**The Reliability of Spirometry Results Performed by Community Pharmacists**

*Dr. Debbie Burton, Charles Sturt University, Orange, NSW, Australia*
*Miss Phillipa Yabsley, Charles Sturt University, Orange, NSW, Australia*
*Dr Lynne Emmerton, The University of Queensland, QLD, Australia*
*A/Prof Ines Krass, University of Sydney, Sydney, NSW, Australia*
*Dr Bandana Saini, University of Sydney, Sydney, NSW, Australia*
*Dr Lorraine Smith, University of Sydney, Sydney, NSW, Australia*
*Dr Sinthia Bosnic-Anticevich, University of Sydney, Sydney, NSW, Australia*
*A/Prof Kay Stewart, Monash University, VIC, Australia*
*Prof. Carol Armour, University of Sydney, Sydney, NSW, Australia*

**Abstract**

**Purpose**
To investigate the acceptability and reproducibility of Spirometry results generated by Community Pharmacists participating in the Pharmacy Asthma Care Program (PACP).

**Methodology**
PACP Pharmacists (n=50) underwent 3 hours of Spirometry practical and theoretical training, using EasyOne™ Spirometers, prior to commencing the Program. Pharmacists were offered telephone support during the study period. The PACP program collected Spirometry results to inform therapeutic management of enrolled participants. Participants (n=351) were between 18 and 75 years of age with a diagnosis of asthma. Spirometric data was collected as a pre-bronchodilator measurement, where possible. Testing conformed to American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines. Pharmacists were encouraged to achieve A or B quality tests as per EasyOne™ QC grades. This corresponded to between test reproducibility of 200ml or less.

**Results**
Complete data from 922 testing sessions were reported throughout the study. Of the Spirometry trials recorded by Pharmacists, 70.1% (n=647) achieved a quality rating of A or B, with 97.1% (n= 895) of all test sessions recording at least one acceptable test maneuver. Of the acceptable results, 50.4% (n=484) of participants recorded a Forced Expiratory Volume in one second ($FEV_1$) below 80% of their predicted result, indicating a respiratory limitation.

**Conclusions**
With limited training and telephone support, Community Pharmacists have demonstrated that they are able to achieve acceptable Spirometry results of diagnostic value in the majority of participants tested. Incorporating Spirometry into Community Pharmacy has the potential to increase the number of people with asthma undertaking regular Spirometry as part of their asthma management.

**Comment [l1]:** Need to link in earlier

**Introduction**

Chronic health care places a continually increasing burden on health services in Australia. The financial and infrastructural repercussions of long-term care for an aging population has resulted in both the review of existing services and the development of innovative, multidisciplinary care models[1,2].

Within the area of asthma management, there is an increasing awareness of the underutilization of community pharmacists as a powerful education resource[3]. Studies have shown that people with asthma see pharmacists as a first and regular point of contact for asthma advice; value services provided by

pharmacists and have high rates of return once engaged[4]. Pharmacy-based asthma care interventions have been shown to have highly positive outcomes, particularly in reducing asthma severity[4,5], improving self-management[3] and quality of life[5].

The National Asthma Council (NAC) currently recommends that spirometry is used in both the diagnosis and monitoring of asthma, and that "all doctors managing asthma should have access to and use a Spirometer for this purpose"[6]. Despite these recommendations, only 45% of people with asthma in metropolitan areas claim to have had their lung function tested at some stage. This percentage is further reduced in rural communities to 11%. Issues such as service centralisation, staff shortages and reduced access to specialist care are widely known causes barriers to care provision[1,7].

With appropriate training in test performance and interpretation, community pharmacists have proven their ability to adopt diagnostic procedures as part of their routine clinical practice. This includes, but is not limited to asthma management[7]. Specialised training was provided by respiratory scientists as part of the Pharmacy Asthma Care Project (PACP). The 2004 study by Burton et al. showed that from these cohorts, pharmacists were able to produce high quality spirometry results. These results were used not only in disease screening and monitoring, but in the detection of lung function abnormalities[5].

