

COMMUNITY PHARMACY

ASTHMA SELF-MANAGEMENT PROGRAM

PHARMACISTS FACILITATING EMPOWERMENT OF

PATIENT SELF-MANAGEMENT PRACTICES

THROUGH COLLABORATION



FINAL REPORT DECEMBER 2005



THE UNIVERSITY OF SYDNEY

FACULTY OF PHARMACY

Chief Researcher

Dr Sinthia Bosnic-Anticevich, Faculty of Pharmacy, University of Sydney

Tel: (02) 9351-5818

Fax: (02) 9351-4391

Email: sinthia@pharm.usyd.edu.au

Project team

Dr Sinthia Bosnic-Anticevich

Dr Lorraine Smith

Assoc. Prof. Ines Krass

Professor Carol Armour

Dr Bandana Saini

Dr Bernadette Mitchell

Acknowledgements

Australian Government Department of Health and Ageing – For funding this project through the Third Community Pharmacy Agreement.

Pharmacy Guild of Australia – For having the vision to support research into new clinical services for community pharmacy.

The Pharmacists – For enthusiastically taking on this program and giving us valuable feedback on the implementation of asthma self management principles in a disease state management service in community pharmacy. The pharmacists who participated were as follows:

Lois Dadd, Maha Ramsay, Michael Cross, Geoffrey Steward, Lois Cooper, Janny Yan, John Carabetta, Elizabeth Yeghykian, David Abeshouse, Julie Griffin, Elizabeth Zyl, Fona Lee, Martin Brooks, Simon Greville, James Boian, Anne Foss, David Preswick, Somaya Salib, John Frazer, Paul Carey, Tony O'Connor, Owen Barnett, Hala Attia.

Ms Minn Quah – For her assistance in conducting the follow-up patient satisfaction survey.

Table of Contents

Project Team	2
Acknowledgements	2
Executive Summary	6
Recommendations	9
1. Background	10
1.1 Asthma – Scope of the problem	10
1.2 Management of Asthma	11
1.3 Role of Pharmacists in Asthma Management	12
1.4 Patient Self-Management of Asthma	13
1.5 Study Rationale	15
1.6 Hypotheses	16
Methods	17
2.1 Research Design	17
2.2 Ethics Approval	17
2.3 Program Delivery	17
2.4 Sample Size	20
2.5 Recruitment of Pharmacists	21
2.6 Training of Pharmacists	21
2.7 Resources for Pharmacists	23
2.8 Recruitment of Participants	23
2.9 Study Protocols	24
2.10 Evaluation of the Program	28
2.11 Communication Strategies	30
2.12 Quality Assurance	30
2.13 Patient Satisfaction	30
2.14 Pharmacist Satisfaction	32
2.15 Statistical Analyses	33
3. Results	35
3.1 Recruitment and Completion	36
3.2 Baseline Assessment	39
3.3 Program Evaluation	49
3.4 Clinical Outcomes	58

3.5 Medication Profile	59
3.6 Humanistic Outcomes	62
4. Discussion	66
5. Study Limitations	74
6. Conclusion	75
7. References	76

List of Figures

Figure 1a: Research Design - Community Pharmacy Asthma Self-Management Program - <i>Intervention</i> Group	18
Figure 1b: Research Design - Community Pharmacy Asthma Self-Management Program - <i>Control</i> Group	19
Figure 2: Flowchart of participant recruitment and completion	37
Figure 3a: Types of New Goals set by Participants	49
Figure 3b: Types of Repeated Goals set by Participants	49
Figure 4: Total of New Goals and Repeated Goals at each Visit	50
Figure 5: Participants' perceptions responding to the usefulness of and satisfaction with the Community Pharmacy Asthma Self-Management Program	54
Figure 6: Proportion of participants' responding to the helpfulness of sections in the workbook provided in the Community Pharmacy Asthma Self-Management Program	55
Figure 7: Setting Goals and Strategies	57

List of Tables

Table 1: Breakdown of target by sample size	21
Table 2: Clinical and Humanistic Outcomes used to evaluate the impact of the Community Pharmacy Asthma Self-Management Program	28
Table 3: Demographic characteristics of Pharmacists	36
Table 4: Demographic characteristics of Pharmacies	37

Table 5:	Demographics and lifestyle characteristics of the Study Participants	40
Table 6:	Asthma, Smoking and Other Lung Conditions	42
Table 7:	Clinical parameters of the participants at baseline	43
Table 8:	Action Plan Ownership	44
Table 9:	Humanistic parameters of participants at baseline	44
Table 10:	Medication profile at baseline	45
Table 11:	Proportion of participants using salbutamol, fluticasone, salmeterol and/or budesonide at baseline	46
Table 12:	Total daily doses at baseline	47
Table 13:	Most commonly set strategies used by the Intervention participants to achieve their goals	51
Table 14:	Median scores of the usefulness of asthma related aspects (interventions) of the program	53
Table 15:	Clinical parameters of participants at baseline (Time 1) and Visit 4 (Time 2)	58
Table 16:	Medication profiles at baseline and final	59
Table 17:	Proportion of participants using salbutamol, fluticasone salmeterol and/or budesonide at baseline and final	60
Table 18:	Total daily doses (prescribed) at baseline and final	61
Table 19:	Humanistic parameters of participants at baseline (Time 1) and at Visit 4 (Time 2)	62

Appendices

Appendix 1:	Ethics approved letters
Appendix 2:	Training of Pharmacists
Appendix 3:	Promotional Material
Appendix 4:	GP Communication
Appendix 5:	Study protocols
Appendix 6:	Questionnaires
Appendix 7:	Pharmacist Newsletters
Appendix 8:	Participant Follow-up Survey
Appendix 9:	Strategies set by Intervention participants

EXECUTIVE SUMMARY

COMMUNITY PHARMACY ASTHMA SELF-MANAGEMENT PROGRAM

An important element of optimal asthma management is for people with asthma to practise productive self-management behaviours. Self-management behaviour is often difficult for patients with asthma and they require the support and commitment of all their health care professionals. Community pharmacists are ideally placed to identify people with asthma who require support in acquiring the skills necessary for optimal asthma self-management.

Objectives

The Community Pharmacy Asthma Self-Management Program was designed to: (i) examine the role of the community pharmacist in the management of patients with asthma; (ii) implement a specialized service for patients with asthma; (iii) equip people with asthma with skills to improve their self-management of their asthma, and (iv) assess the impact of this program on clinical and humanistic outcomes associated with asthma.

Critical Elements

Critical elements of the service included adopting a patient-centred approach to the problems patients were encountering with their asthma; applying a structured, step-wise cognitive-behavioural model of asthma self-management; patient education; support; and feedback to facilitate the acquisition of life-long asthma self-management skills.

Design

A randomised, controlled, parallel group study was designed to assess the impact of the Community Pharmacy Asthma Self-Management Program (Intervention Group) compared with “usual care” (Control Group) on clinical and humanistic outcomes.

Key Findings

Clinical and Humanistic Outcomes

- Patients' asthma control scores in both Intervention and Control groups improved significantly over time ($p=0.03$ and $p=0.01$, respectively), however there were no significant group differences ($p=0.75$).
- Medication adherence scores in the Intervention Group improved significantly over time ($p=0.04$), whilst Control Group scores did not ($p=0.64$).
- Asthma self-efficacy scores in the Intervention Group improved significantly over time ($p=0.01$) whereas Control Group scores did not ($p=0.95$).
- Asthma quality of life scores improved significantly for both Intervention and Control Groups ($p<0.01$ and $p=0.02$), however Intervention Group scores showed a greater improvement over time ($p<0.01$).

Process Evaluation

- Ninety one patients (35 Intervention and 56 Control) completed the service representing a completion rate of 76% (35/46) for the intervention patients and 89% (56/63) for the control patients.
- Over the course of the Asthma Self-Management Service, the pharmacists facilitated the goal setting process resulting in an average of 4 new goals and 5.8 repeated goals per patient.
- For the intervention subjects:
 - New Goals comprised 30.2% relating to triggers, 20.9% relating to asthma control, 17.3% relating to medication adherence and 12.2% relating to lifestyle issues.
 - Repeated Goals comprised 60.6% relating to triggers, 11.3% relating to lifestyle, 9.9% relating to medication adherence and 8.9% relating to exercise tolerance.
 - Patients set a total of 316 strategies representing an average of 9 strategies per patient.
- Patients reported a high level of satisfaction with the Asthma Self-Management Program, citing improvements in their knowledge about asthma and its triggers, self efficacy and the attainment of life-long skills in identifying and prioritizing asthma related issues by utilizing the goal setting process, as major benefits.

Conclusions

This study tested a self-regulatory model of illness behaviour in an asthma population in Australia and has shown that this type of intervention can have positive effects on asthma self-management. Further, the results indicate that community pharmacies can be an appropriate setting for the delivery of such a model.

The results from this study have demonstrated significant improvements in intervention group asthma self-efficacy, asthma quality of life, and adherence to medications ($ps < 0.05$) compared to the control group. Thus, pharmacists facilitating patients to improve their self-management skills can result in improvements in the health of people with asthma. Participant satisfaction with this intervention was very high, and participants reporting that the goals- and strategies- setting process they engaged in with their pharmacist was an extremely useful process. Participants also reported that the medical information and goal setting sections of the workbook as either very or extremely helpful aids. In addition the estimated costs of implementing the program in each pharmacy compare favourably with other specialised services delivered by community pharmacy.

The community pharmacists in the asthma self-management program have facilitated the improvement of patient self-management skills over a nine month period. The participants reported more positive attitudes about their asthma and felt that such a program should be more widespread. The asthma self-management program has the potential to deliver substantial improvements in asthma patient health outcomes.

RECOMMENDATIONS

Based on the results of this asthma self-management project the following recommendations are made:

1. Continuing education programs that incorporate elements of this self-regulation of illness behaviour model be delivered to Australian pharmacists to help improve patient asthma self-management practices. This is particularly important as Australia has one of the highest rates of asthma in the world.
2. Counselling aids (in the form of booklet/brochure/tip sheet) incorporating the wide range of strategies used by patients in the Asthma Self-Management Program which were found to be beneficial for asthma management, can be developed and distributed to community pharmacies.
3. Conduct further research into links between patient self-management of allergies and self-management of asthma.
4. Deliver a self-management intervention program testing its efficacy in a group of patients with mild, moderate and severe asthma.
5. Conduct further research that incorporates a targeted goal setting intervention with *clearly defined roles* for both the pharmacist and the patient and clear methodological links to outcome measures.
6. Develop, standardise and validate a measure of asthma self-management as a tool to measure targeted interventions by community pharmacists.

1. BACKGROUND

1.1 Asthma – Scope of the problem

Asthma is a major health problem in Australia, which affects both the physical and psychological well being of individuals, their families and the community. The incidence of asthma is on the rise worldwide and In August 1999, Australian Health Ministers announced asthma as a National Health Priority Area in recognition of the significant burden that asthma places on the Australian community in terms of health, social, economic and emotional costs. According to the latest National Health Survey, asthma affects 10-12% of adults and 14-16% of children in Australia ¹. The prevalence of asthma, reported as a long-term condition in the National Health Survey 2001, is approximately equal to the prevalence of injuries and diseases of the circulatory system, and greater than the prevalence of mental and behavioural problems, diabetes and cancer ². Also, asthma was the most commonly reported long-term condition in children (both males and females aged 0 to 14 years) ². The European Community Respiratory Health Survey which was conducted among adults aged 20 to 44 years in 35 centres in 16 countries, and included Australian data from Melbourne ³, concluded that Australia and New Zealand had the highest rate of asthma among young adults compared with other, predominantly European, Western countries.

Despite the efficacy of currently available medication, under-treatment and suboptimal management of asthma remain real issues in the Australian community ^{4, 5, 6}. Although not a common cause of death, asthma exacerbations can be fatal. In 2003 there were 388 reported deaths from asthma ⁷. This rate is much lower than death rates reported a decade ago and indeed, since 1989, there has been a steady decrease in asthma mortality rates. However, an issue of concern is that death rates for asthma increase markedly with age and, generally speaking, people living in remote areas and those living in socio-economically disadvantaged areas have higher death rates ^{8, 9}.

Asthma poses a burden at the individual level in addition to public health resources. In the National Health Survey, people with asthma rated their health lower than people without asthma ¹⁰. A greater proportion of people with asthma reported having

days away from work or study over a 2 week period (11.4%) than people without asthma (7.9%). Recent evidence has demonstrated that there is a higher prevalence of depression among people with asthma compared to people without asthma ¹¹.

1.2 Management of Asthma

In an attempt to optimise asthma management in Australia, the National Asthma Council has developed guidelines for asthma management. The guidelines consist of the six key elements to the optimal management of asthma in the acute and chronic state. These six steps have been named the Six Step Asthma Management Plan (AMP).

- Assessment of asthma severity (Step 1)
- Achieving best lung function (Step 2)
- Identifying and avoiding trigger factors (Step 3)
- Optimising medication (Step 4)
- Developing an action plan (Step 5)
- Educating and reviewing regularly (Step 6)

Since the formulation of the AMP plan, the National Asthma Council (NAC) has been actively involved in promoting it to all health professionals, undertaking epidemiological surveys on asthma, developing policies on asthma issues and conducting national public education campaigns. In association with other organisations interested in asthma care in Australia, the NAC has successfully coordinated a decade of education and advocacy about asthma aimed at GPs, health professionals and the general public ¹².

However, despite the active campaigning and promotion of the NAC and other advocacy groups such as State-based Asthma Foundations, asthma management practices in Australia are suboptimal. A recent study conducted in Melbourne has shown that over the past decade, there has been a 6.6% decrease in the proportion of people with asthma who have a written action plan, a 19.8% decrease in the proportion of people with asthma who monitor their peak flow and a 24.6% decrease in the proportion of patients having their lung function measured by their doctor ¹³.

Further, asthma management practices, such as action plan ownership and lung function measurement occur at a lower rate in rural communities compared to urban settings ¹⁴.

1.3 Role of Pharmacists in Asthma Management

Given the focus on improving primary care management of asthma, pharmacists often represent an underutilised resource. Pharmacists have high levels of therapeutic knowledge and skills, and are very often the first point of contact for people with asthma, i.e. to buy bronchodilator medication for worsening asthma or cough and cold remedies for a respiratory tract infection. Since pharmaceutical consumption is usually the main cost in asthma related expenditure, both at a personal and government level, appropriate use of asthma therapies is vital and pharmacists are in an ideal position to contribute to achieving optimal asthma management.

A number of pharmacy based asthma care models have been implemented overseas with a range of clinical outcomes including improved peak flow readings ¹⁵⁻¹⁸; improved symptoms scores ^{15, 18-20}; drug utilisation, e.g., improved regimen profiles ^{15, 18, 19, 21} and improved inhalation technique ^{22, 23}; reduction in health care utilisation, e.g., decrease in number of hospitalisations ^{17, 24} and decreased loss in productivity ²⁰; decreases in emergency room and acute care visits ^{24, 25}. Humanistic outcomes also often improve after pharmacists' asthma related intervention and care provision ^{17, 19, 21, 26, 27}. Improvement in self-efficacy and self management skills has been shown in some programs ^{26, 28, 29}, as has improvement in patients' asthma knowledge ^{19, 20, 26, 27, 30, 31}. Patients have expressed satisfaction with care, and have reported, in some cases, to be willing to pay for asthma care services from their pharmacists ^{16, 32}.

Notwithstanding these improvements, there remains a need to explore different models of care delivery to patients with asthma and make better use of health care resources in the community.

1.4 Patient Self-Management of Asthma

Effective self-management of asthma is a complex process which is influenced by patients' attitudes and beliefs about asthma, their perceived competence and confidence in their ability to self-manage their illness, and perceptions of high-quality healthcare provider support ³³⁻³⁶.

As part of the self-management process, patients are required to actively review their symptoms, medications, and lifestyle and make whatever adjustments necessary. These cognitive and behavioural processes may range from a simple recognition that there is an absence of any asthma symptoms on a given day, to a complex array of almost hourly assessments of symptoms and related daily activities, contact with known environmental triggers of asthma, and subsequent modifications of medications and behaviour. Research indicates that in respect to the management of asthma these self-management attributes are not widespread ³⁷. A diagnosis of asthma also means that the patient will consult with a wide range of healthcare professionals (HCPs), including physicians, nurses and pharmacists on a regular basis. Although campaigns, promotional activities and professional schemes aimed at improving asthma management practices ³⁸⁻⁴⁰ have been instigated, patient management of the disease remains a significant health issue.

In recognition of the importance of self-management in the long-term management of asthma and the need for pharmacy based programs in this area, we have, with the support of a Third Community Pharmacy Agreement Grant, developed the Community Pharmacy Asthma Self-Management Program. This involves the pharmacist assisting patients with self-management strategies so that they can take control of their asthma.

A model of self-regulation of illness behaviour

Self-regulation of illness can be viewed as an interaction of personal, behavioural and environmental processes ⁴¹. It has been defined as "self-generated thoughts, feelings and actions that are planned and cyclically adapted to the attainment of personal goals" ⁴². The term 'self-management' is often used interchangeably with

self-regulation, however self-management indicates a degree of active participation by the patient in management of their illness.

There are a range of physiological, behavioural and psychosocial factors that underpin the model of self-regulation of illness behaviour. This model proposes that the critical components involved in the self-management of an illness include facilitating the acquisition of skills and the development of confidence by the patient within a supportive healthcare environment. In relation to asthma, physiological factors would include establishing and maintaining good lung function and symptom severity/control. Psychosocial factors involve confidence in one's ability to undertake and execute the tasks required for good asthma self-management (termed 'self efficacy'), positive attitudes (eg. optimism), and affect (eg. normal levels of anxiety or depression). Adoption of productive and adaptive behavioural responses to the disease (eg. acquiring a sound knowledge of asthma, attendance at healthcare appointments and adherence to medications) also influence the individual's self-regulation of asthma.

Improving clinical management of chronic illness can be achieved through the application by HCPs of this model of self-regulation of illness behaviour⁴³⁻⁴⁷, which comprises a series of processes, including the development of explicit goals and strategies of personal relevance to the patient which address problem areas of their health. In order for the nominated goals and strategies to be effective the patient needs to know how to monitor their progress towards the achievement of their set goals. The model stipulates that these patient-driven processes require timely and supportive feedback by the HCP. Most importantly, this model of intervention is delivered through a written medium, so that the steps in the process (goals, strategies, monitoring, feedback) are reinforced, providing guidance to the patient at follow-up appointments between the patient and HCP. In keeping with the model of self-regulation of illness behaviour further written information should be provided for the patient, including relevant medical information written in lay terms regarding the illness.

By working with goals that are personally relevant to the patient their level of personal investment is maximized, thus potentiating behaviour change. Mastery of these important behaviours is facilitated through the step-by-step nature of the self-

regulation intervention and the opportunity for regular support and feedback from the HCP. This mastery will contribute positively to patient self-efficacy.

Self-regulation is becoming increasingly important in the community as life expectancy increases and the population becomes more susceptible to chronic illnesses such as circulatory and respiratory disorders. Not all individuals possess productive self-regulatory attributes and these are skills which can be taught to help control chronic illness.

