

This is the Author's version of the paper published as:

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Title: Pharmacy Asthma Care Program (PACP) improves outcomes for patients in the community

Year: 2007

Journal: Thorax

Volume: 62

Issue: June

Pages: 496-592

ISSN: 0040-6376

URL: <http://thorax.bmj.com/>

Keywords: asthma, community pharmacy services, disease management

Abstract: Background: Despite national disease management plans optimal asthma management remains a challenge in Australia. Community pharmacists are ideally placed to implement new strategies that aim to ensure asthma care meets current standards of best practice. In this study, the impact of a pharmacy asthma care program (PACP) on asthma control was assessed using a multi-site, randomised intervention versus control, repeated measures study design. Methods: Fifty Australian pharmacies were randomised into two groups: intervention pharmacies implemented the PACP (an ongoing cycle of assessment, goal setting, monitoring and review) to 191 patients over six months, while control pharmacies gave their usual care to 205 control patients. Both groups administered questionnaires and conducted spirometry testing at baseline and six months later. The main outcome measure was asthma severity/control status. Results: Ninety-one percent (186/205) of control patients and 86% (165/191) of intervention patients completed the study. The intervention resulted in improved asthma control: patients receiving the intervention were 2.7 times more likely to improve from 'severe' to 'not severe' than the control patients (OR=2.68, 95% CI=1.64, 4.37, $p<0.001$). The intervention also resulted in improved adherence to preventer medication (OR=1.89, 95% CI 1.08 to 3.30, $p=0.03$), decreased mean daily dose of reliever medication (difference -149.11mcg, 95% CI -283.87 to -14.36, $p=0.03$), a shift in medication profile from reliever only to a combination of preventer, reliever \pm LABA (OR=3.80, 95% CI 1.40 to 10.32, $p=0.01$) and improved scores on risk of non-adherence (difference -0.44, 95% CI -0.69 to -0.18, $p=0.04$), quality of life (difference -0.23, 95% CI -0.46 to 0.00, $p=0.05$), asthma knowledge (difference 1.18, 95% CI 0.73 to 1.63, $p<0.01$), and perceived control of asthma questionnaires (difference -1.39, 95% CI -2.44 to -0.35, $p<0.01$). No significant change in spirometry measures occurred in either group. Conclusions: A pharmacist delivered asthma care program based on national guidelines improved asthma control. The

sustainability and implementation of the program within the health care system remains to be investigated.

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to be submitted to Thorax

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Keywords: asthma, community pharmacy services, disease management

Word Count: 3643

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ABSTRACT

Background: Despite national disease management plans optimal asthma management remains a challenge in Australia. Community pharmacists are ideally placed to implement new strategies that aim to ensure asthma care meets current standards of best practice. In this study, the impact of a pharmacy asthma care program (PACP) on asthma control was assessed using a multi-site, randomised intervention versus control, repeated measures study design.

Methods: Fifty Australian pharmacies were randomised into two groups: intervention pharmacies implemented the PACP (an ongoing cycle of assessment, goal setting, monitoring and review) to 191 patients over six months, while control pharmacies gave their usual care to 205 control patients. Both groups administered questionnaires and conducted spirometry testing at baseline and six months later. The main outcome measure was asthma severity/control status.

Results: Ninety-one percent (186/205) of control patients and 86% (165/191) of intervention patients completed the study. The intervention resulted in improved asthma control: patients receiving the intervention were 2.7 times more likely to improve from 'severe' to 'not severe' than the control patients (OR=2.68, 95% CI=1.64, 4.37, $p<0.001$). The intervention also resulted in improved adherence to preventer medication (OR=1.89, 95% CI 1.08 to 3.30, $p=0.03$), decreased mean daily dose of reliever medication (difference -149.11mcg, 95% CI -283.87 to -14.36, $p=0.03$), a shift in medication profile from reliever only to a combination of preventer, reliever \pm LABA (OR=3.80, 95% CI 1.40 to 10.32, $p=0.01$) and improved scores on risk of non-adherence

(difference -0.44, 95% CI -0.69 to -0.18, $p=0.04$), quality of life (difference -0.23, 95% CI -0.46 to 0.00, $p=0.05$), asthma knowledge (difference 1.18, 95% CI 0.73 to 1.63, $p<0.01$), and perceived control of asthma questionnaires (difference -1.39, 95% CI -2.44 to -0.35, $p<0.01$). No significant change in spirometry measures occurred in either group.