**Aim**

This was a retrospective observational cohort study using spirometry data collected by community pharmacists involved in the PACP study. We aimed to assess the reliability and repeatability of session quality and any learning effect of repeated testing sessions over the period of the study. We further aimed to assess the rate of detection of abnormality found in this population.

**Methodology**

*Study Design*

The Pharmacy Asthma Care Program (PACP) was a multicentre, randomized control versus Intervention repeat measure study. Community pharmacists recruited participants with diagnosed asthma for a series of visits to monitor the effect of various interventions on self-management of asthma. Each pharmacists (n=50) underwent 3 hours of Spirometry practical and theoretical training, using EasyOne™ Spirometers, prior to commencing the Program. Pharmacists were offered telephone support during the study period. Qualified Respiratory Scientists provided training in Spirometry theory, practice and interpretation as part of the PACP training Workshop.

PACP pharmacists were randomized into control (2-visit) and Intervention (3-visit) groups. At the initial PACP visit, pharmacists recorded participant demographics, asthma and smoking history using validated instruments. Spirometry was performed at each visit for both control and intervention participants with the results used as a clinical indicator of change in management over time.

Spirometric data was collected as a pre-bronchodilator measurement, where possible. For this analysis we included only one Spirometry session from each visit thus excluding results recorded for the purpose of measuring airway reversibility. Testing conformed to the 1994 American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines. Pharmacists were encouraged to achieve A or B quality tests as per EasyOne™ QC grades. This corresponded to between test reproducibility of 200ml or less.

*Recruitment*

*Pharmacy Recruitment and Equipment*

Fifty-seven pharmacies were recruited and trained, with PhARIA ratings between 1 and 6. Fifty pharmacies were then randomly assigned to control and intervention groups. The additional 7 pharmacists were trained to compensate for the anticipated withdrawal of some pharmacies. Of the 50 active pharmacies, 60% were located within PhARIA 1. Each pharmacist was provided with an EasyOne™ Spirometer and spirettes.

*Participant Recruitment*

Pharmacists were required to recruit up to 10 participants at their pharmacy. Inclusion criteria for each participant were: aged 18 to 75 years with a previous diagnosis of asthma and at least one of:

- Use of a reliever medication more than three times a week over the previous four weeks
- Waking at night or morning with cough/chest tightness on at least one occasion over the previous four weeks
- Time off work/study because of asthma over the previous four weeks
- Symptoms of asthma at least once a week, over the previous four weeks or
- No visit to the doctor for asthma within the last six months

Potential participants were excluded from the study if they had a terminal illness, were currently part of another clinical trial, did not self-administer their inhaler and/or did not speak English well enough to complete the study questionnaires independently.

*Outcome Measurements*

*Result Reliability*

The EasyOne™ Spirometer has an inbuilt Acceptability and Reproducibility grading system. Test session results with a quality rating of A or B were considered acceptable for the purposes of the study (Table 1). Other outcome measures included variations in FVC and $FEV_1$ between the best two trials the the number of trials required to achieve the best result.

**Table 1:** EasyOne™ Session Quality Guide

| QC Grade | Criteria |
|---|---|
| A | At least 3 acceptable tests and difference between best two FEV1 and FVC values is ≤ than 150ml |
| B | At least 3 acceptable tests and difference between best two FEV1 and FVC values is ≤ than 200ml |
| C | At least 2 acceptable tests and difference between best two FEV1 and FVC values is ≤ than 250ml |
| D | At least 2 acceptable tests but results are not reproducible |
| F | No acceptable test |

*Between Session Repeatability*

The reported and adjusted session quality ratings were compared across multiple visits to assess the repeatability of results over time.

*Detection of Abnormal Lung Function*

The primary measures used to indicate abnormal lung function were the forced vital capacity (FVC), forced expiratory volume in one second ($FEV_1$), and $FEV_1$/FVC ratio. Results were represented as the percent of predicted values defined by Gore et al.[8]. All results below 80% Predicted were considered abnormal.