1.5 Study Rationale

An important element of optimal asthma management is for people with asthma to practise self-management behaviour. The NAC promotes asthma self-management through the use of Asthma Action Plans which are written by general medical practitioners (GPs) and can be supported by pharmacists. Self-management behaviour is often difficult for patients and they require the support and commitment of all their health care professionals. Community pharmacists are ideally placed to identify people with asthma who require support in acquiring the skills necessary for optimal asthma self-management.

Hence, the aim of the current project was to implement the Community Pharmacy Asthma Self-Management Program (a new cognitive pharmacy program based on the psychosocial model of self-regulation) and to assess its impact on clinical and humanistic outcomes.

1.6 Hypotheses

H₀: There will be no difference between the Community Pharmacy Asthma Self-Management Program versus standard practice “Usual Care” on:

Clinical measures of asthma control

- medication adherence
- asthma action plan ownership

Humanistic outcomes

- asthma self-efficacy
- asthma quality of life
- anxiety
- depression
- patient and pharmacist satisfaction

2. METHODS

2.1 Research design

A randomised, controlled, parallel group study was designed to assess the impact of the Community Pharmacy Asthma Self-Management Program (delivered by specially trained community Pharmacists – Intervention Group) compared with “usual care” (delivered by a group of pharmacists who were not trained to deliver the Community Pharmacy Asthma Self-Management Program – Control Group) on clinical and humanistic outcomes.

The study design is outlined in Figure 1a and Figure 1b for the Intervention and Control Groups respectively.

2.2 Ethics Approval

Ethics approval from the University of Sydney Human Ethics Committee was obtained prior to commencement of this study. All participants were required to sign a “Participant’s information and consent form” prior to enrolment (Appendix 1).

2.3 Program Delivery

The Community Pharmacy Asthma Self-Management Program was developed from the self-regulation model of health behaviour and relates self-management behaviour within the context of asthma management. The Community Pharmacy Asthma Self-Management Program included the following components of service delivery:

- Identifying and prioritizing problem areas associated with asthma management as identified by the study participant
- Reducing exposure to asthma trigger factors
- Setting personal goals and developing strategies to achieve these goals
- Study participant monitoring of progress in terms of achieving their goals
- Study participant rewarding themselves when personal goals are achieved
- Feedback between the pharmacist and study participant at each Visit

Figure 1a: Research Design
Community Pharmacy Asthma Self-Management Program
Intervention Group

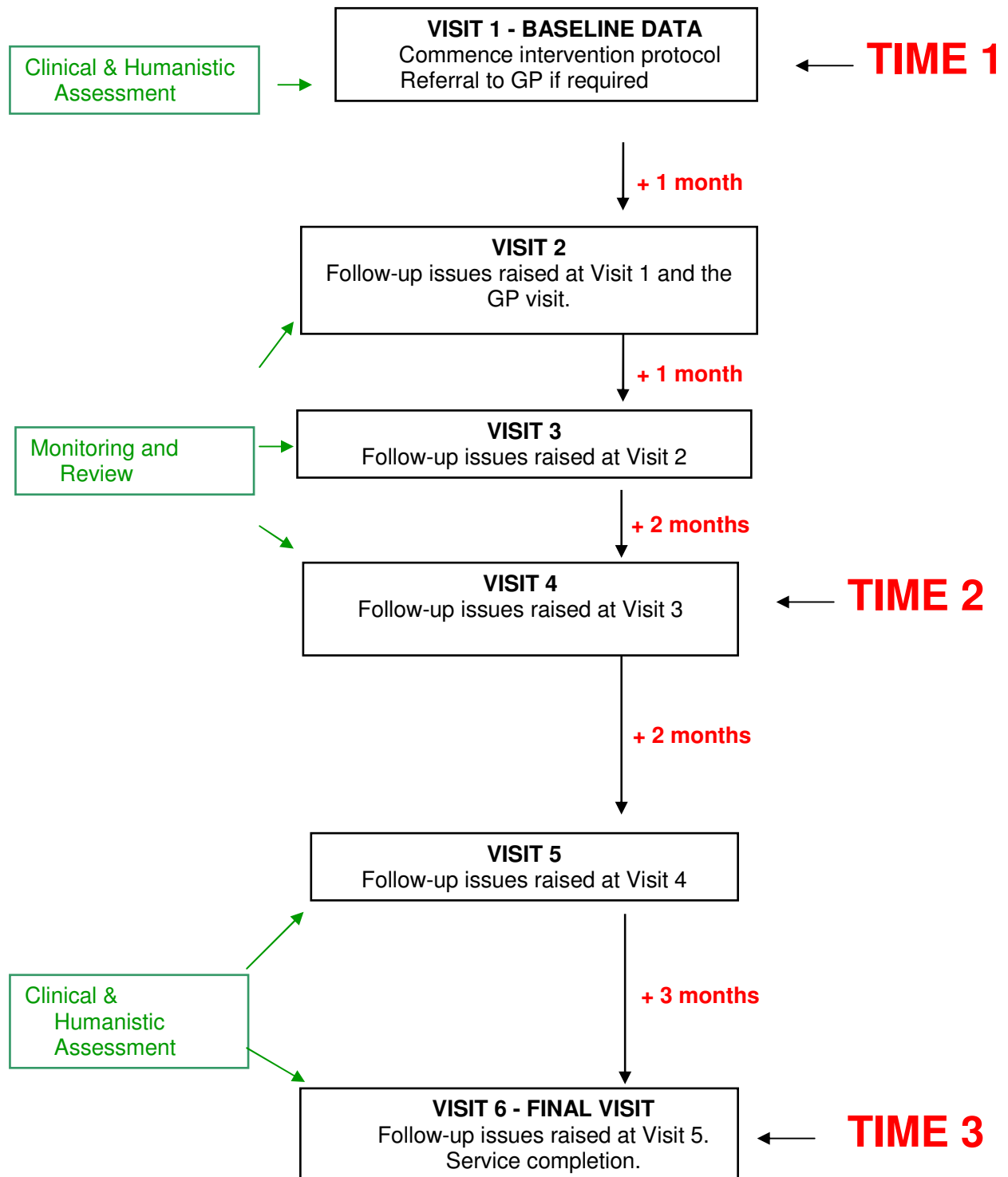
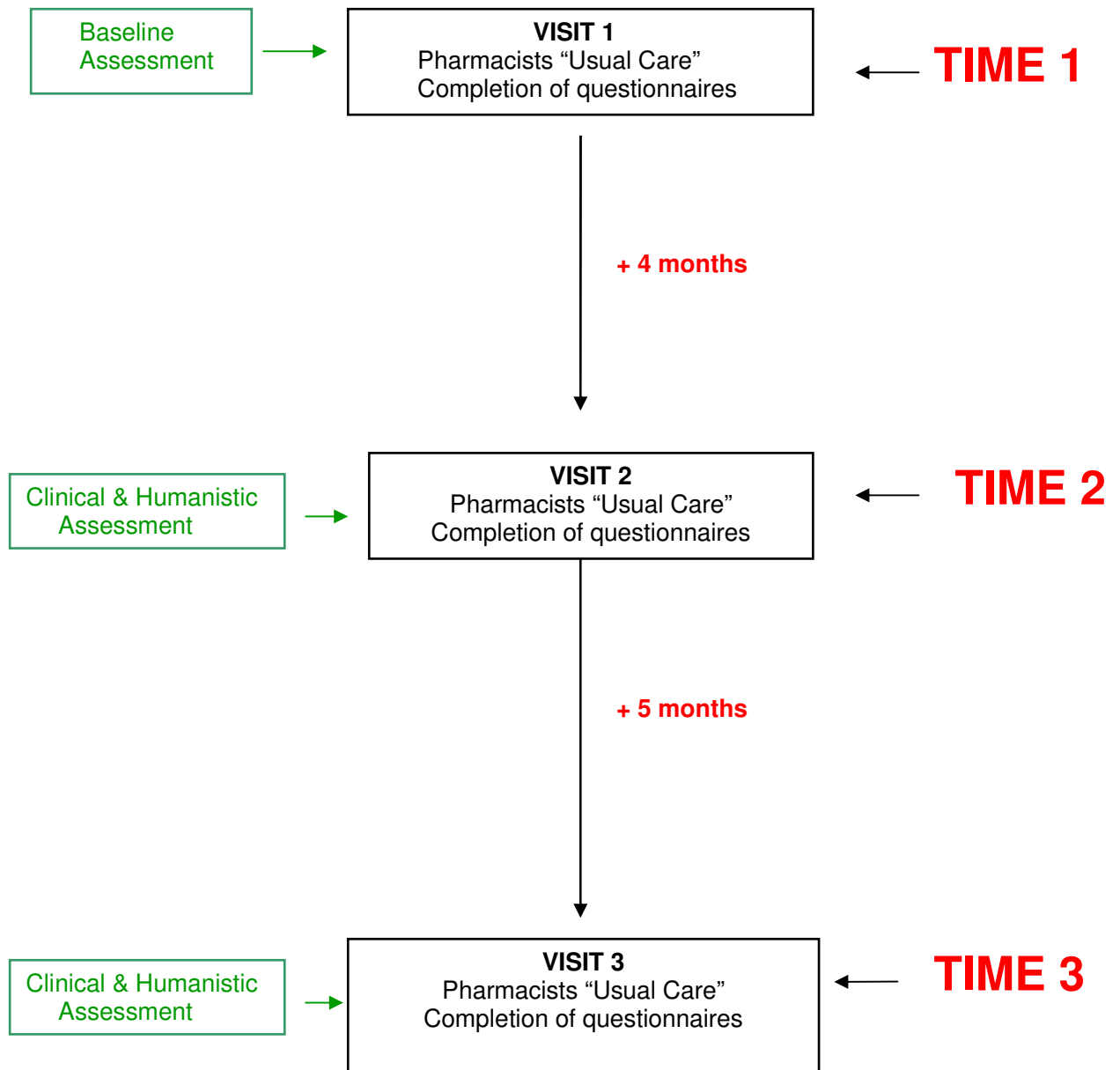


Figure 1b: Research Design
Community Pharmacy Asthma Self-Management Program
Control Group



The study was conducted in matched divisions of general practice, which were randomly assigned to the Control or Intervention Groups.

A total of 6 compulsory Visits were completed by participants in the Intervention Group (Figure 1a). Intervention participants received the program, an on-going cycle of assessment, management and review provided at regular intervals over 9 months in the pharmacy. The critical elements of the program were recorded in the participant workbook and consisted of facilitating participant self-management of asthma via a goal setting process, monitoring, education, adherence assessment, and reminders of follow-up checks related to asthma.

In contrast, 3 Visits were completed by participants in the Control Group (Figure 1b). Control participants completed the same set of questionnaires at 0, 4 and 9 months and received no intervention other than the usual pharmacist's advice/care for the duration of the study. All professional interactions performed by the Control Group were consistent with QCPP accredited standard practice and the pharmacists "Usual Care".

2.4 Sample Size

Based on the proportion of people with asthma who take up the Asthma Action Plan (a written self-management plan), and the current rate of use of these Plans – 20% of the population of people with asthma (unpublished data), increasing this to 50% with a power of 0.9, α 0.05, a total of 57 people with asthma would need to be included in each of the control and intervention groups. In order to account for a 20% drop out rate, this was increased to 70 people with asthma in each group to ensure adequate power for the study and allowing for the recruitment of ineligible subjects.

Therefore, to achieve the required sample size, 14 pharmacies were required for both the Control and Intervention Groups (Table 1). Each pharmacist was to recruit 5 subjects yielding a target sample size of 70 participants in each group (Table 1).

Table 1: Breakdown of target sample size

Intervention		Control	
<i>Pharmacies</i>	<i>Participants</i>	<i>Pharmacies</i>	<i>Participants</i>
14	70	14	70

2.5 Recruitment of Pharmacies

Pharmacists were chosen from a list of Quality Care Pharmacy Program (QCPP) accredited pharmacists in the Sydney Metropolitan area. It was envisaged that pharmacists localized in two Local Government Area Division of General Practice groupings would be recruited into the study. Initially a convenient location of North Shore Division of General Practice was chosen as one area, to which a second Division of General Practice was matched based on population and asthma demographics. These two Divisions of General Practice were then randomly assigned to Control or Intervention.

Every pharmacy in these two Divisions of General Practice was invited to participate in the study. All pharmacies in one Division of General Practice were assigned to the same group i.e. either Control or Intervention. This was to avoid possible contamination of patients which could results from participants inadvertently attending a control and an intervention pharmacy in the same local area. All pharmacists willing to participate in the study were enrolled following the signing of Informed Consent.

This resulted in a total of 28 QCPP accredited pharmacies being enrolled in the study (14 Control and 14 Intervention).

2.6 Training for Pharmacists

A one day workshop to train the pharmacists for participation in this study was held on 20th June 2004 with all pharmacists attending (both control and intervention group pharmacists). The aim of the workshop was to: provide the pharmacists with the most

up to date information on the various aspects of asthma, to train the Intervention community pharmacists to deliver the Asthma Self-Management Program according to the protocol and to train both groups of pharmacists in the document required for evaluation. Training common to both groups was delivered in the morning session. In the afternoon session the two groups received separate training.

All pharmacists (Intervention and Control groups) undertook the following training during the morning session of the workshop:

- * Overview and aims of the program
- * Pharmacists' participation in research
- * Asthma physiology and treatment
- * Asthma management issues in community pharmacy
- * Patient beliefs and attitudes regarding asthma
- * Medication taking behaviours
- * Communications skills

Intervention Group pharmacists undertook the following training during the afternoon session of the workshop:

- * Self-regulation of illness behaviour theory
- * Self-management model of asthma (goal setting, strategies, monitoring etc.)
- * Study protocol
- * Intervention process
- * Data collection
- * Practise

Control Group pharmacists undertook the following training during the afternoon session of the workshop:

- * Protocol
- * Data collection
- * Practise

The workshop content is found in Appendix 2.

2.7 Resources for Pharmacists

At the end of the workshop, pharmacists in both the intervention and control groups were provided with resources as follow up to the training and to assist them in recruiting 5 participants each into the study.

The resources included:

- Training Manuals for Intervention and Control pharmacists (each group received separate training manuals)
- NAC Handbook
- Documentation for participants
- Intervention participant workbooks
- Promotional Material for recruitment of participants
 - Poster to display in the pharmacy (Appendix 3)
 - Proposed content for advertorial in local paper

The pharmacists received remuneration for this program, i.e., \$90 per Intervention participant and \$50 per Control participant.

2.8 Recruitment of Participants

The eligibility criteria for participant enrolment in the Asthma Self-Management Program were as follows:

Subject Inclusion/Exclusion Criteria

A subject was **included** in the study if he/she:

- ◆ was ≥ 18 years of age
- ◆ had a previous diagnosis of asthma
- ◆ was/had been on preventer medication
- ◆ was able to speak and understand English
- ◆ was able to return for all follow-up visits

A subject was **excluded** if he/she:

- ◆ did not self-administer their inhaler
- ◆ did not speak English
- ◆ was currently undergoing review with his/her GP as part of the 3+ Visit Plan
- ◆ was currently involved in another asthma clinical study

Pharmacists utilised a number of strategies to recruit participants as follows:

- Sourcing potential participants with asthma from their customer database by identifying people on asthma preventer medications, such as Flixotide[®] and Pulmicort[®].
- New patients who presented with a script for an asthma medication were informed of the study and asked if they would like to participate.
- Advertorial in local newspaper
- Mail outs to local general practitioners (Appendix 4)
- Promotional material in the pharmacy (Appendix 3)

Once the participant was successfully recruited and met the eligibility criteria, an appointment was made for his/her baseline visit (Visit 1) at the pharmacy.

Participants were remunerated at the completion of the study, i.e., \$50 for each Intervention participant and \$30 for each Control participant.

2.9 Study Protocols

Two study protocols were developed, one for the Intervention group and one for the Control group (Appendix 5). All participating pharmacists were provided with an extensive participant file for each subject, which incorporated the protocol for recruitment, assessment, intervention, questionnaires (Appendix 6) and follow-up of each participant, as well as worksheets for the documentation of their interventions. In addition, a workbook was provided for each Intervention participant which the participant took away with them and brought back to each subsequent visit to record and monitor progress.

Clinical Protocol for Intervention Participants

Visit 1 – Assessment

On the first visit with the pharmacist (Visit 1), the Intervention participants completed 6 questionnaires that served as baseline measures of self-efficacy, self reported asthma-related quality of life, asthma control, medication adherence, anxiety and depression. The validated instruments used are described in detail in the next section. During this visit, the pharmacist recorded the participant's demographic details, asthma history, asthma severity, medication profile, medication adherence, asthma action plan ownership and their use of health care services over the preceding nine months. If the participant did not have a Written Action Plan, or had not had their asthma reviewed by the GP in the last 12 months, the pharmacist arranged a referral to the GP.

The participant set their own goals; strategies on how these might be achieved; and rewards once a particular goal was achieved. All this information was entered into the participant workbook.

Visits 2, 3, 4, 5 and 6 – Management and Review

During the next five visits (Visits 2 - 6), the participant worked together with the pharmacist via a goal setting process which consisted of patient-centred goals, strategies, monitoring and rewards for achieved goals. A Workbook was provided to the participant at Visit 1 which they could take home with them and bring back at the subsequent visits. The pharmacists also provided adherence support, discussed potential or actual drug related problems, and prompted for medical checks. The workbooks were annotated at each visit with progress on goals and strategies and whether any rewards were due. Goals to be achieved by the next visit were discussed by the pharmacist and the participant and documented in the workbook.

Where possible, the intervals between the visits were as follows:

- Recruitment and Visit 1 - 2 weeks

- Visit 1 and Visit 2 - 1 month
- Visit 2 and Visit 3 - 1 months
- Visit 3 and Visit 4 - 2 months
- Visit 4 and Visit 5 - 2 months
- Visit 5 and Visit 6 - 3 months

Ideally, all visits to the community pharmacists were to be completed in approximately 9 months.

Participants completed the same 6 questionnaires at Visit 4 (Time 2) and Visit 6 (Time 3) as they had completed at Visit 1. At Visit 6 the pharmacists also recorded the participant's asthma action plan ownership and their use of health care services over the preceding 9 months.

Intervention Participant Workbook

Each Intervention participant received a workbook from the pharmacist. The workbook was developed to assist the participant to develop useful and lifelong skills in asthma self-management. At each visit, the participant was asked to set personal goal(s) for themselves and discussed with the pharmacist strategies that might be implemented to achieve these goals. In addition, the participant discussed with the pharmacist how progress would be monitored and how the participant would be rewarded if a particular goal was attained.

This workbook was practical, structured, patient focused and was based on basic self-management principles which required the participant to write down explicit issues relating to their asthma. The exercise of getting the participant to write their own issues facilitated the goal setting process and reinforced it over time thereby increasing the likelihood of success. The goal setting sheets in the participant workbook were in duplicate so that the pharmacist could keep a copy in the participant folder while the participant took the workbook home with them.