Conclusions: A pharmacist delivered asthma care program based on national guidelines improved asthma control. The sustainability and implementation of the program within the health care system remains to be investigated.

The global prevalence of asthma ranges from 1% to 18% of the population[1] and it is considered to be one of the most common chronic diseases worldwide.[2] In Australia, asthma affects 11% of adults and 14% of children[3] and is the most commonly reported long-term condition in children aged 0 to 14 years.[4] The economic burden of asthma is substantial and includes both direct (eg hospitalisations and costs of medications) and indirect costs (eg days away from work).[2, 5]

Many countries now have national disease management plans for asthma[6-10] with the goals of reducing asthma severity and improving control. However, several studies have indicated less than optimal uptake of these plans.[11-13] In Australia, the Six Step Asthma Management Plan has been accepted as the national guideline for the optimal management of asthma.[14, 15] Since 1990, the National Asthma Council (NAC) of Australia has promoted this plan to health professionals,[15] undertaken epidemiological surveys on asthma, developed policies on asthma issues, and conducted national public education campaigns.[16] Despite this, asthma management practices in Australia remain suboptimal.[17, 18]

It has been suggested that new strategies are needed within primary care to ensure that asthma care meets current standards of best practice.[19] Community pharmacies offer accessible and convenient venues for patients with chronic illness and are often the first point of contact for people with asthma. Several pharmacy-based asthma care models have been implemented to service people with asthma and a variety of positive outcomes have been demonstrated. These include, improved peak flow readings[20-22] and symptoms scores,[21-23] optimised drug utilisation,[20-22, 24] reduction

in health care utilisation,[20, 25] and improvements in humanistic outcomes, such as self efficacy and asthma knowledge.[20, 24] However, to our knowledge, none of the above-mentioned service models adopted a standard set of national or international guidelines for the management of asthma.

In Australia, a community pharmacy-based asthma care model based on national guidelines (ie the NAC Six Step Asthma Management Plan) has been developed in consultation with pharmacists and was tested in a small pilot study.[26] Subsequently, this model has been refined to become the Pharmacy Asthma Care Program (PACP). The objective of the current study was to implement the PACP in three Australian states (New South Wales, Queensland and Victoria) and evaluate its effect on asthma control and other clinical and humanistic patient outcomes.

METHODS

Ethics

Approval for the study was given by the Human Research Ethics Committees of The University of Sydney, Monash University, Charles Sturt University, and The University of Queensland. Written informed consent was obtained from all participating pharmacists and subjects. The study was initiated in November 2004 and completed in July 2005.

Study design

The study utilised a multi-site, randomised intervention versus control, repeated measures design. Based on detecting a 23% change in asthma severity status,[26] with 90% power at the 5% significance level, and allowing for a 25% dropout rate and a cluster effect, a sample size of 195 in each group was determined. It was anticipated that a minimum of 40 pharmacies would be needed, recruiting an estimated 10 patients per pharmacy.

Pharmacists and patients

The sampling frame was all Quality Care Pharmacy Program (QCPP) accredited pharmacies (www.qcpp.com) in New South Wales, Victoria and Queensland, located within 300km of any of the four participating institutions. To ensure that rural and urban pharmacies were represented, the Pharmacy Access/Remoteness Index of Australia (PhARIA) (www.gisca.adelaide.edu.au/projects/pharia.html) was used to stratify pharmacies. Invitations to participate in the study were made to 174

pharmacies, 65% of which were selected by random number generation from PhARIA 1 (highly accessible) and 35% from PhARIA ≥ 2 (accessible to very remote). The proportions of PhARIA 1 and ≥ 2 reflect population distribution in Australia.

Inclusion criteria for pharmacies were: QCPP accreditation, availability of a computer system compatible with the spirometer software to be used in the study, ability to attend training sessions, and a minimum of two pharmacists on duty at any one time. The exclusion criterion for pharmacies was current involvement in any other research project.