**Table 2: Outcome Measures**

| | **Variables** |
|---|---|
| **Results Reliability** | EasyOne™ Session Quality<br>Variation in FVC between 2 best trials<br>Variation in FEV1 between 2 best trials<br>Number of trials to achieve best result |
| **Between session repeatability** | Variation in EasyOne™ session quality between visits |
| **Detection of abnormal lung function** | FVC (%pred)<br>FEV1 (%pred)<br>FEV1/FVC Ratio |

*Statistical Analysis*

Results were analysed using SPSS Version 16.0. Reported short-acting Bronchodilator use was the same in the Control and Intervention groups. It was decided that results would not be adjust on the basis of pretreatment with reliever medications. For process data, descriptive statistics were performed. For normally distributed outcome variables with three or more variable, we used repeated measure ANOVA. Pearson's Correlation Coefficient was used for the comparison of two continuous variables and chi-squared tests for two categorical variables.

*Ethical Approval*

The PACP study was approved by the Human Ethics Committees of the four Universities involved in the project (Sydney, Monash, Charles Sturt and Queensland). Approval number

**Results**

351 participants recruited across the 50 pharmacies performed spirometry during at least one visit. Table 2 presents patient demographics. There were 922 complete Spirometry sessions recorded over the period of the study with an average of 2.62 testing sessions per participant.

**Table 3. Participant Demographics**

| | Male<br>n = 142<br>(36.4%) | Female<br>n = 248<br>(63.6%) | All<br>n = 390<br>(100.0%) | |
|---|---|---|---|---|
| | Number (%) or Mean ±SD | | | Range |
| Age | 49.7 (±17.7) | 48.8 (±15.9) | 49.1 (±16.6 | 18 - 76 |
| BMI | 27.6 (±6.8) | 28.4 (±6.9) | 28.1 (±6.8) | 13.3 - 58.3 |
| Height (cm) | 175.0 (±8.5) | 161.9 (±7.0) | 166.7 (±9.9) | 143 - 198 |
| Respiratory Co-morbidity | 26 (18%) | 27 (11%) | 53 (13.6%) | |

| | | | | |
|---|---|---|---|---|
| Other Co-Morbidity | | 79 (56%) | 164 (66%) | 243 (62.3%) |
| Smoking History: | Non-Smoker | 74 (52.1%) | 160 (64.3%) | 234 (60.0%) |
| | Current Smoker | 37 (26.1%) | 50 (20.2%) | 87 (22.3%) |
| | Former Smoker | 31 (21.8%) | 38 (15.3%) | 69 (17.7%) |

*Acceptability and reproducibility*

Criteria indicating an acceptable start to spirometry trials were demonstrated in over 95% of all tests. An acceptable flow plateau indicating completion of expiration was evident in 87% of all spirometry tests. No significant improvement in test acceptability was demonstrated on repeat visits.

Reproducibility of trials, as measured by the best two FVC and FEV1 measurements being within 200ml of each other for both indices, was met in 70% of all trials, with a small but not significant improvement on reproducibility of spirometry at repeat visits. Table 4 presents full acceptability and reproducibility results.

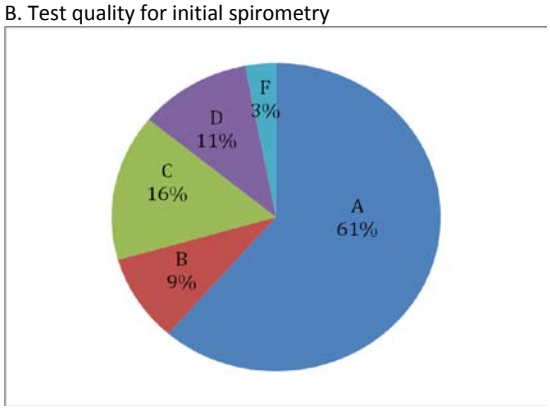
**Table 4: Spirometry acceptability and reproducibility**