To facilitate the patient's approach to setting their own goals and achieving them, the pharmacist asked the participants to follow a six step process as follows:

1. Identifying problem areas by breaking down their asthma-related issues into constituent parts, e.g., many sub-problems often wrapped up in one larger one. Also, the participant may not see the link between asthma control and lifestyle e.g., avoiding social, physical activities or using their medications in front of others.
2. Selecting one or two of the most 'important' issues e.g., may not necessarily be the most 'important' clinical goal but rather the goal(s) the participant wants to deal with. Also, to aim for easy-to-achieve goals at first if possible (this reinforces positive outcomes).
3. Setting goals directly related to step 2, i.e. straight-forward, patient-focused, easy to achieve goals.
4. Developing strategies to achieve their chosen goals. The participant was required to think about how a particular goal might be achieved and to identify a practical tool for achieving that goal.
5. Monitoring progress at each visit with the pharmacist at each visit and modifying goals accordingly.
6. Setting rewards by the participant for achieved goals. These could be directly related to a positive outcome of the achieved goal, e.g., being able to finish a game of basketball, or totally independent of the other elements of the goal setting process, e.g., recreational events, such as holidays, meals out, going to the theatre, etc.

Clinical Protocol for Control Participants

Once the Control participant was successfully recruited and met the eligibility criteria, an appointment was made for his/her baseline visit (Visit 1) to the pharmacy. During this visit, the participant completed 6 questionnaires that served as baseline measures of self reported asthma-related quality of life, asthma control, medication adherence, self-efficacy, anxiety and depression. The pharmacist recorded the participant's demographic details, asthma history, asthma severity, medication profile, medication adherence, and their use of health care services over the preceding nine months.

During the next nine months, the Control participants received “usual care” (i.e., no specialised asthma care in the pharmacy). Four months (Visit 2) and nine months (Visit 3) after Visit 1 the participant returned to the pharmacy and completed the same set of 6 questionnaires.

2.10 Evaluation of the program

The program was evaluated in terms of clinical and humanistic outcomes (Table 2).

Table 2: Clinical and Humanistic Outcomes used to evaluate the impact of the Community Pharmacy Asthma Self-Management Program

Primary Outcomes	Measures
Clinical	Asthma Control (ACQ [®]) Medication Adherence Report Scale (MARS [®]) Action Plan Ownership
Humanistic	Asthma Self-Efficacy (KASE-AQ [®]) Asthma Quality of Life (AQLQ [®]) Anxiety (DASS [®]) Depression (DASS [®]) Pharmacist and patient satisfaction
Secondary Outcomes	Measures
Patient satisfaction Patient perception about goal setting process Willingness to pay	Telephone questionnaire

Questionnaire Properties

The following questionnaires were used during the Asthma Self-Management Program:

The Asthma Control Questionnaire (ACQ[®])⁴⁹ is a validated instrument that contains 6 items relating to the level asthma control, including night and day symptoms, activity limitation, bronchoconstriction, and use of short-acting bronchodilators. The adequacy of asthma control is defined by international guidelines, which suggest that the primary goal of asthma treatment is to achieve optimum control and therefore reduce the risk of life-threatening exacerbations and long-term morbidity^{49, 50}.

The Medication Adherence Report Scale (MARS[®])⁵¹ is a 5-item scale which asks respondents to rate the frequency with which they engage in non-adherent behaviour on a 1-5 Likert scale. Scores for each of the 5 items were summed to give a score range from 5 to 25, where higher scores indicate higher levels of reported adherence.

The Asthma Self-Efficacy Questionnaire (KASE-AQ)⁵² is a validated instrument which contains a series of statements, written in the first person, to assess the participant's self-efficacy regarding their perceived ability to control their asthma and also to establish their opinions and knowledge relating to their condition.

The Asthma Quality of Life Questionnaire (AQLQ[®])⁵³ is a validated 20-item questionnaire developed in Australia and designed to measure the participant's perspective of the impact of asthma on their quality of life. The AQLQ contains subscales for breathlessness, mood disturbance, social disruption and concerns for health. Participants indicate the impact of their asthma on a Likert scale of 1 to 5 (1 = 'not at all', 5 = 'very severely').

The Depression, Anxiety, Stress Scales (DASS[®])^{54, 55} is a set of three self-report scales developed in Australia and designed to measure the negative emotional states of depression, anxiety and stress. To limit the paperwork and because depression and anxiety are known to be associated with asthma, the short version of the 2 scales, with 7 items each, for depression and anxiety were used in this study. The Depression Scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, anhedonia, and inertia. The Anxiety Scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect.

2.11 Communication Strategies

Several different strategies were used to communicate important information and study progress to the pharmacist. These included:

- Regular phone calls
- Emails
- Mail-outs
- Monthly newsletters - the Intervention pharmacies and the Control pharmacies received a different variation of this newsletter (Appendix 6)
- Visits to the pharmacies on a regular basis

To inform GPs on the Community Pharmacy Asthma Self-Management Program being conducted in pharmacies in their local areas, the following strategies were adopted.

- Australian Divisions of General Practice (ADGP) were contacted regarding publishing an item on the project in their newsletter.
- Letters were sent direct to GPs nominated by participating pharmacies.

2.12 Quality Assurance

Adherence to the study protocol was monitored on visits to each pharmacy by project officers. Participant data files were checked for accuracy and completeness to ensure the quality of the data.

2.13 Patient Satisfaction

Patient satisfaction was evaluated by a member of the research team via telephone using a mixed method (qualitative and quantitative) design utilizing a semi-structured survey instrument which included open-ended, yes/no and Likert-type questions (Appendix 7). The telephone questionnaire was conducted 3 months after the last enrolled participant completed the study. Participating pharmacists were asked to seek permission from the participant to allow the researcher to contact the participant directly. Verbal consent was given by the participant at the time of the telephone interview. All information provided by the participants was recorded during and

immediately after the interview session to maximize the accuracy of documentation of information reported. A random sample of intervention participants was interviewed until saturation of data was reached i.e. responses from patients rendered no new information/data. The interviews were conducted during September 2005.

Telephone Survey Development

The survey instrument (Appendix 7) consisted of both quantitative and qualitative components with an introductory statement explaining the purpose of the survey and a question regarding the respondents' willingness to participate in the survey itself.

The interviews took approximately 10 minutes and contained questions examining core issues including overall experience, program approval, participant understanding, participant expectations and outcomes, pharmacist interaction, willingness to pay, and future intentions. The telephone survey also served to verify the outcomes of the workbook.

Questions were formulated according to previously validated instruments^{30, 56} and by the research team. Several items from the Satisfaction with Pharmacist scale⁵⁶, a validated instrument to measure patient satisfaction with pharmaceutical care programs, were included in the participants' interviews. Both Intervention and Control participants were asked about satisfaction with provision of various aspects of the program and the quality of relationship with the pharmacist and level of care provided. Respondents were asked to rate each item on a five point Likert scale scored from 1 ('not useful at all') through 5 ('very useful') to evaluate usefulness of the program. In addition, Intervention participants were asked to rate how helpful they found the various sections of the asthma workbook that were used during the program on a scale of 1 ('not helpful at all') to 5 ('extremely helpful').

The participant interview data were analysed using thematic analysis. The text was coded into manageable thematic categories representing participant opinions of the program.

“Willingness-to-pay” (WTP)

Section 5 of the questionnaire consisted of the WTP questions (Appendix 7). Participants were asked whether they were willing to pay for such a program provided on a regular basis and, if yes, to state the amount they would be willing to pay.

2.14 Pharmacist Satisfaction

Pharmacist satisfaction is yet to be evaluated. The following method will be employed to assess pharmacist experiences and satisfaction:

All pharmacists who delivered the asthma self-management program will be invited to attend a focus group in the early part of 2006 at the University of Sydney. The focus group will take about 1 hour, will be audio taped and will be conducted by University staff members who have not previously been directly involved in the project. The topics covered in the focus groups will be semi structured and contain questions examining overall pharmacist experience of the program, including potential improvements, consumer perspective, GP communication, business impact and implications for future implementation.

2.15 Statistical Analyses

All data were analysed using SPSS 10.0™ for Windows™. An evaluable analysis was employed in this study.

Asthma History, Demographic and Lifestyle Characteristics at Baseline

Frequency tabulations were generated to examine the distribution of asthma history, demographic and lifestyle characteristics of the study participants at baseline. The

Pearson chi-squared test for independent samples (with Yates' continuity correction in the case of dichotomous variables) was used to test for differences in the proportions of categorical characteristics (e.g., gender, employment status, current diabetes management) between the Intervention and Control groups. An independent samples t-test or a Mann Whitney U test was used to test for differences between the Intervention and Control groups in normally (e.g., age) and non-normally distributed (e.g., years since diagnosis, use of medical services) continuous variables respectively.

Clinical, Humanistic and Medication Parameters at Baseline

Continuous parameters of the Intervention and Control groups at baseline were compared using an independent samples t-test (if normally distributed) or a Mann-Whitney U test (if non-normally distributed). Where possible, non-normally distributed variables were transformed to generate normal distributions. Categorical parameters (e.g., smoking status) were compared using Pearson chi-squared test (with Yates' continuity correction in the case of dichotomous variables).

Clinical, Humanistic and Medication Outcomes

If normally distributed, continuous parameters were compared at baseline and final visit using a paired t-test. A general linear model repeated measures multivariate ANOVA was then used to test for differences between the Intervention and Control groups.

Non-normally distributed continuous parameters were compared at baseline and final visit using a Wilcoxon signed ranks test. A Mann Whitney U test was also used to test for differences in score changes between the Intervention and Control group at the final visit. The control and intervention data was also compared in terms of change from baseline. For change in baseline comparisons, an Independent Samples T-test was used

The level of significance for all tests was set at $p < 0.05$.

Patient Satisfaction

Qualitative and quantitative data analysis was performed. Quantitative data assessing participants' perceived usefulness of specific aspects of the program and perceived helpfulness of sections in the workbook were analysed descriptively. Questions with "yes/no" responses were reported as a summary of the most frequently cited responses. Content thematic analysis was used to analyse all qualitative data.

Patient Perceptions about the Goal Setting Process

Data relating to patient perception about the goal setting process were ordinal and not normally distributed. Hence these data were analysed descriptively and represented as median scores.

3. RESULTS

Key Findings

Clinical and Humanistic Outcomes

- Patients' asthma control scores in both Intervention and Control groups improved significantly over time ($p=0.03$ and $p=0.01$, respectively), however there were no significant group differences ($p=0.75$).
- Medication adherence scores in the Intervention Group improved significantly over time ($p=0.04$), whilst Control Group scores did not ($p=0.64$).
- Asthma self-efficacy scores in the Intervention Group improved significantly over time ($p=0.01$) whereas Control Group scores did not ($p=0.95$).
- Asthma quality of life scores improved significantly for both Intervention and Control Groups ($p<0.01$ and $p=0.02$), however Intervention Group scores showed a greater improvement over time ($p<0.01$).

Process Evaluation

- Ninety one patients (35 Intervention and 56 Control) completed the service representing a completion rate of 76% (35/46) for the intervention patients and 89% (56/63) for the control patients.
- Over the course of the Asthma Self-Management Service, the pharmacists facilitated the goal setting process resulting in an average of 4 new goals and 5.8 repeated goals per patient.
- For the intervention subjects:
 - New Goals comprised 30.2% relating to triggers, 20.9% relating to asthma control, 17.3% relating to medication adherence and 12.2% relating to lifestyle issues.
 - Repeated Goals comprised 60.6% relating to triggers, 11.3% relating to lifestyle, 9.9% relating to medication adherence and 8.9% relating to exercise tolerance.
 - Patients set a total of 316 strategies representing an average of 9 strategies per patient.
- Patients reported a high level of satisfaction with the Asthma Self-Management Program, citing improvements in their knowledge about asthma and its triggers, self efficacy and the attainment of life-long skills in identifying and prioritizing asthma related issues by utilizing the goal setting process, as major benefits.

3.1 Recruitment and Completion

Pharmacies

Initially, 10 pharmacies were recruited into the Intervention group and 11 pharmacies into the Control group, all of whom attended the training. One of the Intervention pharmacies did not succeed in recruiting any participants and withdrew from the program, leaving a total of 9 Intervention and 11 Control pharmacies who participated in the Asthma Self-Management study. In the Intervention pharmacies, 10 pharmacists participated in the study while in the Control arm 13 pharmacists took part. A comparison of the demographic characteristics of Control and Intervention pharmacists (Table 3) and pharmacies (Table 4) confirmed their similarity. No statistically significant differences between groups were found with respect to any of the characteristics.

Table 3: Demographic characteristics of pharmacists

		Control n=13	Intervention n=10
		Number (%)	
Gender	male	8(62)	4(40)
	female	5(38)	6(60)
Age group (yr)	18-25	1(8)	1(10)
	26-35	1(8)	0(0)
	36-45	4(31)	2(20)
	46-55	7(54)	6(60)
	56-65	0 (0)	1(10)
	> 65	0(0)	0 (0)
Status	Owner/partner	9 (70)	7 (70)
	Salaried pharmacist	4 (30)	3 (30)

Table 4: Demographic characteristics of pharmacies

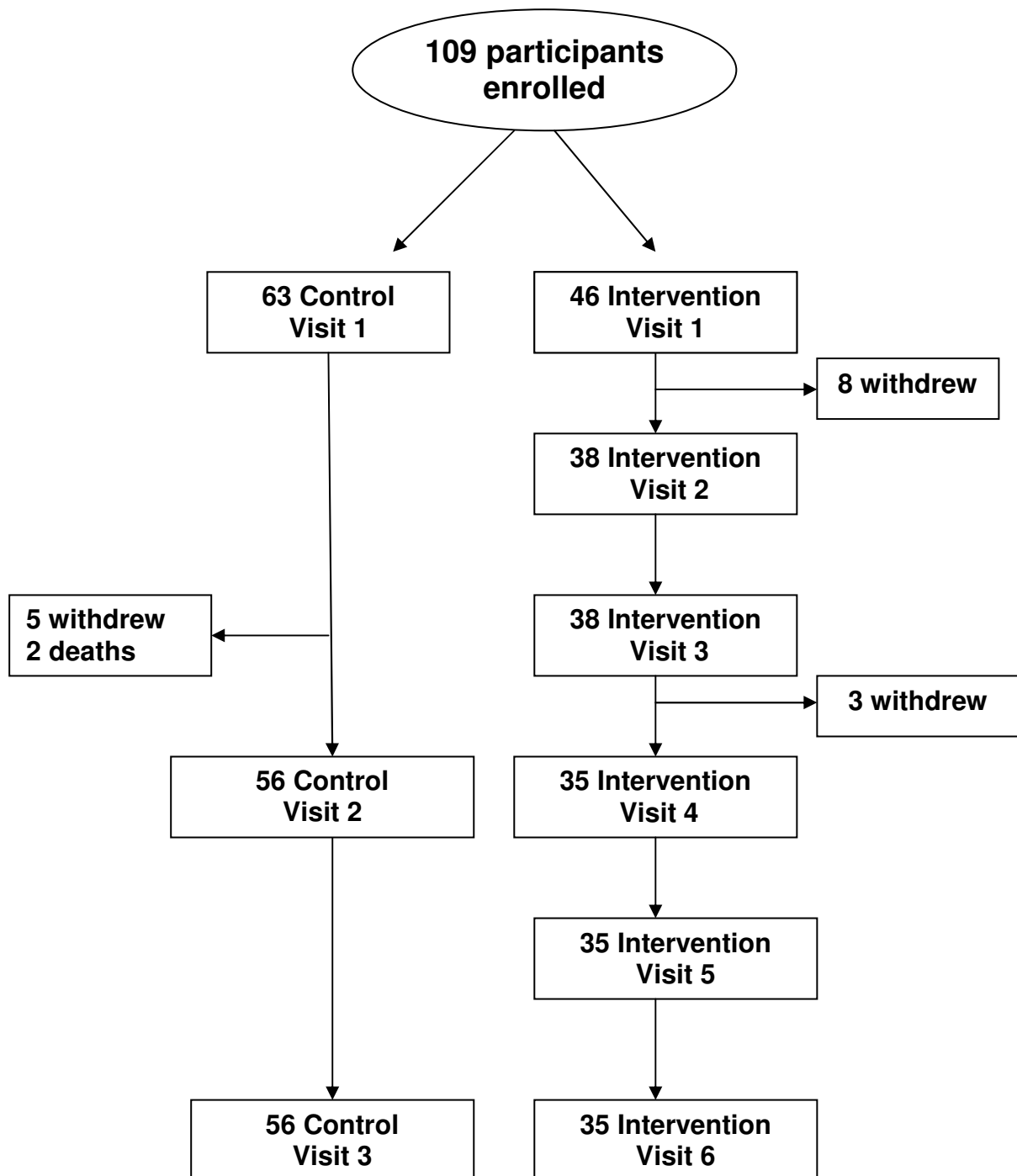
		Control n=11	Intervention n=9
		Number (%)	
Number of staff	1-2	5(4)	4(4)
	3-4	5(32)	4(57)
	5-6	1(64)	1(39)
Location	Stand alone/strip	8(73)	6(67)
	Shopping centre	3(27)	2(22)
	Mall	0(0)	1(11)
	Medical Centre	0(0)	0(0)

Study Participants

A total of 109 eligible participants were initially enrolled into the Asthma Self-Management study, 46 into the Intervention group and 63 into the Control group (Figure 2). Ninety one (35 Intervention, 56 Control) participants fully completed the study representing a completion rate of 76% and 89%, respectively. Difficulties in pharmacist recruitment resulted in not reaching the targeted number of pharmacists as per the research design. The most common barrier for pharmacists was the recruitment of an adequate number of participants into the study and various strategies were adopted to overcome this barrier, including tip sheets for pharmacists, advertising/editorial in local newspapers, form letters to participants on pharmacy databases, suggestions regarding approaching participants and on-going support and encouragement from the project co-ordinator.

It should be noted that there is variation in the denominators (n) in the tables presented throughout the results section and this is due to missing data for different variables.

Figure 2: Flowchart of participant recruitment and completion



3.2 Baseline Assessment

Demographics and Lifestyle Characteristics of Participants

Table 5 shows that the demographics and lifestyle characteristics of the Intervention and Control study participants were generally very similar. A notable exception to this was that although males and females were equally represented in the Intervention group, there were substantially more females in the Control group than in the Intervention group, however this difference was not statistically significant. The Intervention group also had a higher ratio of people working to not working and were slightly younger than the Control group but these differences were not statistically significant.

The Control group participants were very similar with respect to their level of exercise with 69 % overall indicating that they engaged in regular exercise. The most typical exercise was walking, the duration of the exercise 30-60 minutes, and the frequency was mostly more than 5 times per week.

