and test quality has been previously demonstrated.^[23, 24] **A study of 13,599 participants and 16 technicians demonstrated 70-88% of sessions meeting ATS/ERS acceptability criteria with reproducibility within 200ml and demonstrated spirometry technicians with the most experience were more likely to meet quality goals.**^[24]

Spirometry training duration may affect test quality, and varies widely across various studies with four days training for pharmacists in the COPD case-finding study^[14] and two hours for the general practitioners,^[25] compared to three hours plus pre-reading in our studies. The Australian and New Zealand Society of Respiratory Science (ANZSRS) recommends 10 hours of face-to-face training, but this recommendation is based on expert opinion rather than evidence-based assessment.^[27] Modern spirometer design usually incorporates real-time test quality feedback in an easily-understood, A-D and F format, and the ultrasonic sensor used in the spirometer in our study has been shown to be extremely reliable in large-scale community-based surveys of lung function^[28] and general practice.^[29] Our results indicate that a three-hour spirometry

training session with theoretical and practical components, using a spirometer with a stable sensor and direct test quality feedback, in addition to pre-reading, was effective in achieving good quality results for patients.

It is widely recognized that asthma is largely managed in primary care settings,^[30] and the pharmacy is an important setting for asthma management interaction, especially for those who choose to self-manage **without guidance from a medical practitioner. This group** may be at higher risk of poor asthma control due to reliance on reliever medications and infrequent asthma review with general practitioners.^[16] Pharmacists used spirometry as one tool to engage the patient and assess problems with asthma control. The high proportion of participants with obstructive lung disease (**FEV₁/FVC values less than the LLN**) was expected, as the study aimed to recruit participants with risk of poor asthma outcomes using the modified Jones Morbidity Index.^[4,7,16] Spirometry in primary care has been identified in other studies as a useful support in patient education and treatment adherence.^[15] Results of this study reinforce the value of the community pharmacy as a valuable primary care site for successfully engaging participants with poor asthma control and improving their self-management skills.

When spirometry was measured on subsequent occasions during the intervention by pharmacists, FEV₁ and FEV₁/FVC improved. In parallel, significant improvements were also demonstrated in asthma control.^[7] Our results show that measurement of spirometry in pharmacy has utility in terms of assessing improvements in asthma following an intervention.

The spirometry test was useful in the management and referral of people with uncontrolled asthma. Referral on the basis of spirometry results required the pharmacists to be able to interpret both spirometry session quality and the severity of

airway obstruction. The significant difference in session quality and lung function values between those referred and those not referred to the general practitioner on the basis of spirometry results indicates the pharmacists' ability to interpret spirometry quality and lung function in asthma. The advantage of initial review in the pharmacy is the access to patients who don't present to the general practitioner and who may require further follow up. Based on our results the spirometry measurements were reliable and useful in terms of predicting people with asthma who may be at higher risk of **uncontrolled asthma**. There was then an opportunity presented for general practitioner review and improved management.

Spirometry measurement in primary care has been shown to improve the management of respiratory disease.^[31,32] Adequate training and support in spirometry measurement for a wide range of primary healthcare professionals is required to reduce the poor utilization of spirometry in diagnosis and management of asthma and COPD.^[33] Training has been shown to improve the rate of spirometry measurement in general practice staff,^[34,35] and repeated testing experience can improve test quality.^[24] Comparison of spirometry quality and test interpretation between primary care physicians and respiratory specialists has not only demonstrated good agreement, but also changes in management based on lung function results.^[36] The role for primary care-based spirometry in diagnosis and management of obstructive lung disease is now firmly established, with the emergence of comprehensive standards documents.^[12,30] Spirometry test quality must be high, and a mechanism for referral to general practitioners or respiratory specialists when lung function results are reduced is essential. Since spirometry remains an underutilized measurement in primary care,^[33] novel venues, **such as pharmacies**, should be considered as **studies have**

demonstrated that reliable measurements are achievable.^[4,7,16,18,19] Use of a stable spirometer, targeted pre-reading, 3 hours of face-to-face training and support is a good baseline on which to build models of training and primary care spirometry services in future.

Limitations

While the percentage of spirometry sessions of a quality consistent with ATS/ERS guidelines was comparable with the literature for other primary care settings, there is evidence to suggest that spirometry quality would have been further improved by including specific feedback to pharmacists after each spirometry session.[24] Future studies should consider incorporating feedback after each session to further increase quality and utility of lung function results.

We asked pharmacists to provide reasons for referral of participants to their doctor, including on the basis of spirometry results. As pharmacists referred significantly more participants with lower quality spirometry sessions and poorer lung function to their doctor we are able to infer that pharmacists were able to determine spirometry quality and reduced lung function, however, we cannot differentiate between these two reasons for referral. Future studies would be improved by asking pharmacists to differentiate between referral for poor quality spirometry or for poor lung function.

Conclusions/Key findings

Community pharmacists are able to reliably achieve spirometry results meeting ATS/ERS quality in the majority of people with asthma. Significant improvements in airway obstruction were demonstrated with the pharmacy services. Pharmacists

interpreted lung function results to identify airway obstruction for referral, making this a useful technique for review of people with asthma in the community.