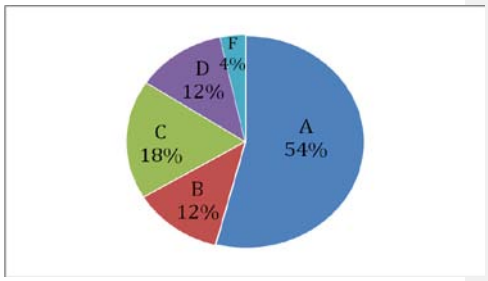
| | All Results | Initial Visit | Repeat visits |
|---|---|---|---|
| | n = 922 | n = 351 | n = 571 |
| FVC and FEV1 variability ≤ 200ml | 564 (70.3%) | 232 (66.0%) | 419 (73.4%) |
| FVC and FEV1 variability ≤ 250ml | 789 (85.6%) | 295 (83.9%) | 496 (86.8%) |
| At least one acceptable trial | 894 (97.0%) | 339 (96.6%) | 555 (97.2%) |
| Unacceptable test session | 133 (14.4%) | 56 (16.0%) | 75 (13.1%) |
| Acceptable Start | 892 (96.7%) | 339 (96.6%) | 554 (97.0%) |
| Acceptable Peak | 879 (95.3%) | 371 (94.5%) | 549 (96.1%) |
| Acceptable Plateau | 803 (87.2%) | 306 (87.2%) | 498 (87.2%) |
| Mean Forced Expiratory Time (sec) | 7.61 (SD 3.30) | 7.87 (SD 3.30) | 7.43 (SD 3.30) |
| FET ≥ 6.0 sec | 631 (68.4%) | 255 (72.7%) | 376 (65.9%) |
| FET < 6.0 sec | 291 (31.6%) | 96 (27.3%) | 195 (34.1%) |

*Test quality*

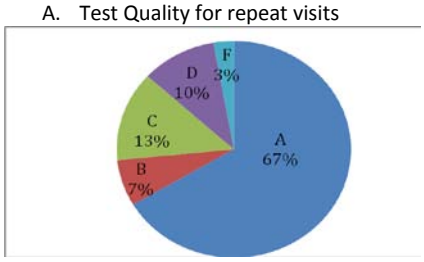
Test quality of A or B was achieved in 70% of all spirometry tests performed by pharmacists in this study. Figure 1 demonstrates test quality for all tests (A) and for initial (B) and repeat visits (C).

A. Test quality for all spirometry
B. Test quality for initial spirometry




A. Test Quality for repeat visits




There was an increase in the number of high quality results produced on repeat visits, but this was not considered significant.

*Diagnostic capacity*

When results for acceptable tests were considered (n=789), the mean value for all participants for FEV1 was 76.8% predicted (SD 22.7, range 19-128%), for FVC was 87.0% predicted (SD 19.2, range 19-141%) and mean FEV1/FVC was 71.6% (SD 13.8, range 29-99%).

*Severity classification*

FEV1 (less than 80% predicted) and FEV1/FVC (less than 75%) were reduced in 50% and 51% of participants respectively indicating clinical airflow obstruction. FEV1 with 24% demonstrating moderate to severe airflow limitation, based on standard criteria (ATS 1995). This was supported by 51% of participants having FEV1/FVC values less than 75%. Reduced FVC values, consistent with restrictive respiratory disease, were evident in 33% of participants/tests?