Table 5: Demographics and lifestyle characteristics of the Study Participants

		Intervention	Control	All
		(Number (%) or Mean \pm SD)		
<i>Age (n= 107)</i>		51.42 (\pm 18.38)	54.45 (\pm 20.13)	53.18 (\pm 19.38)
<i>Gender (n=108)</i>	Male	21 (46.7)	21 (33.3)	42 (38.9)
	Female	24 (53.3)	42 (66.7)	66 (61.1)
<i>Work Status (n=103)</i>	Working	25 (56.8)	28 (47.5)	53 (51.5)
	Not Working	15 (34.1)	26 (44.1)	41 (39.8)
	Student	4 (9.1)	5 (8.5)	9 (8.7)
<i>Engage in exercise (n=106)</i>	Yes	32 (69.6)	41 (68.3)	73 (68.9)
	No	14 (30.4)	19 (31.7)	33 (31.1)
<i>Type of exercise</i>	Walking	21 (63.6)	27 (65.9)	48 (64.9)
	Other	11 (36.4)	14 (34.1)	25 (35.1)
<i>Frequency of exercise</i>	1-2 times p/week	8 (25.0)	13 (32.5)	21 (29.2)
	3-4 times p/week	10 (31.3)	8 (20.0)	18 (25)
	>5 times p/week	14 (43.8)	19 (47.5)	33 (45.8)
<i>Duration of exercise</i>	< 30 mins	4 (12.5)	11 (27.5)	15 (20.8)
	30 – 60 mins	20 (62.5)	18 (45.0)	38 (52.8)
	>60 mins	8 (25)	11 (27.5)	19 (26.4)

P>0.05 for all variable

History of asthma, smoking and other lung conditions

The majority of participants in the study were diagnosed with asthma when they were 13 or more years of age (Table 6). A higher proportion of participants in the Control group had received more asthma reviews from their GP (74.6%) in the preceding 12 months than the Intervention group. In line with the protocol (Refer Figure 1a and 1b), the Intervention and Control participants who had not had their asthma reviewed in the previous 12 months received a referral to the GP. A higher proportion of the Control participants reported having hospital admissions in the previous 12 months

and life threatening attacks in the previous five years relating to their asthma than the Intervention group (8.7% and 6.5%, respectively), but these differences were not statistically significant ($p=0.06$ and $p=0.09$, respectively).

Table 6 also shows the history of smoking and other diagnosed lung conditions for the study participants. Approximately 9% of all participants were current smokers. The smokers in the Control group reported smoking more cigarettes on average per day than the Intervention group (12 vs. 3 cigarettes per day) and had been smoking for a longer period (18.2 years vs. 12.3 years). However, a higher proportion of Intervention participants had been smokers in the past compared with the Control group (37.5% vs. 28.0% respectively) (Table 6). There were no significant differences in the proportion of Intervention and Control participants who had never smoked.

There was a significantly higher proportion of participants in the Intervention group (38.7%) who reported that they had another diagnosed lung condition (Table 6), such as chronic obstructive pulmonary disease (COPD), emphysema, airway limitation or chronic bronchiectasis, than in the Control group (14.9%); $p<0.05$. However, only 78 of the participants responded to these questions which were added as a supplementary page to the participant folders after the study had commenced. Therefore, since there is a substantial proportion of missing data, no firm conclusions can be made from this significant result.

Table 6: Asthma, Smoking and Other Lung Conditions

		Intervention	Control	P-value	All
		(Number (%) or Mean \pm SD)			
<i>Asthma Onset</i> (<i>n</i> =107)	Infancy	4 (8.9)	8 (12.9)	>0.05	12 (11.2)
	2-12 years	14 (31.1)	14 (22.6)		28 (26.2)
	> 12 years	27 (60.0)	40 (64.5)		67 (62.6)
<i>Asthma Review</i> (<i>last 12 months</i>) (<i>n</i> =108)	Yes	31 (68.9)	47 (74.6)	>0/05	78 (72.2)
	No	14 (31.1)	16 (25.4)		30 (27.8)
<i>Hospital admission</i> (<i>n</i> =106)	Yes	4 (8.7)	15 (23.4)	>0.05	19 (17.9)
	No	42 (91.3)	45 (70.3)		87 (82.1)
<i>Life threatening attack</i> (<i>n</i> =106)	Yes	3 (6.5)	12 (20)	>0.05	15 (14.2)
	No	43 (93.5)	48 (80)		91 (85.8)
<i>Other Lung Condition*</i> (<i>n</i> =78)	Yes	12 (38.7)	7 (14.9)	<0.05	19 (24.4)
	No	19 (61.3)	40 (85.1)		59 (75.6)
<i>Smoker*</i> (<i>n</i> =78)	Current	2 (6.3)	5 (12)	<0.05	7 (9.0)
	Former	12 (37.5)	13 (28.0)		25 (32.0)
	Never	18 (56.2)	28 (60.0)		46 (59.0)

**The questions on "Other Lung Conditions" and "Smoking" were added to the participant folders after the commencement of the project and as a result not all participants completed this.*

Clinical Parameters at Baseline

The clinical measures, asthma control and medication adherence, were measured by the self-reported questionnaires ACQ[®] and the MARS[®], respectively. In addition, asthma action plan ownership was also measured. Overall, the Intervention and Control participants were well matched for these parameters at baseline (Time 1) with no significant differences ($p>0.05$) observed between the 2 groups in relation to asthma control and medication adherence (Table 7).

Table 7: Clinical parameters of the participants at baseline (n=88)*

		Intervention	Control	p value
		(Number (%) or Mean \pm SD)		
<i>Asthma Control</i> [#]	ACQ [®]	1.52 (\pm 1.26)	1.83 (\pm 1.15)	>0.05
<i>Medication adherence</i> [±]	MARS [®]	3.99 (\pm 0.84)	4.19 (\pm 0.83)	>0.05

*only calculated for those who completed the study

[#] Score Range 0 – 6

[±] Score Range 1 – 5

At baseline, the asthma control status of both the Intervention and Control groups was mild and although the score for the Control group was higher than for the Intervention group this difference was not significant ($p>0.05$).

There was no statistically significant difference in medication adherence between the Intervention and Control groups (Table 7) with both groups reporting a high level of adherence to their asthma.

In addition, action plan ownership at baseline is shown in Table 8. The overall ownership of written action plans was 28.7%. The Control group had a lower number of written action plans than the Intervention group but this difference was not statistically significant.

Table 8: Action Plan Ownership (n=108)

		Intervention	Control	All
		(Number (%) or Mean \pm SD)		
Written Action Plan	Yes	17 (37.8)	14 (22.2)	31 (28.7)
	No	28 (62.2)	49 (77.8)	77 (71.3)

Humanistic Parameters at Baseline

Overall, the Intervention and Control participants were well matched at baseline in terms of the humanistic parameters being measured in this study (Table 9) with no significant differences observed between the 2 groups in asthma self-efficacy, asthma quality of life, anxiety or depression.

Table 9: Humanistic parameters of participants at baseline (n=88)*

		Intervention	Control	p value
		(Number (%) or Mean \pm SD)		
<i>Asthma Self-Efficacy</i> [#]	KASE-AQ [©]	2.18 (\pm 0.43)	2.15 (\pm 0.61)	>0.05
<i>Asthma Quality of Life</i> [±]	AQLQ [©]	2.20 (\pm 0.89)	2.18 (\pm 0.85)	>0.05
<i>Anxiety</i> [^]	DASS [©]	1.67 (\pm 0.59)	1.70 (\pm 0.68)	>0.05
<i>Depression</i> [»]	DASS [©]	0.47 (\pm 0.68)	0.53 (\pm 0.67)	>0.05

*only calculated for those who completed the study

[#] Score Range 1 - 5

[±] Score Range 1 – 5

[^] Score Range 0 – 3

[»] Score Range 0 – 3

Asthma Medications at Baseline

There was a statistically significant difference ($p = 0.03$) in the medication profile between the Intervention and Control groups at baseline (Table 10). Overall, 10.6% of participants at baseline were on a reliever only and 60% were using both a preventer and a symptom controller in addition to the reliever. None of the Intervention participants were on a reliever only compared with 17.6% of the Control participants. In addition, a higher proportion of Intervention participants at baseline were using both a preventer and a symptom controller in addition to the reliever compared with the Control group ($p=0.03$).

Table 10: Medication profile at baseline (n=85)*

	Control	Intervention	P-values	All
	Number (%)	Number (%)		Number (%)
R only	9 (17.6)	0 (0)	>0.05	9 (10.6)
P ± R	15 (29.4)	10 (29.4)	>0.05	25 (29.4)
P + SC + R	27 (53.0)	24 (70.6)	<0.05	51 (60.0)

R = reliever, P = preventer, SC = symptom controller

* Only for those who completed the study

Medications and Defined Daily Doses

The most common asthma medications used by the participants of the study at baseline were; salbutamol (85.9% of participants), fluticasone (73.8%), salmeterol (51.8%) and budesonide (16.9%). At baseline there were no significant differences in the proportions of Control and Intervention participants using salbutamol, fluticasone, salmeterol or budesonide (Table 11).

There were no significant differences between the Intervention and Control groups in the total daily doses of salbutamol, fluticasone or budesonide at baseline, as recorded from the dispensed medication histories provided by the pharmacists for each participant (Table 12). The Control group had a significantly higher total daily dose for salmeterol than the Intervention group ($p= 0.01$).

Participants using nebulisers to take salbutamol were not included in the dosage analysis as the doses of nebulisers and metered-dose inhalers are not comparable. Salbutamol is available as an over the counter medication and a substantial number of participants reported taking this “as needed”, hence making it impossible to calculate the total daily dose in these cases.

Table 11: Proportion of participants using salbutamol, fluticasone, salmeterol and/or budesonide at baseline

	Control	Intervention	All
	Number (%)	Number (%)	Number (%)
Salbutamol (n=78)	43 (89.6)	24 (80.0)	67 (85.9)
Fluticasone (n=84)	35 (70.0)	27 (79.4)	62 (73.8)
Salmeterol (n=83)	24 (49.0)	19 (55.9)	43 (51.8)
Budesonide (n=83)	7 (14.3)	7 (20.6)	14 (16.9)

Table 12: Total daily doses salbutamol, fluticasone and budesonide at baseline

	Control	Intervention	All
	Mean (\pm SD)	Mean (\pm SD)	Mean (\pm SD)
Salbutamol (mcg)	600 \pm 283 (n=2)	700 \pm 115 (n=4)	667 \pm 163 (n=6)
Fluticasone (mcg)	691 \pm 316 (n=32)	598 \pm 258 (n=23)	652 \pm 294 (n=55)
Salmeterol* (mcg)	90 \pm 37 (n=23)	60 \pm 26 (n=15)	78 \pm 36 (n=38)
Budesonide (mcg)	680 \pm 403 (n=6)	960 \pm 456 (n=5)	807 \pm 431 (n=11)

Prescribed doses as recorded on participants' dispensed medication histories.

* p = 0.01

3.3 Program Evaluation

The Goal Setting Process

The participants received targeted counselling based on the pharmacist's assessment and discussed issues of concern relating to asthma control. Typical topics discussed included trigger factors, exercise tolerance, and issues relating to their medication. The 35 Intervention participants who completed all 6 visits of the program set a total of 139 new goals and 203 repeated goals, which represent an average of 4 new goals and a further 5.8 repeated goals per participant. Typically, new goals that were set at the early visits were repeated one or more times at later visits suggesting that it took more than one iteration to achieve a goal. The type of goals set by the Intervention participants were grouped into seven different themes (Figure 3a and 3b). Some goals were complex and were therefore classified into two themes. The most common theme related to asthma triggers (e.g. *"avoid smoke"* and *"avoid animal dander"*), with 30.2% of all new goals and 60.6% of all repeated goals set in this category. The second and third most common themes were related to asthma control (e.g. *"not wake up at night with asthma"*) and medications (e.g. *"remembering to take medication even when well"* and *"reducing Ventolin[®] use"*). Exercise tolerance was another common theme (e.g. *"being able to finish a game of basketball without getting puffed"*).

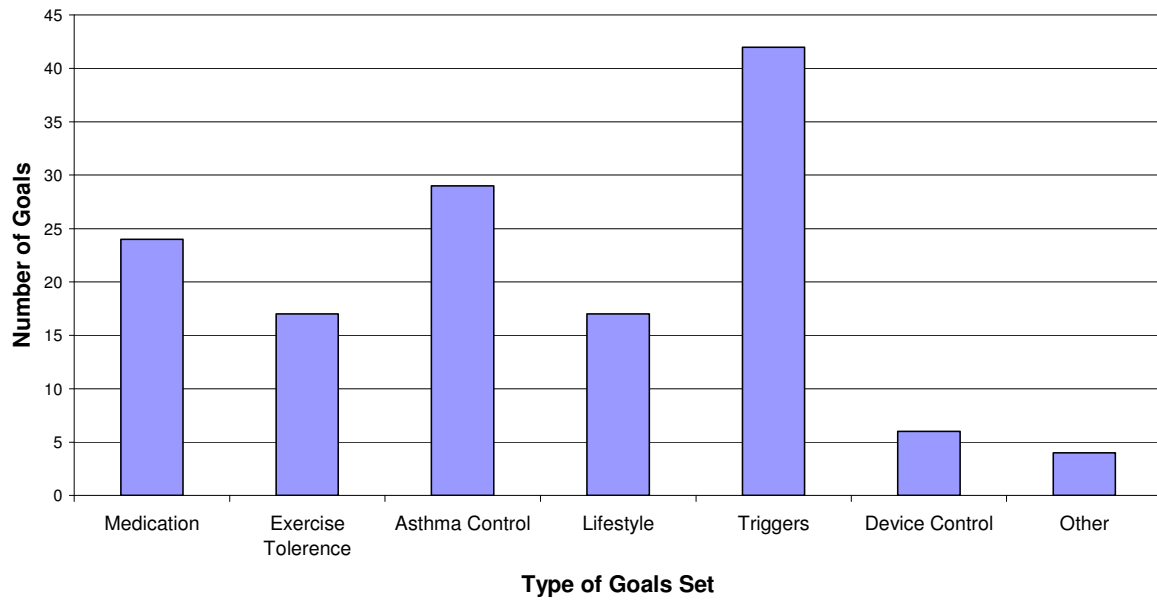
The goal setting process was not conducted in the Control group.

Figure 3a shows the types of new goals set by participants receiving the program. The most common new goals related to triggers (30.2%), asthma control (20.9%), medication adherence (17.3%) and lifestyle (12.2%). Figure 3b shows the types of repeated goals set by participants receiving the program. The most common repeated goals related to triggers (60.6%), lifestyle (11.3%), medication adherence (9.9%) and exercise tolerance (8.9%).

Figure 4 shows that the setting of new goals is inversely related to the setting of repeated goals. The setting of new goals decreased rapidly after Visit 1 and is approaching zero by Visit 6. The setting of repeated goals commenced at Visit 2 and remained consistent at just over one repeated goal on average per participant over subsequent Visits.

Figure 3: Types of Goals set by Participants

(a) New Goals



(b) Repeated Goals

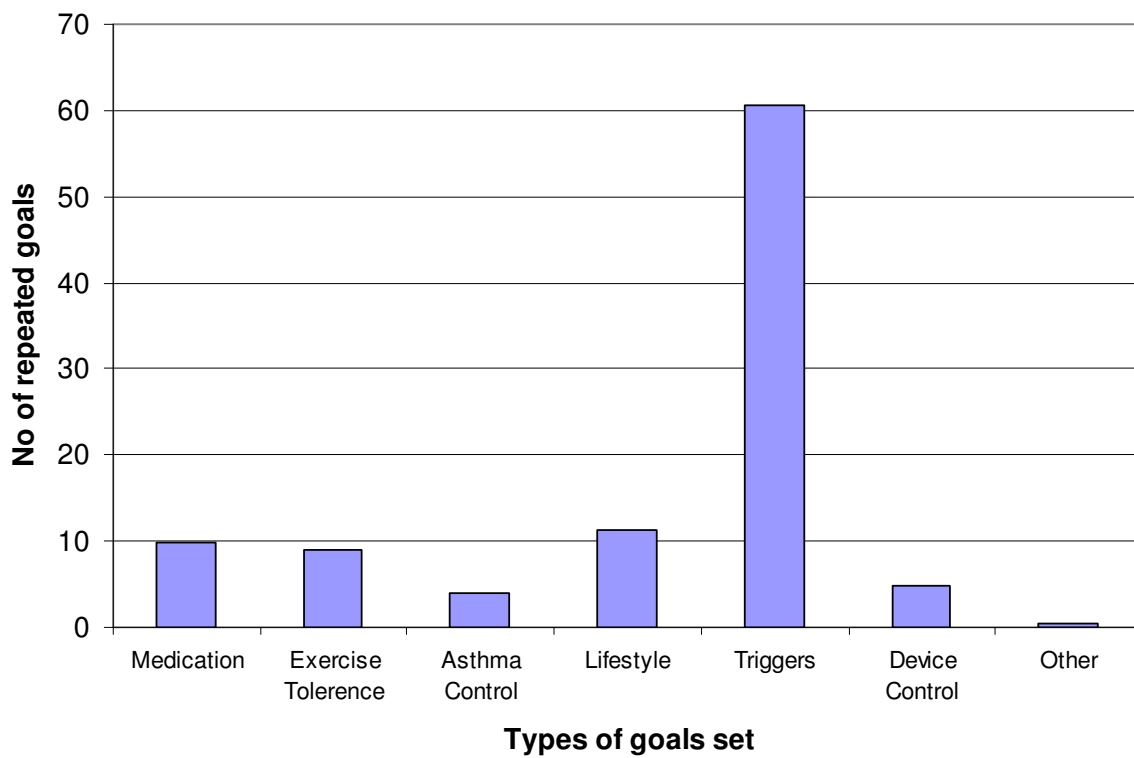
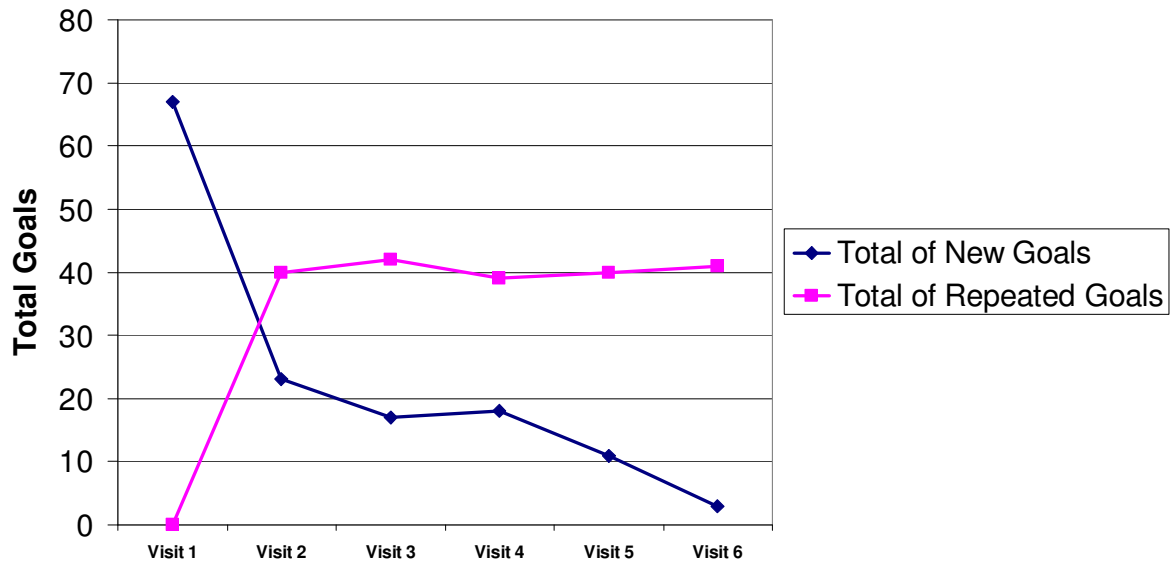


Figure 4: Total of New Goals and Repeated Goals at each Visit



A total of 316 strategies were written down in the workbooks by the Intervention participants during the course of the study and this represents an average of 9 strategies being set by each participant during the 9 month study period. The most common strategies used to achieve patient goals are listed in Table 13. For patient goals relating to medications, going to the GP to change their medication(s) or alter a medication dose was the most commonly set strategy. For patient goals relating to asthma triggers, the most commonly set strategy was to avoid triggers. For goals relating to exercise tolerance the most commonly set strategies was to take medications before/during exercise and to increase exercise/set schedule for exercise. For patient goals relating to asthma control the most commonly set strategy was to take medications as prescribed.