Pharmacists were offered remuneration (AU\$200) for their participation on a per patient completed basis. Fifty-seven pharmacies agreed to participate and were randomly allocated to the intervention or control group (28 control and 29 intervention). Pharmacists were not informed as to group allocation; both groups were informed that they were providing an asthma care service involving spirometry.

Pharmacies were asked to recruit up to 10 subjects from amongst their customers. Inclusion criteria for the subjects were: age 18 to 75 years, previous diagnosis of asthma, and fulfilment of one or more of the following sub-criteria from the Revised Jones' Morbidity Index[27]:

- 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 (cough, breathlessness, wheeze etc), at least once a week, over the previous four weeks.
- No visit to a doctor for asthma within the last six months.

Subjects were excluded from the study if they had a terminal illness, were currently enrolled in another clinical trial, did not self-administer their inhaler, and/or did not speak English well enough to communicate with the pharmacist and complete the questionnaires independently.

Pharmacist training

Intervention pharmacists were given an asthma education manual and were trained on: risk assessment, pathophysiology of asthma, asthma medications, the NAC six-step asthma management plan, patient education, goal setting, adherence assessment, spirometry (by qualified respiratory scientists), and the PACP protocol, during a two day workshop delivered by the research team. Control pharmacists were trained on risk assessment, spirometry, and the control protocol during a one day workshop. All pharmacies were provided with EasyOne™ spirometers, spirettes and software. The EasyOne™ spirometer was selected as it meets all ATS/ERS recommendations for diagnostic spirometers[28] and has recently been demonstrated to maintain calibration with routine clinical use.[29]

Outcome measures

Both clinical and humanistic outcomes were used to evaluate the service (table 1).

Table 1 Measures used to evaluate the PACP

Outcome	Measure	Data Source
Clinical	Asthma severity/control	NAC's asthma severity assessment table[15]
	Lung function (FEV1, FEV1/FVC)	Spirometry
	Medication profile	Dispensed medication history
	Daily dose of medications	Dispensed medication history
	Inhaler technique	Inhaler technique checklist
	Adherence	Brief medication questionnaire[30]
	Action plan ownership	Self-reported data
Humanistic	Asthma-related quality of life	Asthma-related quality of life questionnaire[31]
	Perceived control of asthma	Perceived control of asthma questionnaire[32]
	Asthma knowledge	Consumer asthma knowledge questionnaire[33]

The primary outcome measure was change in overall asthma severity/control. This was assessed using a tool adapted from the NAC's asthma severity assessment table (www.nationalasthma.org.au).[15] Asthma severity/control was assessed based on self-reported frequency during the previous month of: asthma-related symptoms (eg cough, wheeze, shortness

of breath); waking at night due to asthma; chest tightness on waking; limitation in vigorous or moderate physical activities. Subjects who reported “never” for all parameters were classified as ‘mild’, those who reported 0-1 times per week for any parameter were classified as ‘moderate’, and those who reported >1 times per week for any parameter were classified as ‘severe’.

Inhaler technique was assessed using device-specific checklists,[26] which were consistent with GINA guidelines.[9] Subjects who demonstrated all steps in the checklist in the correct order were classified as having ‘correct’ inhaler technique. Pharmacists then demonstrated correct technique if needed. Risk of non-adherence was assessed using the Brief Medication Questionnaire,[30] in addition, subjects were classified as ‘adherent’ to preventer medications if they took 80 to 120% of preventer medication prescribed.

Procedures

At the beginning of the study, both intervention and control pharmacists assessed asthma severity/control,[15] conducted lung function testing (by spirometry) and had patients complete questionnaires to collect baseline data on outcome measures (table 1). These were repeated at six months post-baseline. Pharmacists were asked to achieve a spirometry quality grade of A, B or C in patient testing with the lowest grade equivalent to at least 2 acceptable tests with the best two FEV1 values within 250ml. Both groups also collected demographic details and asthma history. During the period between the baseline and six month visit, control patients received no intervention other than the pharmacist’s usual care, while the intervention

pharmacies instituted the PACP, beginning at the baseline visit. The PACP (based on the NAC's Six Step Asthma Management Plan)[14, 15] provided an ongoing cycle of assessment, management and review in collaboration with general practitioners (GPs). The PACP included: targeted counselling and education on the condition, medication, and lifestyle issues (eg trigger factors); inhaler technique review; adherence assessment; detection of drug-related problems; goal setting and review; and referral to a GP as appropriate (e.g. for a medication or dose change). All interventions were documented manually. In addition to the baseline and six month visits, the intervention patients visited the pharmacy at one month post-baseline, and had a three month post-baseline visit if there were outstanding issues (fig 1).