**Table 5: Spirometric classification**

| Parameter | Classification Range | n | % of total |
|---|---|---|---|
| FEV1 | ≥ 80% predicted* | 395 | 50.1% |

| | | | |
|---|---|---|---|
| | < 80% predicted | 394 | 49.9% |
| | 60 - 79% predicted (mild) | 206 | 26.1% |
| | 40 - 59% predicted (mod) | 143 | 18.1% |
| | < 40% predicted (severe) | 45 | 5.7% |
| FVC | > 120% predicted | 27 | 3.4% |
| | 80 - 120% predicted* | 502 | 63.6% |
| | < 80% predicted | 260 | 33.0% |
| FEV1/FVC | <75% | 403 | 51.0% |
| | 75 - 85%* | 294 | 37.3% |
| | > 85% | 92 | 11.7% |

* Normal Range (ATS, 1995)

*Discussion*

This study has demonstrated the capability of pharmacists to measure spirometry acceptably and reproducibly with improvement in test quality with increased experience of the pharmacist and participant team.

Spirometry measurement by the pharmacists in this study detected airflow limitation in over 50% of the participants which resulted in interaction with the pharmacist on asthma management and referral to general practitioners.

Alternative methods of feedback to pharmacists on test quality after their initial test sessions would enhance test quality.

*References*

Armour, C, Bosnic-Anticevich, S, Brillant, M, Burton, DL, Emmerton, L, Krass, I, Saini, B, Smith, L and Stewart, K. 2007, Pharmacy Asthma Care Program (PACP) improves outcomes for patients in the community. Thorax, Jun; vol. 62, 496 - 592.

National Asthma Council Australia. *Asthma Management Handbook 2006*. Melbourne, 2006.

Burton, MA, Burton, DL, Simpson, MD, Gissing, PM & Bowman, SL. 2004, Respiratory Function Testing: The impact of respiratory scientists on the training and support of primary health care providers. Respirology, 9 (2), 260-264.

American Thoracic Society, 'Standardization of spirometry, 1994 update', American Journal of Respiratory and Critical Care Medicine, 1995, vol. 152, pp. 1107–36.

Gore CJ, Crockett AJ, Pederson DG, Booth ML, Bauman A and Owen N. 1995, Spirometric standards for healthy adult lifetime nonsmokers in Australia. European Respiratory Journal, vol.8, 773-782.

References

Burton, M. A., Burton, D. L., Simpson, M. D., Gissing, P. M., & Bowman, S. L. (2004). Respiratory function testing: The impact of respiratory scientists on the training and support of primary health care providers. *Respirology, 9*(2), 260-264.

Eaton, T., Withy, S., Garrett, J. E., Mercer, J., Whitlock, R. M. L., & Rea, H. H. (1999). Spirometry in primary care practice: The importance of quality assurance and the impact of spirometry workshops. *CHEST, 116*(2), 416-423.

Miller, M. R., Hankinson, J., Brusasco, V., Burgos, F., Casaburi, R., Coates, A., et al. (2005). Standardisation of spirometry. [Article]. *European Respiratory Journal, 26*(2), 319-338.

Poels, P., Schermer, T., Jacobs, A., Akkermans, r., Hartman, J., Bottema, B., et al. (2006). Variation in spirometry utilization between trained general practitioners in practices equipped with a spirometer. *Scandinavian Journal of Primary Health Care, 24*(2), 81-87.

Schermer, T. R., Jacobs, J. E., Chavannes, N. H., Hartman, J., Folgering, H. T., Bottema, B. J., et al. (2003). Validity of spirometric testing in a general practice population of patients with chronic obstructive pulmonary disease (COPD). *Thorax, 58*(10), 861-866.

Standardization of Spirometry, 1994 Update. American Thoracic Society (1995). *Am. J. Respir. Crit. Care Med., 152*(3), 1107-1136.

White, P., Wong, W., Fleming, T., & Gray, B. (2007). Primary care spirometry: Test quality and the feasibility and usefulness of specialist reporting. *British Journal of General Practice, 57*(542), 701-705.

Yawn, B. P., Enright, P. L., Lemanske Jr, R. F., Israel, E., Pace, W., Wollan, P., et al. (2007). Spirometry Can Be Done in Family Physicians' Offices and Alters Clinical Decisions in Management of Asthma and COPD. *CHEST, 132*(4), 1162-1168.

National Asthma Council Australia. *Asthma Management Handbook 2006*. Melbourne, 2006