Strategies set by participants tended to be highly varied and individualised and a detailed description of the strategies used to achieve patient goals appear in the Appendices to this Report.

Table 13: Most commonly set strategies (n = 316) used by Intervention participants to achieve their goals.

Strategies used for “Medications” Goals (n=19)

- Go to GP to change medication or alter dose (26%)
- Remember to take dose (21%)
- Take medications as prescribed (21%)

Strategies used for “Asthma Triggers” Goals (n=46)

- Avoid Triggers (59%)
- Reduce nasal inflammation (11%)
- Go to GP (4%)

Strategies used for “Exercise Tolerance” Goals (n=16)

- Take medications before/during exercise (31%)
- Increase exercise/set schedule for exercise (31%)
- Take preventive medication regularly (25%)

Strategies used for “Asthma Control” Goals (n=47)

- Take medications as prescribed (23%)
 - Avoid triggers (15%)
 - See GP/Specialist (15%)
-

Participant Perceptions about the Goal Setting Process

To determine participant perceptions regarding the Goal Setting process, a telephone survey was conducted (Appendix 7). Intervention participants were interviewed until saturation of data was reached (n=22). One participant withdrew halfway through this study.

The intervention: Participants' perceived usefulness of the intervention

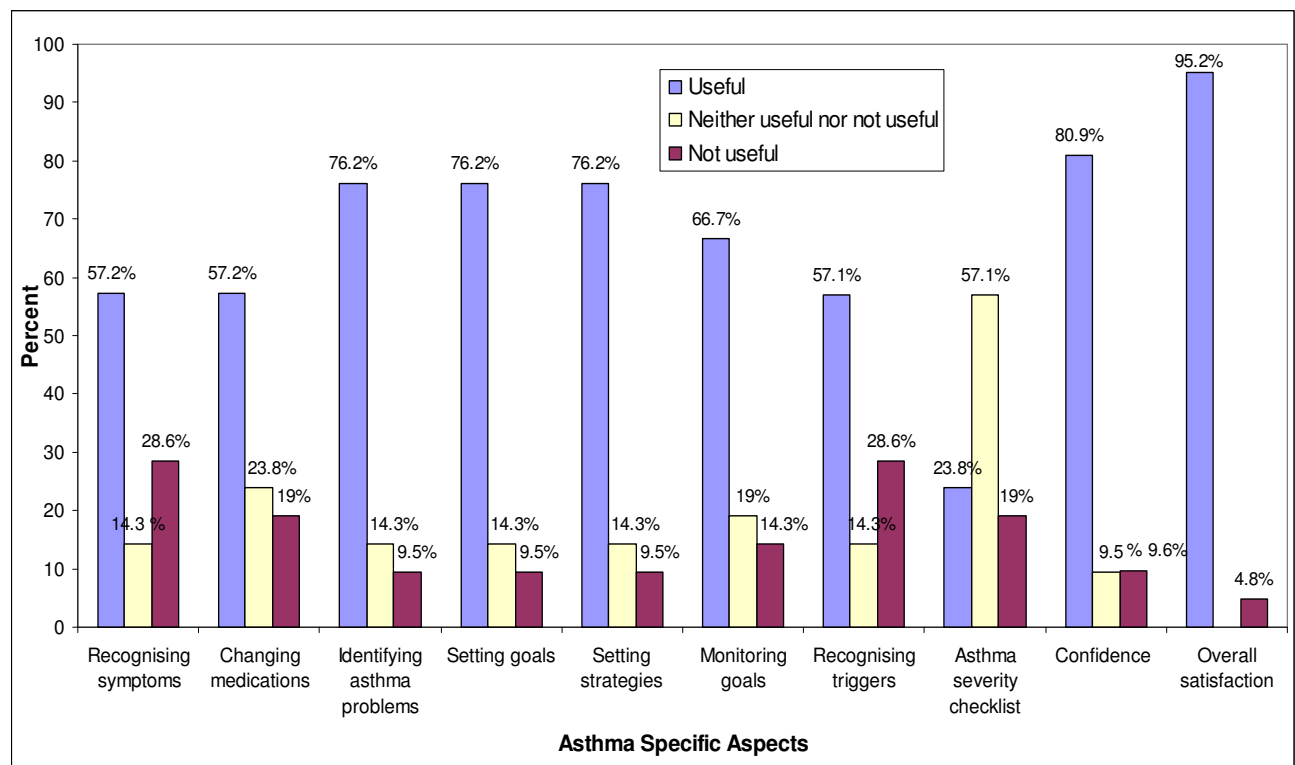
Table 14 summarizes the median scores relating to specific aspects of the program. When the participants were asked about the usefulness of the interventions provided in the program based on the ten different items, 76.2% of participants found “identifying problems relating to asthma” and “setting goals” and “setting strategies” to be either useful or very useful (Figure 5). Less than 50% of participants found “using the asthma severity checklist to monitor asthma symptoms” to be useful. A large proportion of respondents reported a high degree of usefulness of the interventions in improving their confidence and overall satisfaction of the asthma program with a percentage of 80.9% and 95.2% respectively.

Table 14: Median scores of the usefulness of asthma related aspects (interventions) of the program

(1=not useful at all, 5= very useful) n = 22 (intervention)

Asthma specific aspects in the program	Usefulness for Intervention Participants
	Median
Recognizing/Understanding your asthma symptoms	4
When your asthma gets worse, knowing how to change your medications	4
Recognizing/Understanding asthma triggers	4
Identifying problems relating to asthma	4
Setting goals to improve asthma	4
Setting strategies to achieve goals	4
Monitoring goals	4
Using asthma severity checklist table to monitor asthma symptoms	3
Confidence in managing asthma	4
Overall satisfaction with the asthma program provided	5

Figure 5: Participants' perceptions responding to the usefulness of and satisfaction with the Community Pharmacy Asthma Self-Management Program (n=21)



Useful = scores 4 and 5 (useful, very useful)

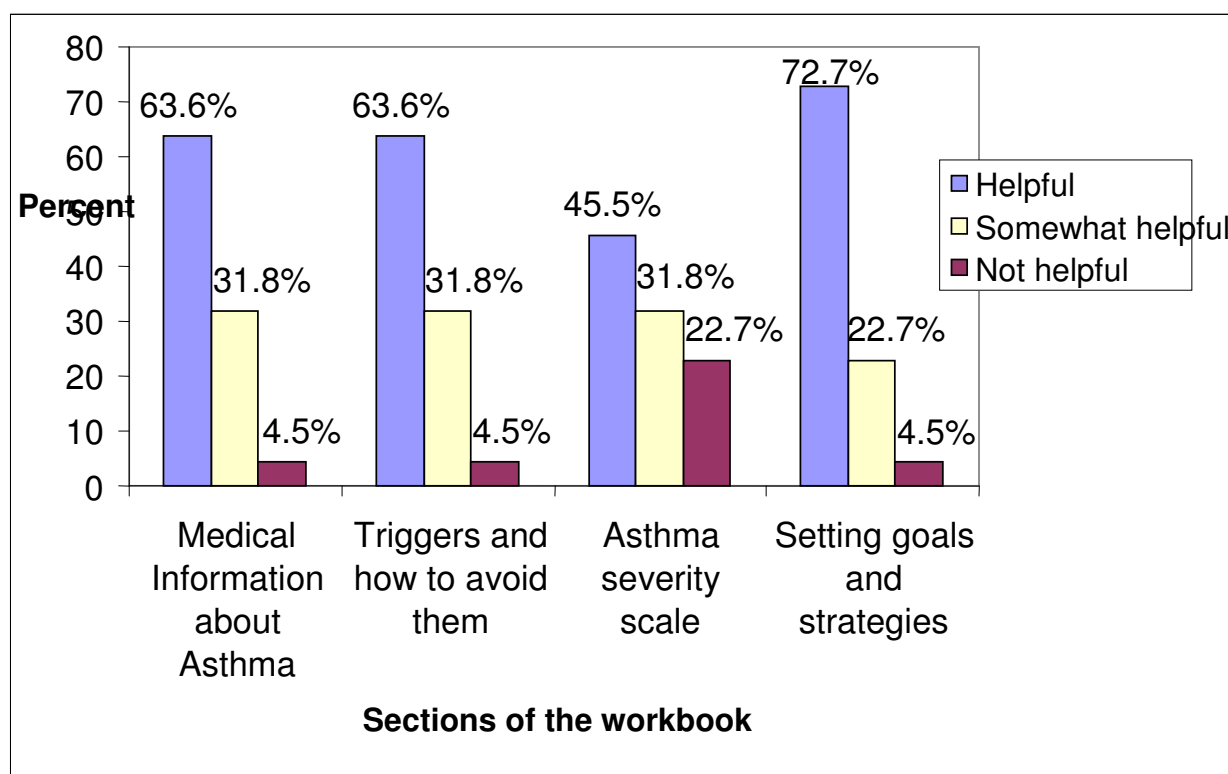
Neither useful nor not useful = score 3

Not useful = scores 1 and 2 (not useful at all, not useful)

The workbook: Perceived helpfulness of sections in the asthma workbook

Intervention participants were asked about their perceptions regarding helpfulness of the workbook. Their responses pertaining to the four sections of the asthma workbook is summarized in Figure 6. A high percentage of participants (76.2%) found the goals and strategies section to be very helpful or extremely helpful. Whilst participants found the sections on medical information about asthma, triggers and setting goals and strategies to be very helpful or extremely helpful (median score 4), 59% of the participants said that they would not continue to use the workbook in the future.

Figure 6: Proportion of participants' responding to the helpfulness of sections in the workbook provided in the Community Pharmacy Asthma Self-Management Program (n=22)



Very Helpful = Score 4 and 5 (very helpful, extremely helpful)

Somewhat helpful = Score 3

Not helpful = Score 1 and 2 (not helpful at all, not helpful)

Perceived aim or purpose of the program

Of the 22 Intervention participants who were interviewed, the majority of participants thought that the aim or the purpose of the program was to gauge how people were using their medications and whether they were taking them correctly. A number of participants also thought that this program was aimed to improve their asthma control and to see how people were managing their asthma.

Perceived most useful intervention

Most participants reported that the goals and strategies setting section was the most useful intervention in the program. A number of participants also reported getting their medications and doses changed, and speaking to the pharmacist about their asthma as the most useful intervention. When the participants were asked the reason

why they found the goals setting section most useful, they reported that it improved their medication use, understanding, knowledge, adherence to medications and asthma control.

“I found the goals setting section most usefulit drove me to ask more questions about my medications and..... know what they were used for. One of my goals was to speak to the doctor about my asthma medications.....my medications were changed put on Seretide[®].”

“The discussions with my pharmacist were really good. She managed to identify, at one stage, that I was taking two preventative medications which were doing the same thing. She spoke to my doctor about itI’m only on Seretide[®] now.”

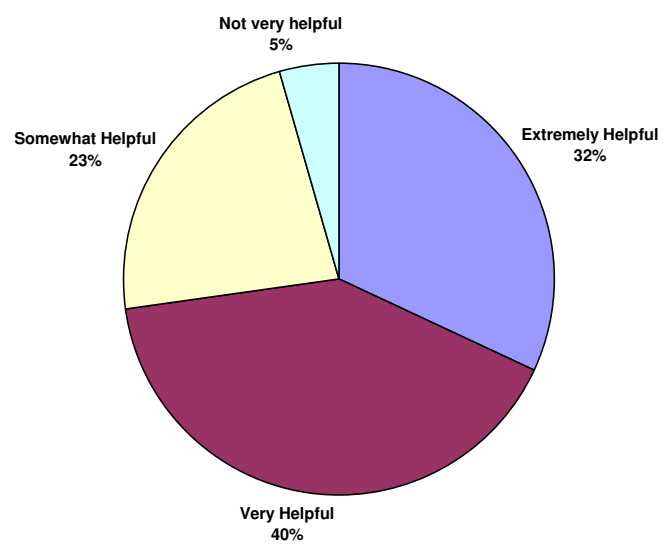
Perceived usefulness of the workbook

As reported in the quantitative results above, 13 (59%) of participants said that they would not continue to use the workbook in the future. The most common reason was that their asthma was already well controlled and they felt that they already had a strong understanding of asthma. Of the participants who stated that they would continue to use the workbook, most said that they would use the goals, strategies and monitoring section of the workbook.

Input in setting goals and strategies

The majority of participants reported that they set the goals together with their pharmacists and they felt good about it. The remainder stated that they set their goals by themselves and discussed their goals with their pharmacists during their scheduled visits. The vast majority of participants rated setting goals and strategies very highly with 32% finding this extremely helpful; 40% very helpful; and 23% somewhat helpful (Figure 7)

Figure 7: Setting Goals and Strategies



3.4 Clinical Outcomes

Clinical parameters were measured at Time 1 (Baseline), Time 2 (Visit 4), and Time 3 (Visit 6). The risk of non-adherence to medications was measured using the MARS[®] questionnaire. A significant improvement over time was found for the Intervention group but not the Control group (Table 15). Whilst there was a significant improvement in asthma control at Time 2 compared with Time 1 for the Intervention and Control group scores, there were no significant group differences. There were no further improvements/changes observed at Time 3 compared with Time 2 for asthma control or medication adherence ($p > 0.05$).

Table 15: Clinical parameters of participants at Baseline (Time 1) and at Visit 4 (Time 2) including change from baseline statistics

	Time 1 (Number (%) or Mean \pm SD)	Time 2 (Number (%) or Mean \pm SD)	Baseline -vs- Time 2 p value	Intervention -vs- Control p value	Change from Baseline p value
<i>Asthma Control</i>					
Intervention (n=34)	1.52 (\pm 1.26)	1.24 (\pm 1.19)	0.03[#]	0.75*	0.17 [@]
Control (n=54)	1.83 (\pm 1.15)	1.43 (\pm 1.26)	0.01[#]		
<i>Medication Adherence</i>					
Intervention	3.99 (\pm 0.84)	4.37 (\pm 0.68)	0.04[^]	0.34 ⁺	0.05 [@]
Control	4.17 (\pm 0.83)	4.24 (\pm 0.76)	0.64 [^]		

* Repeated Measures ANOVA [#] Paired t-test [^] Wilcoxon signed ranks test ⁺ Mann Whitney U test
[@] Independent Samples T-Test

There was no significant difference in the proportions of Intervention and Control group participants with action plan ownership between baseline and final visits ($p > 0.05$).

3.5 Medication Profile

The medication profiles of the Intervention and Control participants did not change over the duration of the study. Table 16 shows that there were no significant differences in the proportions of participants using a reliever alone; using both a reliever and preventer; and using a preventer and symptom controller in addition to a reliever when comparing baseline and final visit.

Table 16: Medication profiles at baseline and final

		R only n (%)	P±R n (%)	P+SC+R n (%)	Baseline vs. Final p value*
Intervention (n=159)	Baseline	0 (0)	10 (29.4)	24 (70.6)	0.32
	Final	1 (2.9)	9 (26.5)	24 (70.6)	
Control (n=177)	Baseline	9 (17.6)	15 (29.4)	27 (52.9)	0.10
	Final	7 (13.7)	14 (27.5)	30 (58.8)	

R = reliever, P = preventer, SC = symptom controller

*Test for marginal homogeneity

Medications and Total Daily Doses

There were no statistically significant changes in the proportion of participants using the most common asthma medications over the duration of the study (Table 17).

There were no differences observed in the total daily prescribed dose of salbutamol, fluticasone, salmeterol and budesonide taken between Baseline and Final Visit for either the Intervention or Control groups (Table 18).

Table 17: Proportion of participants using salbutamol, fluticasone, salmeterol and/or budesonide at baseline and final

		Baseline n (%)	Final n (%)	Baseline vs. Final p value*
Salbutamol	Intervention (n=30)	24 (80.0)	25 (86.2)	1.00
	Control (n=48)	43 (89.6)	42 (89.4)	1.00
Fluticasone	Intervention (n=34)	27 (79.4)	27 (79.4)	1.00
	Control (n=50)	35 (70.0)	36 (72.0)	1.00
Salmeterol	Intervention (n=34)	19 (55.9)	21 (67.7)	0.50
	Control (n=49)	24 (49.0)	28 (56.0)	0.25
Budesonide	Intervention (n=34)	7 (20.6)	8 (25.8)	1.00
	Control (n=49)	7 (14.3)	8 (16)	1.00

*McNemar's test

Table 18: Total daily doses (prescribed) at baseline and final

		Baseline n ±SD	Final n ±SD	Baseline vs. Final p value*
Salbutamol (mcg)	Intervention (n=4)	700 ±115	700 ±115	1.00
	Control (n=2)	600 ±283	600 ±283	1.00
Fluticasone (mcg)	Intervention (n=23)	598 ±258	598 ±258	1.00
	Control (n=32)	691 ±316	769 ±295	0.06
Salmeterol (mcg)	Intervention (n=15)	60 ±26	60 ±26	1.00
	Control (n=23)	90 ±37	98 ±39	0.16
Budesonide (mcg)	Intervention (n=5)	960 ±456	960 ±456	1.00
	Control (n=5)	816 ±255	720 ±179	0.28

* paired t-test; † repeated measures multivariate ANOVA

3.6 Humanistic Outcomes

Humanistic parameters were measured at Time 1 (Baseline), Time 2 (Visit 4), and Time 3 (Visit 6). Table 19 shows that there were significant improvements at Time 2 compared with Time 1 for the Intervention group participants' scores on measures of asthma self-efficacy and quality of life. Anxiety scores also improved over time, however there were no significant differences between groups. At Time 3, there were no further improvements and the improvements observed at Time 2 were sustained. An exception to this was a significant improvement in depression scores for the Control group between Time 2 and Time 3 ($p=0.04$). However, there is insufficient evidence to draw any firm conclusions about this outcome.

Table 19: Humanistic parameters of participants at Baseline (T1) and at Visit 4 (T2) including change from baseline statistics

	Time 1 (Mean \pm SD)	Time 2 (Mean \pm SD)	Baseline -vs- Time 2 p value	Intervention -vs- Control p value	Change from Baseline p value
<i>Asthma Self-Efficacy</i>					
Intervention (n=34)	2.18 (\pm 0.43)	1.77 (\pm 0.40)	0.01[#]	< 0.02[*]	0.03[@]
Control (n=54)	2.15 (\pm 0.61)	1.95 (\pm 0.64)	0.95 [#]		
<i>Asthma Quality of Life</i>					
Intervention	2.20 (\pm 0.89)	1.79 (\pm 0.68)	< 0.01[#]	< 0.01[*]	0.01[@]
Control	2.18 (\pm 0.85)	1.95 (\pm 0.81)	0.02[#]		
<i>Anxiety</i>					
Intervention	1.67 (\pm 0.59)	1.42 (\pm 0.36)	< 0.01[^]	0.98 ⁺	0.06 [@]
Control	1.7(\pm 0.68)	1.61 (\pm 0.69)	0.01[^]		
<i>Depression</i>					
Intervention	0.47 (\pm 0.68)	0.40 (\pm 0.58)	0.28 [^]	0.59 ⁺	0.36 [@]
Control	0.53 (\pm 0.67)	0.45 (\pm 0.67)	0.57 [^]		

* Repeated Measures ANOVA [#] Paired t-test [^] Wilcoxon signed ranks test ⁺ Mann Whitney U test
[@] Independent Samples T-test

Patient satisfaction

To determine patient satisfaction with the program 22 participants who completed the study were interviewed.