Adherence to the study protocol was monitored and facilitated during visits of project staff to the pharmacies. Pharmacists were also contacted regularly by telephone and sent monthly newsletters to keep them informed and motivated. Separate newsletters were provided to control and intervention pharmacies.

Statistical analysis

All data were analysed using SPSS for Windows 10.0™ or the SAS System for Windows 9.1™. A 2-tailed significance level of 0.05 was used in all analyses. Between group differences at baseline were compared using independent sample Student *t*-test for continuous parameters, and Pearson chi-squared test (with Yates' continuity correction in the case of dichotomous variables) for categorical parameters.

Outcomes for continuous parameters were evaluated using repeated measures multivariate ANOVA. For variables with differences at baseline, a univariate analysis of variance was conducted with baseline values as a covariate. For non-normally distributed data a non-parametric test (Mann Whitney U test) was used to confirm the results of the parametric analysis. Outcomes of categorical parameters were evaluated by binomial logistic regression with baseline data and group as covariates. For categorical parameters conducted solely on the intervention group McNemar's test was utilised to test for changes over time.

To account for any cluster effect (ie correlation of patients within pharmacies)[34] a multilevel logistic regression was performed on the primary outcome measure (asthma severity) using the SAS GLIMMIX procedure. Patients were defined as level 1 observations, and pharmacies defined as level 2 observations.

As final visit data could not be collected on non-completers, outcomes analyses were conducted on the available group only (ie those who completed the study). However, to reduce any bias, the analyses of the primary outcome measure (asthma severity) was repeated using an intention to treat approach assuming that for those with missing final data there was no change in initial values.

RESULTS

Comparison of control and intervention groups at baseline

During the course of the study, four control pharmacies and three intervention pharmacies failed to recruit any subjects, leaving 24 control and 26 intervention pharmacies. There were no significant differences in the characteristics of the participating pharmacies or pharmacists between the control and intervention groups (table 2).

Table 2 Characteristics of PACP pharmacies and pharmacists

	Control	Intervention
Number of participating pharmacies	24	26
Mean (SD) number of pharmacists on duty	1.9 (0.7)	2.0 (0.8)
Mean (SD) number of prescriptions dispensed per week	1161 (617)	1262 (810)
Location (N(%))		
stand-alone	18 (75)	14 (56)
shopping centre	3 (12.5)	4 (16)
other	3 (12.5)	7 (28)
Number of participating pharmacists	25	32
Male/female (%)	44/56	56/44
Age group (years) (N(%))		
≤35	10 (40)	14 (44)
36-55	14 (56)	12 (38)
≥56	1 (4)	6 (19)
Owner/employee (%)	52/48	44/56

In all, 396 patients (205 control and 191 intervention) were recruited and attended the baseline visit at their respective pharmacies. Of these, 186 control and 165 intervention patients completed the study (completion rates of

90.7% and 86.4% respectively). Forty-five subjects (19 control and 26 intervention) did not complete the study (fig 1). Ten intervention patients did not complete either intermediate visit (ie visit 2 or 3), but did return for the final visit.

The baseline characteristics of the patients are summarised in table 3. There were no significant differences in the baseline characteristics between those patients who were recruited and those who completed the study. Patients in both the intervention and control groups had similar demographic characteristics, spirometry measures, medication profiles, doses of asthma medications, adherence and humanistic measures at baseline (table 3). There was a higher proportion of previous smokers ($p=0.05$), and patients with another lung disease in addition to asthma (eg chronic obstructive pulmonary disease) ($p<0.001$) in the control group than in the intervention group. The control patients scored slightly better on the Brief Medication Questionnaire as well ($p=0.01$). The asthma severity/control status of the majority of patients (79%) was 'severe', with a higher proportion of intervention patients classified as 'severe' compared to control patients (88% vs 71%; $p<0.001$) (table 3).