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Declaration of interest statement

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Table 1. Pharmacy and Participant Demographics

		PACP		PAMS	
Pharmacies		50		97	
Participants		n = 351 (186 control; 165 intervention) Number (%) or Mean $\pm$ SD		n=541 (275, 3 visit; 266, 4 visit) Number (%) or Mean $\pm$ SD	
		Range		Range	
Age		49.1 ($\pm$ 16.6)	18 - 76	50.5 ($\pm$ 16.6)	18-80
Gender (male)		30%		36.6%	
Body Mass Index (kg/m ²)		28.1 ($\pm$ 6.8)	13.3 - 58.3	28.8 ($\pm$ 7.1)	16.8-65.4
Height (cm)		166.7 ($\pm$ 9.9)	143 - 198	167.8 ($\pm$ 9.8)	141-203
Respiratory Co-morbidity		53 (13.6%)			
Other Co-Morbidity		243 (62.3%)			
Smoking History:	Non-Smoker	234 (60.0%)		300 (55.5%)	
	Current Smoker	87 (22.3%)		137 (25.3%)	
	Former Smoker	69 (17.7%)		104 (19.2%)	
Baseline Lung Function ^a	% Predicted	n=255		n=348	
	^b FVC	85.7 $\pm$ 19.4	40-133	81.9 $\pm$ 16.3	36-125
	^c FEV ₁	76.6 $\pm$ 23.3	23-144	75.2 $\pm$ 21.3	23-127
	FEV ₁ /FVC	88.4 $\pm$ 15.6	35-121	90.4 $\pm$ 14.4	44-128
	^d FEF _{25-75%}	64.7 $\pm$ 37.8	9-177	66.3 $\pm$ 35.7	9-156
	Measured FEV ₁ /FVC %	70.2 $\pm$ 13.6	40-95	71.9 $\pm$ 12.6	33-98

^aSpirometry results for 3 acceptable tests with reproducibility within 150ml

^bFVC = Forced Vital Capacity

^cFEV₁ = Forced Expiratory Volume in one second

^dFEF_{25-75%} = Forced Expiratory Flow 25-75% FVC

Table 2: Percentage of A/B Quality ^a spirometry tests with repeat visits		
Visit	# of tests	A/B session quality (%) ^b
1 (baseline)	920	65.5
2	608	67.9
3	243	73.3
Final	700	69.3
Follow-up	122	78.7
Total	2593	68.5

^aQuality=A (PACP/PAMS) and B (PAMS)

^bChi-square =27.8 (p=0.03)

Table 3: Participant matched spirometry results on successive visits

	^b V2	^a V1	Mean difference		
% Predicted	Mean±SD	Mean±SD	(n=293)	95% CI	^d T (p)
FVC	85.0±17.4	84.2±17.1	0.8±9.9	-0.2 - 1.9	1.58 (0.114)
FEV ₁	79.6±22.2	77.5±21.9	2.1±9.1	1.0 - 3.1	3.87 (0.000)
FEV ₁ /FVC	92.2±13.7	90.7±14.6	1.5±6.8	0.7 - 2.3	3.76 (0.000)
PEF	91.7±24.8	89.9±25.2	1.8±14.1	0.2 - 3.4	2.15 (0.032)
FEF _{25-75%}	72.5±38.2	68.4±37.8	4.1±17.0	2.1 - 6.1	4.11 (0.000)

	^c VF	V1	Mean difference		
%Predicted	Mean±SD	Mean±SD	(n=252)	95% CI	T(p)
FVC	83.6±17.7	84.6±17.5	-1.0 ± 8.9	-2.1 - 0.1	-1.77 (0.077)
FEV ₁	79.4±21.4	78.6±21.9	0.9±8.1	-0.2 - 1.9	1.67 (0.097)
FEV ₁ /FVC	93.9±13.6	91.6±14.2	2.4±7.5	1.4 - 3.3	5.01 (0.000)
PEF	92.7±25.3	91.8±26.0	0.9±13.4	-0.8 - 2.5	1.02 (0.307)
FEF _{25-75%}	75.1±38.2	71.0±38.1	4.1±20.0	1.6 - 6.6	3.26 (0.001)

^aV1= Visit 1

^bV2= Visit 2

^cVF= Visit final

^dT(p)= Students T value (probability)

Table 4: Comparison of Lung Function (% predicted) based on spirometry referral to general practitioner

	No spirometry referral (n=1546) ^a	Spirometry referral (n=147)	Mean difference	95% CI	T (p)
% pred	Mean±SD	Mean±SD	Mean±SE		
FVC	83.9±17.4	73.8±16.0	10.1±1.5	13.0 - 7.2	-6.76 (0.000)
FEV ₁	78.0±21.7	61.9±18.5	16.1±1.9	19.7 - 12.5	-8.72 (0.000)
FEV ₁ /FVC	91.0±16.8	83.2±15.0	7.8±1.3	10.6 - 5.0	-5.42 (0.000)
PEF	89.5±24.9	72.0±21.8	17.5±2.1	21.7 - 13.3	-8.24 (0.000)
FEF _{25-75%}	70.9±37.3	45.6±28.4	25.4±3.2	31.6 - 19.2	-8.03 (0.000)

^aVisit 5 (follow-up) tests not included as pharmacists did not record referrals as the study was complete

APPENDIX 1

Spirometry skills assessment

SKILLS ASSESSMENT CHECKLIST

NAME:..... DATE: VENUE:

Competent / **Not yet competent** (please circle)

STEP	PERFORMANCE CRITERIA – STEP DESCRIPTION	YES	NO
1	Clearly explains the procedure to the patient		
2	Demonstrates the procedure to the patient		
3	Asks the patient to seal their lips around the mouthpiece while breathing normally		
4	Asks the patient to breathe in fully, to maximal inspiration		
5	Asks the patient to force out as much breath as possible as quickly as possible		
6	Encourages the patient to continue forcing breath out until there is no more air coming out		
7	Asks the patient to inspire quickly and maximally until the lungs are fully inflated		
8	Asks the patient to remove the mouthpiece		
9	Ensures the test is acceptable		
10	Repeats the procedure three times		
11	Checks reproducibility criteria (Continues testing until quality =A or B or up to eight tests)		
12	Prints the spirogram		

Comments

.....

Candidate signature **Date**

Trainer signature **Date**