Perceived benefits of the program

When participants were asked what the program did for them personally, the most frequent response obtained was that they had changes made to their medications.

“I had my medications changed from high dose Flixotide[®] to Seretide[®]. This improved my asthma control andfewer side effects.”

A number of participants also stated that they became more focused on their asthma after the program and their asthma control improved.

“The program made me think and become more focused on my asthma as I tend to take it for granted at times.”

“The asthma program improved my asthma control. I was not able to play golf without getting an asthma attack for yearsNow; I am able to enjoy my golf.”

Improvements to the program

When asked on ways that participants thought the asthma program could be improved, the most common response was they did not have any comments and they didn't think that the program could be further improved as the program covered everything very well. However, an interesting comment made by one participant was that the asthma program should probably target participants who have just been diagnosed with asthma as they think that they would benefit the most out of it. Similarly, when participants were asked things that they would like the asthma program to include in the future, most participants did not have any comments and said that the program that they participated in covered everything very well. All the 22 Intervention participants said that they didn't have any complaints or problems with the length of the visits that they had with their pharmacists and 21 participants said that they would recommend this program to a friend or family member.

Willingness to pay

When participants were asked about their willingness to pay for the asthma program if they were to be offered a similar program in community pharmacy in the future, 15 out of the 22 participants said that they would be willing to pay. Of these, most stated that the amount depended on the type of program that they would be receiving. Eight of the respondents who were willing to pay for the program were unable to give an amount and the remaining 15 respondents indicated that this would be within the range of \$10.00 to \$50.00.

Control Patients' feedback

Control patients were followed up with regards to their experience with the study. Control patients were only asked to respond to a portion of question 5 of the Participant Follow-Up Survey.

Eighty five percent of control patients reported that they found the study either “useful” or “very useful”. Further, feedback from the control patients indicates that: 90% of them found the study either “useful” or “very useful” in helping them to recognising /understanding their asthma symptoms, 60% of the found the study “useful” or “very useful” with regards to knowing how to change their medication when their asthma got worse and recognising/understanding their asthma triggers; 75 % of them found the study “useful” or “very useful” with regards to gaining confidence in managing their asthma.

Pharmacist Satisfaction

Anecdotally, pharmacists reported that they were very satisfied with their participation in the asthma self management program and that there were many benefits both for themselves personally, for the professional profile of the pharmacy and for their participants. Some pharmacists also commented on the challenges of effecting behaviour change in their participants and the need to set small achievable goals.

Focus groups will be held during the early part of 2006 to evaluate some of these issues.

Pharmacist Time

The estimated amount of time that pharmacists needed to deliver the program for the intervention was 2 hours 40 minutes over 6 visits. Based on pharmacist feedback the cost of this intervention is seen to be comparable to the Home Medicine Review (HMR) service which is reimbursed under the Medical Benefits Schedule (MBS). Under Item 900 of the MBS, accredited pharmacists are reimbursed \$140 for each HMR which takes approximately 2 hours.

Pharmacy costs

Advertising posters costing \$15.00 each were used in the 9 Intervention pharmacies giving a total cost of \$135.00. Training and training manuals cost \$1,100.00 and \$225.00 respectively. Intervention participant workbooks cost \$10.00 for each participant who received the program giving a total for this item of \$350.00. These items combined produced a total cost of \$1810.00 giving a mean across the Intervention group of 35 participants of \$51.71 per participant.

4. DISCUSSION

The aim of the Asthma Self-Management Program was to facilitate self-management practices via collaboration between the patient and the community pharmacist. The main intervention of the program comprised a patient-centred goal setting process. The current study is the first of its kind to investigate the role of the community pharmacist in facilitating the self-management in asthma and to determine whether improving patient self-management skills will lead to improved clinical and humanistic outcomes for the patient.

The results from this study have demonstrated significant improvements in intervention group asthma self-efficacy, asthma quality of life, anxiety and adherence to medications ($p < 0.05$) compared to the control group. Thus, pharmacists facilitating patients to improve their self-management skills can result in improvements in the health of people with asthma. Participant satisfaction with this intervention was very high with Intervention group participants reporting that the goals- and strategies- setting process they engaged in with their pharmacist was an extremely useful process. These participants also reported that the medical information and goal setting sections of the workbook as either very or extremely helpful aids.

The underlying theory used to develop the protocol for the Asthma Self-Management Program which was delivered by the pharmacists, was based on the self-regulation model of illness behaviour and there is evidence to show that a range of personal beliefs and behaviours are necessary for optimal self-management of chronic illness^{44, 57}. These include:

- a sound understanding of the illness and its treatment.
- a willingness to participate in decisions made about its management.
- a capacity to establish and maintain good working relationships with HCPs involved in the treatment of the illness.
- an ability to take medications as directed.
- awareness of symptom severity and symptom control.
- the capacity to self-monitor.
- confidence in undertaking and executing these tasks.

The results from this study are consistent with self-regulation of illness behaviour theory⁵⁸⁻⁶⁰, and this supports the notion that mastery of self-regulatory processes is a powerful determinant of behaviour change. There is a large body of empirical literature demonstrating its efficacy across a range of domains^{33, 35, 41, 45, 46, 61}.

Recent research into the psychosocial aspects of asthma management has centred around patient perceptions and beliefs about asthma^{44, 62}, the development of asthma-related measuring instruments^{36, 53, 63}, and the delivery of an intervention based on pharmacist- or HCP-directed methods to implement changes in patient illness behaviour⁶⁴⁻⁶⁶. Whilst these intervention studies have sought to equip the patient with the desired asthma self-management skills, there does not appear to have been any pharmacist-led intervention studies designed to test a patient-centred goal setting model. This study tested a self-regulatory model of illness behaviour in an asthma population in Australia and has shown that this type of intervention can have positive effects on asthma self-management, and, that community pharmacies can be an appropriate setting for the delivery of such a model.

Patient-centred Goals and Strategies

During the course of the Asthma Self-Management Program, there were 35 Intervention patients who completed all 6 visits of the program and who set totals of 139 new goals and 203 repeated goals. The number of repeated goals suggests that the goal setting process involves an iterative procedure around a single theme or goal. This iterative procedure is facilitated by the act of the participant thinking about the goals they need to achieve, devising strategies that might work for them and writing these goals and strategies into a workbook that the participant keeps. The act of writing these things down in the workbook gives the patient a platform from which to think about and reflect about their asthma as a first step to improving the participant's perception of having control over their asthma and, therefore, providing an environment for behaviour change. This process was facilitated and supported by the trained pharmacist in the community pharmacy setting.

In addition, the setting of new goals was found to be inversely related to the setting of repeated goals, i.e., the setting of new goals was highest at the first Visit and

gradually declined at each Visit until it was approaching zero by Visit 6. In contrast, repeated goals commenced at Visit 2 and remained at approximately the same level at each Visit with no observable decline over time. This suggests that each patient was focused on a narrow range of goals that were important for them in order to achieve improved control over their asthma and that this does not change over time.

The largest proportion of both new goals and repeated goals related to triggers. In addition, the highest ratio of repeated goals to new goals (~2:1) was for trigger avoidance, highlighting the importance of triggers and their avoidance to the patient in the self-management of their asthma. On the other hand, other goals such as medications or exercise tolerance were not nearly as often cited as repeated goals (~1:1 ratio of repeated goals to new goals), suggesting that some goals are more easily achieved than others. Interestingly, the majority of patients enrolled in the study were also observed to be taking a wide range of OTC medications for allergy and hay fever symptoms, such as nasal sprays and antihistamines and this is consistent with the view that there is a close connection between asthma and allergies, and between asthma and hay fever in particular ⁶⁷. Therefore, the ability of patients to self-manage their asthma appears to be closely related to their ability to self-manage their allergies/hay fever, both of which involve the identification and avoidance of triggers. An interesting question is the extent to which an individual's hay fever/allergies and their asthma have the same or different triggers and further studies should be considered to investigate the role of trigger factors and the relationship between a patient's asthma and their other allergies, such as hay fever.

A total of 316 strategies were written down in the workbooks by the Intervention participants during the course of the study and this represents an average of 9 strategies set by each patient. Since the number of strategies was about double the number of new goals set, this indicates that on average two different strategies were set for each goal. One would expect that trying a number of different strategies would result in a higher level of achieved goals. Previous research shows that the greater the number of strategies the better management the patient has of their asthma ⁶⁸. Strategies set by participants tended to be highly varied and individualised and a detailed description of the strategies used to achieve patient goals appear in the Appendices to this Report (Appendix 8). This variability and level of detail was

considered to be crucial to the nature of the patient-centred goal setting process as it is the micro self-management details of an individual's day to day behaviour that has the potential for change. For example, individual patients used a variety of strategies to achieve the same goal and it was noted that in relation to medication adherence that for some patients, the positioning of the medication (handbag, on front desk, note on fridge) was the important act that would remind them to take their medications whereas for others it was the timing of the medication (alarm clock, with dinner, etc) that was important. On the surface, patients were using the same general strategies but at the micro level, the actual details that were affecting behaviour change were enormously variable.

Interestingly, the monitoring and rewards sections of the goal sheets were largely underutilised by the participants indicating that these aspects of the goal setting process were less important to the participant. Some reasons for this may be that (i) there were too many steps in the intervention process adopted for this study, and/or (ii) there was inadequate training of the participating pharmacists. Future research should consider streamlining this process, especially to provide support for the implementation and completion of the monitoring and reward components by the participant, such as keeping a diary of symptom severity or enlisting the help of family members in providing feedback on asthma control. Although not many rewards were recorded it was observed that rewards that were recorded tended to relate to the successful outcome of the set goal. In future studies pharmacists could take a more active role in the providing a structured monitoring and reward process once the participant has set their goal. Training of community pharmacists therefore needs to be refined so that they can more effectively facilitate the participants' involvement at defined points along the goal setting process. This will facilitate the progression and links between the various components of the goal setting process in an ordered step-wise process as follows:

Goal → Strategy → Monitoring → Achieved → Reward

Previous studies which have investigated the role of community pharmacist in providing services to people with asthma, and which included a goal-setting process, have demonstrated significant improvements in clinical, humanistic and economic

outcomes for people with asthma^{69, 70}. However, because the goal setting process was only part of a more complex intervention in these studies^{69, 70}, the extent to which the goal setting process contributed to these results is unknown.

In this study we sought to redress these issues by incorporating more detailed education on self-regulation theory and intervention, material aids such as workbooks, communications skills and the inclusion of regular visits between the participant and the pharmacist to enable feedback to take place. Furthermore, this project was designed to focus almost entirely on patient self-regulation of asthma management behaviour. The key components of the self-regulatory model – goals, strategies, monitoring, rewards and feedback – were included in the intervention. The pharmacists in this program were trained to facilitate rather than direct their patient's self-management behaviours. This was achieved by encouraging the patient to select those problem areas of asthma control that were of personal rather than clinical relevance, to set achievable goals directly relating to those problem areas, and to devise appropriate strategies for achieving those goals.

For instance, one participant in this study set as his primary goal that of remaining on court for an entire basketball game without having to come off early due to an exacerbation of asthma symptoms. As the pharmacist and participant reviewed his typical basketball preparation activities it emerged that inadequate symptom control and physical warm-up was occurring. Addressing these shortcomings became strategies for achieving the goal. The goal and strategies were noted in the participant's workbook, along with space to record monitoring of the effectiveness of the strategies to achieve the goal. This allowed for targeted feedback to take place between the participant and pharmacist at his regular follow up visits. Thus, implementation of a self-regulatory model to guide patient behaviour enables the identification of problem areas of asthma control, and a structured step-wise process for the patient to improve asthma control. This process builds a means for the patient to acquire the cognitive and behavioural attributes necessary for optimal daily management of chronic illness.

Based on the results of this study we recommend that further research be conducted that incorporates a targeted goal setting intervention with *clearly defined roles* for

both the pharmacist and the patient and clear methodological links to outcome measures.

In summary, the goal-setting process was the focus of the Asthma Self-Management Program, with the training and the protocol dedicated to this process. In order to achieve better asthma management it is essential that patients take on the role of self-management and some responsibility for their asthma control. Indeed, other studies have shown that patients retain and use a range of self-management skills acquired from an intervention^{28, 68, 71}.

It is not clear to what extent pharmacists influenced the goal setting process. It was observed that individual pharmacists often had a particular emphasis or focus, such as medication issues, and that this may have influenced the goals set by the participants attending that pharmacy. This is interesting but may not be so important given that the study patients improved overall across 9 different sites.

Pharmacy set-up costs for intervention

No economic analysis was conducted on the outcomes of this study and future research should be included to determine the cost-effectiveness of the program from the perspective of the health care system. The major driver of an economic model is asthma severity, which measures change in health state or utility associated with better asthma control and this parameter would need to be included for any future economic analysis.

However, we were able to estimate the cost of implementing the program in each pharmacy, i.e., \$105-43 per patient. This covered promotional material (eg. posters), training of pharmacists, (eg training manuals), and the intervention participant workbooks for the goal setting process. Overall, the proportion of participants who attended the six visits was high. This suggests that patients felt that it was worthwhile to return to the pharmacy for follow up and monitoring. This was despite the time commitment, given that the estimated total time the pharmacist spent with them over the nine month period was 145 min. Whereas the total time taken to deliver the program may seem like a major time commitment for both the pharmacist and the participant it should be remembered that in any service to be adopted within community pharmacy the research element of the project and the lengthy

documentation would be omitted. In addition, the observation that no further improvement was achieved after Visit 4 (Time 2) indicates that an effective intervention for this type of program would be a maximum of 4 visits and this would reduce the time of the intervention to 105 minutes. Thus it is likely that any specialised asthma self-management service instituted more widely, following on from this study, could be delivered in a much shorter time period. This would not only make the program more acceptable but also more cost effective. These estimated costs compare favourably with other specialised services delivered by community pharmacy, such as HMR, which takes approximately 2 hours and for which pharmacists are reimbursed \$140-00.

Patient Perceptions

Taking a patient perspective, it is clear that the program delivered considerable benefit to those enrolled in the study. The scores for asthma self-efficacy and medication adherence were significantly improved in the Intervention group, while they remained unchanged in the Control group. These results indicate that the program had been of value to the patients and that they felt more in control of their disease. When asked what they thought of the program, a number of participants thought that this program was aimed at improving their asthma control and to see how people were managing their asthma. However, the majority of participants thought that the main purpose of the program was to gauge how people were using their medications and whether they were taking them correctly. This response is encouraging as adopting self-management behaviour involves taking medications regularly and correctly when needed ⁷². Furthermore, this response may reflect a common perception of a community pharmacist's role, which is to ensure the quality and appropriate use of medications. In contrast, the participants did not find using the asthma severity checklist to monitor their asthma symptoms to be as useful as the other interventions in the program. This may be explained because the study participants on average were mildly asthmatic and/or well-controlled. Self-monitoring of asthma symptoms is an important part of self-management to be able to recognise when there is deterioration in their asthma symptoms and hence modify medication use accordingly ⁷³. Further studies should be undertaken to investigate alternative self-monitoring tools that would be more acceptable to the participants.

The findings of this study indicate that a high percentage (76.2%) of the participants found the goals and strategies section to be the most useful intervention in the asthma program. This result corresponds with the qualitative data whereby participants identified setting goals and strategies as the most useful aspects in the program. This result is consistent with the aim of the self-regulation model^{74, 75} which underpins this program. Studies have shown that an intervention which involves setting and achieving goals that are important to the participants, such as being able to play golf without getting breathless or sleeping well through the night without waking up to cough, can encourage active participation, enhance the partnership, and improve asthma management⁷². It could be argued that on the basis of these results, participants were satisfied because particular issues that were relevant to their quality of life or activities of daily living were addressed through the goal setting process. This result could also be due to the fact that the pharmacist spent most of their time with the participants on the goals and strategies section.

This study shows that an asthma program based on self-management was seen as valuable by the patients as they found the program useful and beneficial in improving self management of their asthma. We found that the participants were confident in managing their asthma after completing the program and were very satisfied with the interventions that were provided. In addition, the participants identified the goal and strategy setting section as the most useful intervention and were very positive towards the pharmacist delivering the program. Furthermore, this study indicates that pharmacists have an important role in educating patients on asthma and helping patients to improve their self-management behaviour. The findings obtained from this study also suggest that collaborative goal setting between the pharmacist and patient is a useful intervention that should be included in asthma self-management programs in the future.

5. STUDY LIMITATIONS

In our study the majority of patients were either mildly asthmatic and/or well-controlled and the observed improvements, although significant, were small as patient's measures on all parameters at baseline were already good. This was not surprising as there were no eligibility criteria for the selection of patients in relation to the severity or control of their asthma. Therefore, future studies should include eligibility criteria for asthma severity to investigate a self-management program on a group of patients with mild/moderate/severe asthma. This will enable the evaluation of an asthma self-management program across a broader spectrum of asthma severity and control. Whether the results reported here could be generalised to the entire asthma population is not known. What is known is that pharmacists can help patients whose asthma is mild and/or well-controlled. Therefore, this research should be extended to include a range of asthma severity and/or control to determine the capacity of this program to be applied across the spectrum of people in the community living with asthma.

The sample of community pharmacies used in this study was from the Sydney Metropolitan area and as such it may not be possible to extrapolate the results to community pharmacies generally. Future studies should include a range of both metropolitan and rural pharmacies from across Australia.

Given limited resources within the health care sector it is also important to evaluate new interventions from an economic perspective. An economic analysis was not conducted as part of this study. The standard tool for conducting this type of evaluation is cost-effectiveness analysis, where the costs and effects are quantified and expressed as a ratio in order to compare different programs. Future studies should incorporate an independent economic analysis and include the parameters which are necessary to measure cost-effectiveness, cost per life years and quality of life years (QALY).

6. CONCLUSION

In summary, the community pharmacists in the asthma self-management program have facilitated the improvement of patient self-management skills over a nine month period. The participants reported more positive attitudes about their asthma and felt that such a program should be more widespread. The asthma self-management program has the potential to deliver substantial improvements in asthma patient health outcomes.

There is wide scope for further research into patient self-management of asthma and the current study shows promising results for community pharmacy-led interventions. However, as leaders in the field of self-regulation have recently commented, continued research into this area is important because despite an extensive knowledge and research base, an understanding of the *processes* underlying health and illness behaviours is scant^{43, 46, 76}. From our recently conducted studies we know that pharmacists are well-placed to deliver interventions such as these, and that their patients report high levels of satisfaction with such programs. However, firmer links between the intervention methodology and improvements in patient illness behaviours must be demonstrated with regards to both clinical and humanistic outcomes.

This current study has tested a patient self-management model of illness behaviour in Australian community pharmacy and has shown that this type of intervention can deliver significant health outcomes for the patient with asthma. Pharmacists have demonstrated that they are a valuable addition to the asthma care team and that they should be integral participants in asthma services of the future.