Table 3 Baseline characteristics of PACP patients

	Control		Intervention		p value*
	Recruited	Completed	Recruited	Completed	
Number of patients†	205	186	191	165	
Age at recruitment (years)	50.4 (16.1)	50.9 (15.9)	47.5 (17.1)	49.3 (17.0)	0.08
Male/female (%)	39.5/60.5	39.2/60.8	32.5/67.5	30.3/69.7	0.18‡
Asthma severity/control					
mild	3 [1.5%]	3 [1.6%]	5 [2.6%]	5 [3.0%]	
moderate	56 [27.7%]	50 [27.2%]	18 [9.4%]	15 [9.1%]	p<0.001‡
severe	143 [70.8%]	131 [71.2%]	168 [88.0%]	145 [87.9%]	
Smoking status					
current	47 [23.0%]	41 [22%]	40 [20.9%]	32 [19.4%]	
former	45 [22.1%]	40 [21.5%]	26 [13.6%]	22 [13.3%]	0.05‡
never	112 [54.9%]	105 [56.5%]	125 [65.4%]	111 [67.3%]	
Other lung disease	39 [19.2%]	37 [19.9%]	15 [7.9%]	14 [8.5%]	<0.001‡

Spirometry

FEV1(% predicted)	75.4 (22.5)	74.1 (22.0)	79.3 (22.8)	79.7 (22.9)	0.12
FEV1/FVC (% predicted)	86.2 (15.7)	86.0 (15.6)	87.8 (15.8)	88.2 (15.9)	0.37
Daily dose of salbutamol (mcg)	382.8 (515.3)	328.6 (371.9)	436.3 (532.9)	450.9 (566.2)	0.41
BMQ Regimen screen¶	1.21 (1.11)	1.17 (1.09)	1.51 (1.09)	1.51 (1.11)	0.01
AQLQ§	4.26 (1.53)	4.21 (1.53)	4.45 (1.40)	4.45 (1.41)	0.22
CQ **	7.68 (2.29)	7.77 (2.24)	7.80 (2.24)	7.75 (2.23)	0.59
PCAQ††	25.09 (5.78)	24.97 (5.71)	26.15 (5.92)	25.96 (5.85)	0.08
Correct inhaler technique	not assessed		41 [23%]	39 [25.5%]	N/A
Asthma action plan	not assessed		36 [20.1%]	36 [22.9%]	N/A
Adherent to preventer medication	88 [57.9%]	82 [60.3%]	83 [53.2%]	74 [55.2%]	0.48‡
Medication profile					
reliever only	31 [15.7%]	30 [16.9%]	24 [12.8%]	22 [13.6%]	0.51‡
preventer + reliever ± LABA	166 [84.3%]	148 [83.2%]	163 [87.2%]	140 [86.4%]	

Values are mean (SD) or number [percent]; FEV1= forced expiratory volume in 1 second; FEV1/FVC = forced expiratory volume in 1 second / forced vital capacity; BMQ = brief medication questionnaire; AQLQ = Asthma-related Quality of Life Questionnaire; CQ = Consumer Asthma Knowledge Questionnaire; PCAQ = Perceived Control of Asthma Questionnaire; Reliever = short-acting beta 2

agonists or anticholinergic bronchodilators; Preventer = inhaled corticosteroids, theophylline derivatives, cromolyns, leukotriene-receptor antagonists, or oral corticosteroids; LABA = long-acting beta 2 agonists

* comparing intervention and control groups at recruitment using independent samples t-test unless otherwise noted

†not all patients responded to all questions and therefore numbers do not always add up to total

‡ chi-square test

¶ Range (best – worst): 1-7

§Range (best – worst): 2-10

**Range (worst – best): 0-12

††Range (best – worst): 11-55

Process evaluation

A total of 4747 interventions were delivered by the intervention pharmacists, with a mean (SD) of 27 (14) interventions per patient. The number of interventions delivered decreased with each subsequent visit. Overall, 96% (158/165) of intervention patients received interventions related to assessing asthma severity and control (eg identifying medication problems; education on asthma and its management; discussing health beliefs), 95% received medication adherence-related interventions, and 93% received interventions related to identifying and avoiding trigger factors. Interventions related to not having or not using an action plan were delivered to 89% of intervention patients, and 76% received interventions related to their inhaler technique.