7. REFERENCES

1. Australian Bureau of Statistics. National Health Survey. Canberra; 2001.
2. Australian Institute of Health and Welfare. Australia's Health No. 9. Canberra: AIHW; 2004.
3. Chinn S, Burney P, Jarvis D, Luczynska C. Variation in bronchial responsiveness in the European Community Respiratory Health Survey (ECRHS). *European Respiratory Journal* 1997;10(11):2495-501.
4. Henry D, Sutherland D, Francis L. The use of non-prescription salbutamol inhalers by asthmatic patients in the Hunter Valley, New South Wales. *Medical Journal of Australia* 1987;150(445-449).
5. Peat J, Woolcock A. New approaches to old problems. Why not prevent asthma? *Medical Journal of Australia* 1994;160:604-605.
6. Comino E, Mitchell C, Bauman A, Henry R, Robertson C, et al. Asthma management in Eastern Australia 1990 and 1993. *Medical Journal of Australia* 1996;164:403-406.
7. Australian Bureau of Statistics. National Health Survey, 2001. In: *Health Status Indicators Chapter 3*. Cannbera; 2005.
8. Tong S, Drake P. Hospital admission and mortality differentials of asthma between urban and rural populations in New South Wales. *Aust J Rural Health* 1999;7:18-22.
9. Australian Centre for Asthma Monitoring. *Asthma in Australia 2003*. Canberra: AIHW; 2003.
10. Australian Centre for Asthma Monitoring. *Health care expenditure and the burden of disease due to asthma in Australia*. Canberra: AIHW; 2005.
11. Goldney RD, Ruffin R, Fisher LJ, Wilson DH. Asthma symptoms associated with depression and lower quality of life: a population survey. *Medical Journal of Australia* 2003;178:437-41.
12. Comino E, Henry R. Changing approaches to asthma management in Australia: effects on asthma morbidity. *Drugs* 2001;61(9):289-300.
13. Matheson M, Wicking J, Raven J et al. Asthma management: how effective is it in the community. *Intern Med J* 2002;32:451-456.
14. Burton DL, McKenzie G, Comino E. Asthma management in young adults in rural NSW. *Respirology* 1999;4(supplement):A5.
15. McLean W, Gillis J, Waller R. The BC Community Pharmacy Asthma Study: A study of clinical, economic and holistic outcomes influenced by an asthma

- care protocol provided by specially trained community pharmacists in British Columbia. *Canadian Respiratory Journal* 2003;10(4):195-202.
16. Weinberger M, Murray MD, Marrero DG. Effectiveness of pharmacist care for patients with reactive airways disease: a randomized controlled trial. *J Am Med Assoc* 2002;288(13):1594-1602.
 17. Cordina M, McElnay JC, Hughes CM. Assessment of a community pharmacy-based program for patients with asthma. *Pharmacotherapy* 2001;21(10):1196-1203.
 18. Narhi U, Airaksinen M, Tanskanen P, Erlund H. Therapeutic outcomes monitoring by community pharmacists for improving clinical outcomes in asthma. *J Clin Phar Ther* 2000;25(3):177-183.
 19. Herborg H, Soendergaard B, Jorgensen T, Fonnesbaek L, Hepler CD, Holst H. Improving drug therapy for patients with asthma-part 2: Use of antiasthma medications. *J Am Pharm Assoc* 2001;41(4):551-559.
 20. Knoell DL, Pierson JF, Marsh CB, JN A, Pathak DS. Measurement of outcomes in adults receiving pharmaceutical care in a comprehensive asthma outpatient clinic. *Pharmacotherapy* 1998;18(6):1365-1374.
 21. Emmerton L, Shaw J, Kheir N. Asthma management by New Zealand pharmacists: a pharmaceutical care demonstration project. *Journal of Clinical Pharmacy & Therapeutics* 2003;28(5):395-402.
 22. Ekedahl A. 'Open-ended questions' and 'show-and-tell'--a way to improve pharmacist counselling and patients' handling of their medicines. *J Clin Pharm Ther* 1996;2:95-9.
 23. Self T, Brooks JB, Liberman P, Ryan MR. The value of demonstration and the role of the pharmacist in teaching the correct use of personalized bronchodilator. *Can Med Assoc J* 1998;128:129-131.
 24. Stiegler KA, Yunker NS, Crouch MA. Effect of pharmacist counseling in patients hospitalized with acute exacerbation of asthma. *American Journal of Health-System Pharmacy*. 2003;60(5):473-6.
 25. Watanabe T, Ohta M, Murata M, Yamamoto T. Decrease in emergency room or urgent care visits due to management of bronchial asthma inpatients and outpatients with pharmaceutical services. *J Clin Pharm Ther* 1998;23(4):303-309.
 26. Schulz M, Verheyen F, Muhlig S et al. Pharmaceutical care services for asthma: a controlled intervention study. *J Clin Pharmacol* 2001;41(6):668-676.
 27. Buchner DA, Butt LT, De Stefano A, Edgren B, Suarez A, Evans RM. Effects of an asthma management program on the asthmatic member: patient - centered results of a 2-year study in a managed care organization. *Am J Manag Care* 1998;4(9):1288-1297.

28. Barbanel D, Eldridge S, Griffiths C. Can a self-management programme delivered by a community pharmacist improve asthma control? A randomised trial. *Thorax* 2003;58(10):851-4.
29. Odedina FK, Leader FT, Venkataraman K, Cole R. Feasibility of a community asthma management network (CAMN) PROGRAM: lessons learnt from an exploratory investigation. *J Soc Admn Pharm* 2000;17(1):15-22.
30. Narhi U, Airaksinen M, Tanskanen P, Enlund H. The effects of a pharmacy based intervention on the knowledge and attitudes of asthma patients. *Pat Educ Couns* 2001;43:171-177.
31. Lisper B, Nilsson JL. The asthma year in Swedish pharmacies: a nationwide information and pharmaceutical care program for patients with asthma. *Ann Pharmacotherapy* 1996;30:455-460.
32. Blumenschein K, Johannesson M. Relationship between quality of life instruments, health state utilities, and willingness to pay in patients with asthma. *Ann Allergy Asthma Immunol* 1998;80(2):189-194.
33. Bandura A. *Self Efficacy. The Exercise of Control*. New York: W. H. Freeman and Company; 1997.
34. Bender BG. Overcoming barriers to non-adherence in asthma treatment. *The Journal of Allergy and Clinical Immunology* 2002;109(6):S554-S559.
35. Carver CS, Schier MF. *On the Self-Regulation of Behavior*. Cambridge University Press 1998;Cambridge.
36. Hicks RE, Harris R. Identifying patients with asthma whose beliefs and attitudes may place them "at risk": The development and initial validation of the Asthma Navigator. *Journal of Applied Health Behaviour* 2001;2(2):1-7.
37. Clark NM, Partridge MR. Strengthening asthma education to enhance disease control. *Chest* 2002;121(5):1661-1669.
38. Coughlin J, Wilson A, Gibson P. Summary Report of the 1999 Evidence-based Review of the Australian Six Step Asthma Plan.: NSW Health; 2000.
39. Reid D. Management and treatment perceptions among young adults with asthma in Melbourne: The Australian experience from the European Community Respiratory Health Survey. *Respirology* 2000;5:281-287.
40. Ruffin RE, Wilson D, Southcott AM, Smith B, Adams RJ. A South Australian population survey of the ownership of asthma action plans. *Medical Journal of Australia* 1999;171:348-351.
41. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory*. Englewood Cliffs, New Jersey: Englewood Prentice-Hall, Inc.; 1986.

42. Zimmerman B. Attaining self-regulation: A social cognitive perspective. In: Boekhaerts P, Pintrich P, Zeidner M, editors. *Handbook of Self-Regulation*. San Diego: Academic Press; 2000. p. Chapter 1, pp 13-35.
43. Bandura A. The primacy of self-regulation in health promotion. *Applied Psychology and International Review* 2005;54(2):245-254.
44. Horne R, Weinman J. Self-regulation and self-management in asthma: exploring the role of illness perceptions and treatment beliefs in explaining non-adherence to preventer medication. *Psychology and Health* 2002;17(1):17-32.
45. Leventhal H, Brissette I, Leventhal EA. The common-sense model of self-regulation of health and illness. In: Cameron LD, Leventhal H, editors. *The self-regulation of health and illness behaviour*. London: Routledge; 2003.
46. Maes S, Karoly P. Self-regulation assessment and intervention in physical health and illness. *Applied Psychology An International Review* 2005;54(2):267-299.
47. Wright CC, Barlow JH, Turner AP, Bancroft GV. Self-management training for people with chronic disease: An exploratory study. *British Journal of Health Psychology*. 2003;8:465-476.
48. http://www.qcpp.com/pharmacy_standards_checklist_july04.pdf. Last sighted January 2005.
49. Juniper E, O'Byrne P, Guyatt G, Ferrie P, King D. Development and validation of a questionnaire to measure asthma control. *Eur Respir J* 1999;14(4):902-907.
50. Juniper EF, O'Byrne PM, Roberts JN. Measuring asthma control in group studies: do we need airway calibre and rescue [beta]₂-agonist use? *Respiratory Medicine* 2001;95(5):319-323.
51. Horne R, Hankins M. The Medication Adherence Report Scale (MARS). www.teqs.co.uk; Last sighted October 2005.
52. Wigal JK, Stout C, Brandon M, Winder JA, McConnaughy K, Creer TL, Kotses H. The Knowledge, Attitude, and Self-Efficacy Asthma Questionnaire. *Chest* 1993;104(4):1144-1148.
53. Marks G, Dunn S, Woolcock A. A scale for the measurement of quality of life in adults with asthma. *Journal of Clinical Epidemiology* 1992;45(5):461-472.
54. Lovibond SH, Lovibond PF. *Manual for the Depression Anxiety Stress Scales*. 2nd Edition ed. Sydney: Psychology Foundation; 1995.
55. Lovibond PF, Lovibond SH. The structure of negative emotional states: Comparison of the Depression, Anxiety, Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behaviour Research and Therapy* 1995;33:335-343.

56. Hernandez L, Chang CH. Development and validation of the Satisfaction with Pharmacist Scale. *Pharmacotherapy* 2000;20(7):837-843.
57. Battersby MW, Ask A, Reece MM, Markwick M, Collins JP. The Partners in Health Scale: The development of psychometric properties of a generic assessment scale for chronic self-management. *Australian Journal of Primary Health* 2004;9:41-52.
58. Smith L, Sinclair KE, Chapman EL. Students' goals, self-efficacy, self-handicapping and negative affective responses: An Australian senior school study. *Contemporary Educational Psychology*. 2002;27:471-485.
59. Smith L. Changes in student motivation over the final year of high school. *Journal of Educational Enquiry* 2004;5(2):64-85.
60. Smith L, Sinclair KE. Empirical evidence for multiple goals: A gender-based , senior high school student perspective. *Australian Journal of Educational and Development Psychology*. 2005;5:55-70.
61. Bandura A. Perceived self-efficacy in cognitive development and functioning. *Educational Psychologist* 1993;28:17-148.
62. Goeman D, Aroni R, Stewart K, Sawyer S, Thien F, Abramson M,J. D. Patients' views of the burden of asthma: a qualitative study. *Medical Journal of Australia* 2002;177:295-299.
63. Tobin D, Wigal JK, Winder J, Holroyd K, Creer T. The "Asthma Self-Efficacy Scale". *Annals of Allergy* 1987;59:273-277.
64. Narhi U, Airaksinen M. Pharmacists solving problems in asthma management - experiences from a one-year intervention programme in Finland. *The International Journal of Pharmacy Practice* 2001:55-59.
65. Put C, van der Bergh O, Lemaigre V, Demedts M, Verleden G. Evaluation of an individualised asthma program directed at behavioural change. *Eur Res J* 2003;21:109-115.
66. Thoonen B, Schermer T, Jansen M, Smeele I, Jacobs A, Grol R, Van Schayck O. Asthma education tailored to individual patient needs can optimise partnerships in asthma self-management. *Patient Education & Counselling* 2002;47:355-360.
67. Li J. Double Trouble: The link between allergies and asthma. In: www.mayoclinic.com/allergies-and-asthma; 2005.
68. Caplin DL, Creer TL. A self-management program for adult asthma. III. Maintenance and relapse of skills. *Journal of Asthma* 2001;38(4):343-56.
69. Saini B, Krass I, Armour C. Development, Implementation, and Evaluation of a Community Pharmacy-Based Asthma Care Model. *Ann Pharmacotherapy* 2004;38:1954-60.

70. Armour C, Bosnic-Anticevich S, Krass I, Saini B, Smith L, Pryor M, Filipovska J,Brillant M. Pharmacy Asthma Care Program. 2005.
71. Gibson PG, Powell H, Coughlan J, Wilson AJ, Abramson M, Haywood P, Bauman A, Hensley MJ,Walters EH. Self-management education and regular practitioner review for adults with asthma. Cochrane Database of Systematic Reviews, 3 2003.
72. Clinical Practice Guidelines, Expert Panel Report 2:Guidelines for the Diagnosis and Management of Asthma, NHLBI. In: National Institutes of Health; 1997.
73. Global Initiative for asthma, Global Strategy for asthma management and prevention, NHLBI/WHO workshop report. In: National Institutes of Health; 2002.
74. Maes S. KP. Self-regulation assessment and intervention in physical health and illness: A review. In: Applied Psychology: An international review; 2005. p. 267-299.
75. Clark N, Zimmerman, B. A social cognitive view of self-regulated learning about health. In: Health Education Research; 1990. p. 371-379.
76. Leventhal H,P.A M. Is there a science of the processes underlying health and illness behaviours ? Applied Psychology An International Review 2005;54(2):255-256.

Appendix 1

Ethics Approved Letters



Faculty of Pharmacy, University of Sydney
Tel: (02) 9351 5818, Fax: (02) 9351 4391

INTERVENTION PARTICIPANT INFORMATION SHEET

Re: **“Asthma management in the community”**.

Asthma is a common condition of the airways in which the person with asthma regularly interacts with a wide range of health care professionals. These include not only their general practitioner or respiratory physician, but also the community pharmacy, through the purchase of their asthma medication.

The aim of this project is to investigate the way in which pharmacists are able to help people with asthma take a more active role in the self-management of their asthma.

This project will achieve this aim by assessing the impact of a new service to be provided by pharmacists to the person with asthma. It is envisaged that in the future, this service could be provided by all pharmacists within the context of the current practice of pharmacy. This service will then be compared to impact of the standard practice of pharmacy on asthma self-management.

As part of this project, each participating pharmacist has been randomly assigned to one of two groups. As you pharmacist has already been randomized into one group, if you choose to participate in this study,, you will be required to meet with your pharmacist 6 times over a 9 month period in your community pharmacy. Each visit will last between 10 - 15 minutes. You will receive up to a maximum of \$50 for any costs incurred for attending the 6 visits in your pharmacy. At the completion of the 6 visits, your pharmacist will receive a total of \$90 for providing you with this special service and for the extra administration associated with it.

By agreeing to participate in this study, you will be providing evidence relating to the important impact of the community pharmacist in asthma management.

Participation in this project is entirely voluntary and you can withdraw at any time with-out any short- or long-term consequences. For further information please contact Dr Sinthia Bosnic-Anticevich at the Faculty of Pharmacy, University of Sydney on (02) 9351 5818 or sinthia@pharm.usyd.edu.au.

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.



Faculty of Pharmacy, University of Sydney
Tel: (02) 9351 5818, Fax: (02) 9351 4391

INTERVENTION PARTICIPANT CONSENT FORM

I,
(*print name*)

hereby voluntarily consent to participate in the study entitled “**Asthma management in the community**”.

This project is being conducted by the Dr Sinthia Bosnic-Anticevich, Prof Carol Armour, Dr Bandana Saini, Dr Ines Krass from the Faculty of Pharmacy and Dr Lorraine Smith from the Faculty of Nursing, University of Sydney.

I understand that any data collected for the purposes of this study will remain strictly confidential. I have been informed that information obtained from this research may be used in future research or published.

Details of this study have been clearly explained by the pharmacist. I am aware of the purpose of this project and what my involvement entails. I have read the Subject Information attached. My participation is entirely voluntary. I have been informed of my right to question any part of the procedure or withdraw from the project at any time.

Name:

Signature: Date:.....

Parent / Guardian Name (*if applicable*):.....

Signature:..... Date:.....

Witness Name:

Witness

Signature: Date:.....

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.



Faculty of Pharmacy, University of Sydney
Tel: (02) 9351 5818, Fax: (02) 9351 4391

CONTROL PARTICIPANT INFORMATION SHEET

Re: “**Asthma management in the community**”.

Asthma is a common condition of the airways in which people with asthma regularly interact with a wide range of health care professionals. These include not only their general practitioner or respiratory physician, but also the community pharmacy, through the purchase of their asthma medication.

The aim of this study is to investigate the potential role of the pharmacist in helping people with asthma manage their asthma.

As part of this project, each participating pharmacist has been randomly assigned to one of two groups. As your pharmacist has already been randomized into one group, if you choose to participate in this study, you will be required to attend your pharmacy on 3 occasions over a 9 month period. During each visit (approx 10 min each), the pharmacist will be providing you with your usual care however, you will be required to complete some extra administration. As a result, you shall be reimbursed up to a maximum of \$30 at the end of the 3 visits for any travel costs incurred and the pharmacist shall be reimbursed a total of \$50 for the completion of addition paper work.

Participation in this project is entirely voluntary and if you wish, you can withdraw from the study at any time without any short- or long-term consequences.

By agreeing to participate in this study, you will be helping provide evidence for the role of the community pharmacist in helping to improve asthma management.

If you require further information or have any other questions please contact Dr Sinthia Bosnic-Anticevich at the Faculty of Pharmacy, University of Sydney on (02) 9351 5818 or sinthia@pharm.usyd.edu.au.

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.



Faculty of Pharmacy, University of Sydney
Tel: (02) 9351 5818, Fax: (02) 9351 4391

CONTROL PARTICIPANT CONSENT FORM

I,
(print name)

hereby voluntarily consent to participate in the study entitled “**Asthma management in the community**”.

This project is being conducted by Dr Sinthia Bosnic-Anticevich, Prof Carol Armour, Dr Bandana Saini, Dr Ines Krass and Dr Lorraine Smith from the Faculty of Pharmacy, University of Sydney.

I understand that any data collected for the purposes of this study will remain strictly confidential. I have been informed that information obtained from this research may be used in future research or published.

Details of this study have been clearly explained by the pharmacist. I am aware of the purpose of this project and what my involvement entails. I have read the subject information attached. My participation is entirely voluntary. I have been informed of my right to question any part of the procedure or to withdraw from the project at any time.

Name:

Signature: Date:.....

Parent / Guardian Name (if applicable):.....

Signature:..... Date:.....

Witness Name:

Witness

Signature: Date:.....

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.



Faculty of Pharmacy, University of Sydney
Tel: (02) 9351 5818, Fax: (02) 9351 4391

CONTROL PHARMACY INFORMATION SHEET

Re: “Asthma management in the community”

Asthma is a common chronic condition of the airways with a variable nature in which the person with asthma regularly interacts with a wide range of health professionals, including their pharmacist. Unfortunately, asthma self-management can be quite complex and we still do not have sufficient data relating to the management of asthma in the community nor do we have a appreciation of all the potential roles of different health care professionals in the management of asthma.

The aim of this project is to investigate the potential ways in which pharmacy care can be integrated into asthma management.