Intervention patients, in partnership with their pharmacist, set a mean (SD) of 3 (2) goals for themselves during the study. Thirty percent (50/165) reported that they had achieved all of their goals by the end of the study, and 61% were continuing to work towards their goals. Fifty-three percent (87/165) of the intervention patients set goals related to medications (eg “*remembering to take medication even when well*” and “*reducing Ventolin[®] use*”). Exercise tolerance (eg “*increase exercise*” and “*be more active*”) was another common theme of goals (34% of intervention patients), as were asthma control (eg “*not wake up at night with asthma*”) (34%) and lifestyle triggers (eg “*quit smoking*” and “*avoid triggers*”) (27%).

Eighty percent (131/164) of intervention patients were referred to their GP at least once during the study, compared to only 21% (34/163) of the control patients ($p < 0.001$). The subsequent self-reported referral uptake rate was

72% (94/131) for the intervention group and 47% (16/34) for the control group. The most common reason for referral was "*Patient does not have a written asthma action plan*" (fig 2).

Primary outcome – asthma severity

The proportion of intervention patients who were classified as having 'severe' asthma declined significantly from 87.9% to 52.7% ($p < 0.001$) during the study, while that of the control group remained unchanged (71.2% to 67.9%; $p = 0.11$) (fig 3). A multilevel logistic regression model was used to adjust for the difference in severity at baseline, and account for any effect of cluster (ie pharmacy), and identified that patients in the intervention group were almost three times more likely to change from the 'severe' to 'not severe' (ie 'moderate' or 'mild') category compared to the control group (OR=2.68, 95% CI=1.64, 4.37, $p < 0.001$). The intra-pharmacy correlation coefficient (ie cluster effect) was very small (-0.006). When a more conservative intention to treat approach was used the results were similar (adjusted OR=2.42, 95% CI=1.51, 3.88, $p < 0.001$).

Secondary outcome measures

There were no significant changes in spirometry measures over the course of the study in either % predicted FEV1 or % predicted FEV1/FVC (table 4). Pharmacists achieved a quality grade of A, B or C in 85% of spirometry measurements; any measurements below a grade of C were excluded from analysis.

The PACP intervention, when compared with the control group, resulted in an increase in the proportion of patients adherent to preventer medications (OR=1.89, 95% CI=1.08, 3.30), an improvement in risk of non-adherence to medications (indicated by a decreased Brief Medication Questionnaire regimen score) (p=0.04), and a decrease in the mean daily dose of the reliever medication, salbutamol (p=0.03). The intervention also resulted in an increase in the proportion of patients using a combination of reliever, preventer, ± long-acting beta 2 agonist (OR=3.80, 95% CI=1.40 to 10.32) as opposed to a reliever only. The proportion of intervention patients with correct inhaler technique increased significantly during the study (p<0.001), as did the proportion of patients with an asthma action plan (p<0.001) (table 4). Inhaler technique and action plan ownership were not measured in the control group.

Significant beneficial effects of the PACP intervention were seen in the Asthma Quality of Life score (p=0.05), Consumer Asthma Knowledge scores (p<0.01) and Perceived Control of Asthma score (p<0.01) (table 4).

Table 4 Secondary outcome measures

Outcome Measure	Group	Mean change from baseline (95% CI)	p value on change*	Mean difference (95% CI)†	p value on difference‡
Spirometry					
FEV1 (% predicted)	Intervention (n=122)	-0.52 (-2.45 to 1.40)	0.59	-1.81 (-4.21 to 0.59)	0.14
	Control (n=135)	1.29 (-0.20 to 2.78)	0.09		
FEV1/FVC (% predicted)	Intervention (n=122)	1.39 (-0.29 to 3.08)	0.10	0.41 (-1.76 to 2.57)	0.71
	Control (n=135)	0.99 (-0.41 to 2.38)	0.17		
Daily dose of salbutamol (mcg)	Intervention (n=90)	-145.4 (-263.4 to -27.3)	0.02	-149.1 (-283.9 to -14.4)	0.03
	Control (n=92)	3.8 (-62.6 to 70.1)	0.91		
BMQ Regimen screen (range 1-7)	Intervention (n=156)	-0.64 (-0.84 to -0.44)	<0.01	-0.44 (-0.69 to -0.18)	0.04¶
	Control (n=173)	-0.20 (-0.36 to -0.04)	0.01		
AQLQ (range 2-10)	Intervention (n=160)	-0.64 (-0.83 to -0.45)	<0.001	-0.23 (-0.46 to 0.00)	0.05

CQ (range 0-12)	Control (n=186)	-0.41 (-0.55 to -0.27)	<0.001	1.18 (0.73 to 1.63)	<0.01	
	Intervention (n=160)	1.11 (0.80 to 1.41)	<0.001			
PCAQ (range 11-55)	Control (n=184)	-0.07 (-0.40 to 0.25)	0.67	-1.39 (-2.44 to -0.35)	<0.01	
	Intervention (n=153)	-2.53 (-3.36 to -1.70)	<0.001			
	Control (n=176)	-1.14 (-1.78 to -0.49)	0.001			
		Percent change from baseline (95% CI)	p value on change§	Odds ratio (95% CI)	p value on odds ratio**	
Correct inhaler technique	Intervention (n=140)	48.6% (39.2 to 58.0%)	<0.001	NA	NA	
	Control	NA	NA			
Asthma action plan	Intervention (n=156)	40.4% (31.9 to 48.9%)	<0.001	NA	NA	
	Control (n=191)	NA	NA			
Adherence to preventer medication	Intervention (n=127)	16.6% (6.4 to 26.7%)	<0.01	1.89 (1.08 to 3.30)	0.03	
	Control (n=121)	-1.7% (-11.9 to 8.6%)	0.88			
Medication profile						
	Intervention	reliever only	-5.7% (-10.0 to -1.3%)	0.02	3.80	0.01

(n=159)	preventer + reliever ± LABA	5.7% (-10.0 to -1.3%)		(1.40 to 10.32)
Control (n=177)	reliever only	0% (-3.8 to 3.8%)		
	preventer + reliever ± LABA	0% (-3.8 to 3.8%)	1.00	

Values are mean (SD) or number [percent]; NA= not applicable; FEV1= forced expiratory volume in 1 second; FEV1/FVC = forced expiratory volume in 1 second / forced vital capacity; BMQ = brief medication questionnaire; AQLQ = Asthma-related Quality of Life Questionnaire; CQ = Consumer Asthma Knowledge Questionnaire; PCAQ = Perceived Control of Asthma Questionnaire; Reliever = short-acting beta 2 agonists or anticholinergic bronchodilators; Preventer = inhaled corticosteroids, theophylline derivatives, cromolyns, leukotriene-receptor antagonists, or oral corticosteroids; LABA = long-acting beta 2 agonists

* paired t-test unless otherwise noted

†change in intervention group – change in control group

‡ repeated measures multivariate ANOVA unless otherwise noted

¶ ANCOVA

§McNemar test

**binomial logistic regression

DISCUSSION

A national pharmacy-based service (the PACP) for care of asthma patients has been implemented and has resulted in improved clinical and humanistic outcomes. Over the six months of the study, pharmacists' interventions resulted in improvements in: asthma severity/control, adherence to preventer medication, quality of life, asthma knowledge, and perceived control of asthma; as well as a decrease in the mean dose of the reliever medication, salbutamol and fewer patients relying solely on a reliever medication. The intervention patients also had improved inhaler technique and increased action plan ownership at six months compared to baseline.

These results are consistent with those achieved by other pharmacy-based asthma care models,[20-24] however in this case national asthma management guidelines were used as the framework for the service model so that current standards of best practice were met. In addition, local needs of pharmacists were incorporated into the pilot model[26] and therefore the sustainability of the service is likely to be higher.

The intervention pharmacists delivered a mean (SD) of 27 (14) interventions per patient. This suggests that management of asthma was less than optimal in the patients recruited to the study. In many previous studies, interviews and data collection have been performed by project staff and interventions carried out by the pharmacist.[35] In this study the pharmacist was the driver of the service and documented everything he/she did. The majority of interventions focussed on improving asthma control, adherence to medications, avoidance of trigger factors, inhaler technique, and action plan ownership. Inhaler technique was poor initially (24% with correct technique)

and improved substantially by the end of six months (71% with correct technique). Adherence to preventer medications also improved (from 54% to 71% adherent). Optimal inhaler technique will result in greater drug delivery and in the case of preventer medication, lead to better control of inflammation and asthma. Which of these interventions, alone or in combination, had a major impact on the improvement seen in asthma severity/control would need to be explored in future.

Asthma action plan ownership is a recommendation of the Six Step Asthma Management Plan.[14] Action plans are intended to enable people with asthma to recognise deterioration promptly and respond appropriately, and thus aid patients in maintaining control of their condition.[15] Referral for an action plan was the most commonly documented reason for GP referral. At baseline, the level of action plan ownership (23%) was similar to national data,[18] and this improved significantly to 64% of intervention patients after six months. Nonetheless it is still somewhat disappointing that not all patients had an action plan by the end of the study. While the reasons for this were not explored, we have previously reported that it is not possible to achieve ownership in 100% of people with asthma, despite referrals for this purpose.[26] Perhaps in future a better collaborative inter-professional network would need to be established so that all health care professionals supported action plan ownership.

The goal-setting process was an integral part of the PACP. Self-management of a condition such as asthma is vital, given its chronic and episodic nature. Other studies have shown that patients retain and use self-management skills effectively.[23, 36, 37] By working with explicit goals that

are personally relevant to the patient, rather than set by the healthcare professional, the patient invests energy and enthusiasm, and behaviour change is more likely.

The PACP was a service that involved, in the majority of cases, three visits over six months, and the follow-up rate was extremely high, suggesting that patients found the service worthwhile. Whether this was also due to the motivation of the pharmacists was not tested. Whether the service would need to be offered at the same intensity over a longer time period is not known, however given that the number of interventions decreased at each visit, the need for regular review should occur less often.

There are several limitations to this study. Firstly, the patients recruited to the study were selected based on a risk assessment for poorly controlled asthma,[27] and therefore the majority of patients were 'severe' or 'moderate' in terms of their asthma severity/control. Whether the positive results found in this study are generalisable to the whole community is not known. Secondly, there was a difference in asthma severity/control at baseline between the intervention and control group of patients. This concern was limited by performing a logistic regression, with patients re-categorised as 'severe' or 'not severe'. There were also more smokers and patients with other respiratory diseases in the control group. How this affected our results is uncertain. Thirdly, the outcomes we described were achieved in 6 months, we do not know if they are sustainable long term, or what further intervention would be required to sustain them. Fourthly, there were some changes in the control group over time, suggesting that administration of the questionnaires may have changed pharmacist and/or patient behaviour. Finally, the

diagnosis of asthma and the main outcome measure of asthma severity/control was based on self-reported data.[15] However, self reported asthma symptom scales are commonly used as an indicator of asthma severity[20-23] and in the pilot study for this project,[26] improvements in peak flow indices were seen concurrently with improvements in asthma severity/control.

Pharmacists are underutilised healthcare professionals who frequently see asthma patients in the community, many of whom may rarely consult a physician. Therefore, community pharmacies represent an excellent site to screen for patients at risk from their asthma. This study has shown that they can also add value to the care of asthma both in terms of clinical and humanistic outcomes for patients. Further studies are required to determine which components of the service are critical to improve asthma control and to determine the intensity of service required to sustain the improvement.

ACKNOWLEDGEMENT

We would like to thank the participating patients and community pharmacists. Our reference group, Professor Sandra Anderson, Drs Ron Tomlinson and Helen Reddel were all invaluable in our project design and implementation.

FUNDING

This work was funded by the Australian Department of Health and Ageing as part of the Third Community Pharmacy Agreement. The funding source had no involvement in the study design; in the collection, analysis, and interpretation of data; in the writing of this paper; nor in the decision to submit this paper for publication.

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Figure Legends

- Figure 1** Flowchart of PACP recruitment and completion.
- Figure 2** Reasons for referral to GP of intervention patients (N=128). Pharmacists could nominate one or more reasons per referral. *[15]
- Figure 3** Asthma severity status at baseline and six month (final) visit. The proportion of patients with severe asthma declined significantly in the intervention group but not the control group (OR=2.68, 95% CI=1.64, 4.37, $p < 0.001$).