In order to do this, however, it is important for us to collect data about what people with asthma are currently doing with the management of their disease. Therefore, if you choose to participate in this study, you will only be required to provide the usual care to people with asthma, however, you will be required to collect documentation about the person with asthma on 3 occasions over a 9 month period. For each participant (person with asthma) who completes the 3 visits, you shall be reimbursed a total of \$50. Participants will receive up to a maximum of \$30 for any costs incurred for attending the 3 visits in your pharmacy.

By agreeing to participate in this study, you will be providing evidence relating to the important impact of the community pharmacist in asthma self-management.

This study will not interfere with the professional relationship between you and your patients and is designed to fit in with your current work environment.

Participation in this project is entirely voluntary and you can withdraw at any time. For further information please contact Dr Sinthia Bosnic-Anticevich at the Faculty of Pharmacy, University of Sydney on (02) 9351 5818 or sinthia@pharm.usyd.edu.au.

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.



Faculty of Pharmacy, University of Sydney
Tel: (02) 9351 5818, Fax: (02) 9351 4391

CONTROL PHARMACY CONSENT FORM

I,
(print name)

hereby voluntarily consent to participate in the study entitled “**Asthma management in the community**”.

This project is being conducted by Dr Sinthia Bosnic-Anticevich, Prof Carol Armour, Dr Bandana Saini, Dr Ines Krass and Dr Lorraine Smith from the Faculty of Pharmacy.

I understand that any data collected for the purposes of this study will remain strictly confidential. I have been informed that information obtained from this research may be used in future research or be published.

Details of this study have been clearly explained by the research team. I am aware of the purpose of this project and what my involvement entails. I have read the Pharmacy Information attached. My participation is entirely voluntary. I have been informed of my right to question any part of the procedure or withdraw from the project at any time.

Name:

Signature: Date:.....

Witness Name:

Witness

Signature: Date:.....

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.



Faculty of Pharmacy, University of Sydney
Tel: (02) 9351 5818, Fax: (02) 9351 4391

INTERVENTION PHARMACY INFORMATION SHEET

Re: **“Asthma management in the community”**

Asthma is a common chronic condition of the airways with a variable nature which requires the person with asthma to be able to take an active role in the day to day management of their disease. Self-management, however, is a complex issue as there are many factors which may affect the way in which individuals view their illness and their ability to manage it. Further, current literature suggests that self-management practises of people with asthma are still suboptimal.

The aim of this project is to investigate the way in which pharmacists are able to help people with asthma take a more active role in the self-management of their asthma.

This project will achieve this aim by assessing the impact of a new service to be provided by pharmacists to the person with asthma. This service is designed to specifically target asthma self-management. It is envisaged that in the future, this service could be provided by all pharmacists within the context of the current practice of pharmacy. This service will then be compared to impact of the standard practice of pharmacy on asthma self-management.

If you chose to participate in this study, you will be required to see each participant (person with asthma) 6 times over a 9 month period in your community pharmacy. Each visit will involve a specific discussion related to self-management and will last between 10 - 15 minutes. You will receive a total of \$90 for each participant completing 6 visits. Participants will receive up to a maximum of \$50 for any costs incurred for attending the 6 visits in your pharmacy.

By agreeing to participate in this study, you will be providing evidence relating to the important impact of the community pharmacist in asthma self-management.

This study will not interfere with the professional relationship between you and your patients and is designed to fit in with your current work environment. Participation in this project is entirely voluntary and you can withdraw at any time. For further information please contact Dr Sinthia Bosnic-Anticevich at the Faculty of Pharmacy, University of Sydney on (02) 9351 5818 or sinthia@pharm.usyd.edu.au.

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.

Faculty of Pharmacy, University of Sydney
Tel: (02) 9351 5818, Fax: (02) 9351 4391

INTERVENTION PHARMACY CONSENT FORM

I,
(*print name*)

hereby voluntarily consent to participate in the study entitled “**Asthma management in the community**”.

This project is being conducted by the Dr Sinthia Bosnic-Anticevich, Prof Carol Armour, Dr Bandana Saini, Dr Ines Krass and Dr Lorraine Smith from the Faculty of Pharmacy.

I understand that any data collected for the purposes of this study will remain strictly confidential. I have been informed that information obtained from this research may be used in future research or published.

Details of this study have been clearly explained by the research team. I am aware of the purpose of this project and what my involvement entails. I have read the Pharmacy Information attached. My participation is entirely voluntary. I have been informed of my right to question any part of the procedure or withdraw from the project at any time.

Name:

Signature: Date:.....

Witness Name:

Witness

Signature: Date:.....

Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.

Appendix 2

Training of Pharmacists



Community Pharmacy Asthma Self-Management Program

COMMUNITY PHARMACIST TRAINING DAY

SUNDAY, 20 JUNE, 2004

TIMETABLE

10am	Welcome, introductions, overview of project - Dr Sinthia Bosnic-Anticevich
10.15	Asthma physiology and treatment - Professor Carol Armour
11.00	Asthma management issues exercise
11.30	Morning tea
11.45	The self-regulation of asthma - Dr Lorraine Smith
12.45	Lunch
1.30pm	Research project protocols, data collection, case studies,
to	
2.45	Afternoon tea
3.00	Practise
4.00	Close

Appendix 3

Promotional Material



The University of Sydney

Community Pharmacy Asthma
Self-Management Program

IS YOUR **ASTHMA** TROUBLING YOU?

Join the asthma program and
CONTROL YOUR ASTHMA!

See your Pharmacist for details

Appendix 4

GP Communication



The University of Sydney
Faculty of Pharmacy

9351 5818 (ph)
9351 4447 (fax)

2 July, 2004

Dear Dr Lau,

I am writing to advise you of a new research project starting soon in your area. The Faculty of Pharmacy at the University of Sydney is conducting this project, in conjunction with community pharmacists. The project is funded by the Pharmacy Guild of Australia. Your local Division of General Practice Co-ordinator has been contacted regarding this project and an item will be appearing in your next newsletter.

The aim of this project is to investigate the ways in which pharmacists are able to help people with asthma take a more active role in the management of their asthma. This project will assess the impact of a new adherence support service to be provided by pharmacists to the person with asthma. The service will start in July and will finish by April, 2005.

Participants who have not had their asthma reviewed in the last 12 months, who do not have a written asthma action plan, or whose asthma control indicates that they may require physician review, will be referred by the pharmacist to their GP/Specialist. Should you have any questions regarding this project please do not hesitate to contact me.

Yours sincerely,

Dr Sinthia Bosnic-Anticevich
Chief Investigator

Appendix 5

Study Protocols

PROTOCOL (Intervention)

Recruit Patient	<ul style="list-style-type: none"> Provide overview of asthma management program, including purpose Complete eligibility for study checklist Give subject information sheet to Participant Ask Participant to sign consent form 	Page No. 1 2 3
Visit 1	<ul style="list-style-type: none"> Complete general patient information and asthma history Complete medication log Print out dispensing history and place in manual Ask Participant to complete asthma quality of life, medication use, self-regulation questions, emotional responses, asthma management questionnaires Complete asthma control questionnaire with Participant Go to Workbook and complete goal setting process with Participant Remove carbonised pages and put in Manual for Visit 2 Complete Checklist in Manual Enter appointment time onto your calendar/diary 	Page No. 4 74 6 18 21
Between Visit 1 & 2	<ul style="list-style-type: none"> Telephone call follow-up 7-10 days following Visit 1 (Pharmacy Assistant) Telephone call prior to Visit 2 to remind re appointment and to bring Workbook 	Page No 22
Visit 2 (1 month after Visit 1)	<ul style="list-style-type: none"> Complete medication log Print out dispensing history and place in manual Complete Asthma Control Questionnaire with Participant Go to Workbook to review goal setting/strategies etc. Removed carbonised pages and put in Manual for Visit 3 Complete Checklist in Manual Enter appointment time onto your calendar/diary 	Page No. 75 24 27
Between Visit 2 & 3	<ul style="list-style-type: none"> Telephone call follow-up 7-10 days following Visit 2 (Optional) (Pharmacy Assistant) Telephone call prior to Visit 3 to remind re appointment and to bring Workbook 	Page No 28
Visit 3 (1 month after Visit 2)	<ul style="list-style-type: none"> Complete medication log Print out dispensing history and place in manual Complete asthma control questionnaire with Participant Go to Workbook and review goal setting/strategies etc. Remove carbonised pages and put in Manual for Visit 4 Complete Checklist in Manual Enter appointment time onto your calendar/diary 	Page No 76 30 33

PROTOCOL (Intervention)

**Between
Visit 3 & 4**

- Telephone call follow-up 7-10 days following Visit 3 (Optional)
- (Pharmacy Assistant) Telephone call prior to Visit 4 to remind re appointment and to bring Workbook

Page No
34

**Visit 4
(2 months
after Visit 3)**

- Complete medication log
- Print out dispensing history and place in manual
- Ask Participant to complete asthma quality of life, medication use, self-regulation questions, emotional responses, asthma management questionnaires
- Complete asthma control questionnaire with Participant
- Go to Workbook and review goal setting/strategies etc.
- Remove carbonised pages and put in Manual for Visit 5
- Complete Checklist in Manual
- Enter appointment time onto your calendar/diary

Page No
77

36

46

49

**Between
Visit 4 & 5**

- Telephone call follow-up 7-10 days following Visit 4 (Optional)
- (Pharmacy Assistant) Telephone call prior to Visit 5 to remind re appointment and to bring Workbook

Page No
50

**Visit 5
(2 months
after Visit 4)**

- Complete medication log
- Print out dispensing history and place in manual
- Complete asthma control questionnaire with Participant
- Go to Workbook and review goal setting/strategies etc.
- Remove carbonised pages and put in Manual for Visit 6
- Complete Checklist in Manual
- Enter appointment time onto your calendar/diary

Page No
78

52

55

**Between
Visit 5 & 6**

- Telephone call follow up 7-10 days following Visit 5 (Optional)
- (Pharmacy Assistant) Telephone call prior to Visit 6 to remind re appointment and to bring Workbook

Page No
56

**Visit 6
(3 months
after visit 5)**

- Complete medication log
- Ask Participant to complete asthma quality of life, medication use, self-regulation questions, emotional responses, asthma management questionnaires
- Print out dispensing history and place in manual
- Complete asthma control questionnaire with Participant
- Go to Workbook and review goal setting/strategies etc.
- Complete Checklist in Manual
- Closure

Page No
79

58

70

73

PROTOCOL (Control)

Recruit Patient

	Page No.
▪ Provide overview of asthma management program, including purpose	1
▪ Complete eligibility for study checklist	2
▪ Give subject information sheet to Participant	3
▪ Ask Participant to sign consent form	3

Visit 1

	Page No.
▪ Complete general patient information and asthma history	4
▪ Complete medication log	57
▪ Print out dispensing history and place in manual	
▪ Ask Participant to complete asthma quality of life, medication use, self-regulation questions, emotional responses, asthma management questionnaires	6
▪ Complete asthma control questionnaire with Participant	18
▪ Ask Participant about any problems experiencing with asthma control. Provide standard Pharmacy service	21
▪ Complete check box re services provided	22
▪ Make time for Visit 2; provide Appointment Card	22
▪ Enter appointment time onto your calendar/diary	

Visit 2 (4 months after Visit 1)

	Page No.
▪ Complete medication log	58
▪ Print out dispensing history and place in manual	
▪ Ask Participant to complete asthma quality of life, medication use, self-regulation questions, emotional responses, asthma management questionnaires	24
▪ Complete asthma control questionnaire with Participant	34
▪ Ask Participant about any problems experiencing with asthma control. Provide standard Pharmacy service	37
▪ Complete check box re services provided	38
▪ Make time Visit 3; provide Appointment Card	38
▪ Enter appointment time onto your calendar/diary	

Visit 3

	Page No
▪ Complete medication log	59
▪ Print out dispensing history and place in manual	
▪ Ask Participant to complete asthma quality of life, medication use, self-regulation questions, emotional responses, asthma management questionnaires	40
▪ Complete asthma control questionnaire with Participant	52
▪ Ask Participant about any problems experiencing with asthma control. Provide standard Pharmacy service	55
▪ Complete check box re services provided	56
▪ Closure	

Appendix 6

Questionnaires

VALIDATED QUESTIONNAIRES

1) Asthma Quality of Life Questionnaire

Please read the following statements and circle the option that best applies to you over the last 4 WEEKS.

1. I have been troubled by episodes of shortness of breath

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

2. I have been troubled by wheezing attacks

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

3. I have been troubled by tightness in the chest

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

4. I have been restricted in walking down the street on level ground or doing light housework because of asthma

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

5. I have been restricted in walking up hills or doing heavy housework because of asthma

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

6. I have felt tired or a general lack of energy

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

7. I have been unable to sleep at night

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

8. I have felt sad or depressed

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

9. I have felt frustrated with myself

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

10. I have felt anxious, under tension or stressed

Not at all	Mildly	Moderately	Severely	Very Severely
1 _____	2 _____	3 _____	4 _____	5 _____

11. I have felt that asthma is preventing me from achieving what I want from life

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

12. Asthma has interfered with my social life

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

13. I have been limited in going to certain places because they are bad for my asthma

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

14. I have been limited in going to certain places because I have been afraid of getting an asthma attack and not being able to get help

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

15. I have been restricted in sports, hobbies or other recreations, because of my asthma

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

16. I have felt generally restricted

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

17. I have felt that asthma is controlling my life

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

18. I have been worried about my present or future health because of asthma

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

19. I have worried about asthma shortening my life

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

20. I have felt dependent on my asthma sprays

Not at all	Mildly	Moderately	Severely	Very Severely
1_____	2_____	3_____	4_____	5_____

Marks G, Dunn S, Woolcock A. A scale for the measurement of quality of life in adults with asthma. Journal of Clinical Epidemiology 1992;45(5):461 72.

2) Medication Adherence Report Scale

Many people find a way of using their asthma medicines which suits them. This may differ from the instructions on the label or from what their doctor has said. We would like to ask you a few questions about how you use your medicines. In the box below are some ways in which people have said they use their medicines. For each of the statements, please tick the box which best applies to you.

Your own way of using your asthma medicines	Always	Often	Sometimes	Rarely	Never
I forget to take them					
I alter the dose					
I stop taking them for a while					
I decide to miss out a dose					
I take less than instructed					

MARS©

Horne R, Hankins M. The Medication Adherence Report Scale (MARS). www.teqs.co.uk.

3) Depression, Anxiety Stress Scale

Everyone experiences strong feelings from time to time. Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

- 0 Did not apply to me at all
 - 1 Applied to me to some degree, or some of the time
 - 2 Applied to me a considerable degree, or a good part of the time
 - 3 Applied to me very much, or most of the time
-

- | | |
|--|---------|
| 1. I was aware of dryness of my mouth | 0 1 2 3 |
| 2. I couldn't seem to experience any positive feeling at all | 0 1 2 3 |
| 3. I experienced breathing difficulty (eg. excessively rapid
breathlessness in the absence of any physical exertion) | 0 1 2 3 |
| 4. I found it difficult to work up the initiative to do things | 0 1 2 3 |
| 5. I experienced trembling (eg. in the hands) | 0 1 2 3 |
| 6. I was worried about situations in which I might panic and
make a fool of myself | 0 1 2 3 |
| 7. I felt that I had nothing to look forward to | 0 1 2 3 |
| 8. I felt down-hearted and blue | 0 1 2 3 |
| 9. I felt I was close to panic | 0 1 2 3 |
| 10. I was unable to become enthusiastic about anything | 0 1 2 3 |
| 11. I felt I wasn't worth much as a person | 0 1 2 3 |
| 12. I was aware of the action of my heart in the absence of
physical exertion (eg. sense of heart rate increase, heart
missing a beat) | 0 1 2 3 |
| 13. I felt scared without any good reason | 0 1 2 3 |
| 14. I felt that life was meaningless | 0 1 2 3 |

Lovibond SH, Lovibond PF. Manual for the Depression Anxiety Stress Scales. 2nd Edition ed. Sydney: Psychology Foundation; 1995.

4) Asthma Self-Efficacy Scale

The following questions are concerned with your opinions about your asthma. Please read each statement and circle the letter that you feel answers the question best.

1. I can recognise the changes that occur in my lungs before an asthma attack begins.
 - a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
2. I can do a great deal to solve the problems that asthma can cause.
 - a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
3. When it comes to my asthma, I feel that I can avoid having to miss work or other daily responsibilities.
 - a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
4. I can prevent asthma in almost all situations.
 - a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False

cont'd ...

5. I have confidence in my ability to keep my asthma under control when I am away on holiday or on a business trip.
 - a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
6. I can take the necessary steps to avoid or to manage an asthma attack effectively.
 - a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
7. I feel confident in my ability to exercise without having an asthma attack.
 - a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False

8. I do very well at perceiving the level of my asthma at all times, including when I am experiencing no asthma at all, when I am experiencing slight asthma, when I am experiencing moderate asthma, and when I am experiencing severe asthma.
- a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
9. I have confidence in my ability to keep my asthma under control when problems arise in my family.
- a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
10. I can handle the problems that asthma may cause.
- a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
11. I can learn to be an effective asthma self-manager.
- a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
12. If cigarette smoke is bothering me, I feel that I can ask the person to stop smoking.
- a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
13. I feel that I can take my asthma medications as prescribed by my doctor.
- a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False
14. During an asthma episode, I can refrain from panicking in order to better manage the attack.
- a. True
 - b. Mostly true
 - c. Sometimes true and sometimes false
 - d. Mostly false
 - e. False

- 15. I have confidence in my ability to avoid frequent trips to Accident and Emergency at hospital because of my asthma.**
- a. True**
 - b. Mostly true**
 - c. Sometimes true and sometimes false**
 - d. Mostly false**
 - e. False**
- 16. I don't have a lot of confidence in my ability to manage my asthma.**
- a. True**
 - b. Mostly true**
 - c. Sometimes true and sometimes false**
 - d. Mostly false**
 - e. False**
- 17. Once an attack starts, I am not capable of stopping it: I just have to wait until it subsides.**
- a. True**
 - b. Mostly true**
 - c. Sometimes true and sometimes false**
 - d. Mostly false**
 - e. False**
- 18. I have a lot of confidence in my ability to detect the early warning signs of my asthma.**
- a. True**
 - b. Mostly true**
 - c. Sometimes true and sometimes false**
 - d. Mostly false**
 - e. False**
- 19. I can avoid or minimise most of my asthma triggers.**
- a. True**
 - b. Mostly true**
 - c. Sometimes true and sometimes false**
 - d. Mostly false**
 - e. False**
- 20. I can use positive self-talk to help control my asthma.**
- a. True**
 - b. Mostly true**
 - c. Sometimes true and sometimes false**
 - d. Mostly false**
 - e. False**

Copyright, 1994 – ICKE. Inc.

Wigal JK, Stout C, Brandon M, Winder JA, McConnaughy K, Creer TL, Kotses H. The Knowledge, Attitude, and Self-Efficacy Asthma Questionnaire. Chest 1993;104(4):1144-1148.

5) Asthma Control Questionnaire

Circle the number of the response that best describes your asthma control:

1. On average, during the past week, how often were you woken by your asthma during the night?

- 0 Never**
- 1 Hardly ever**
- 2 A few times**
- 3 Several times**
- 4 Many times**
- 5 A great many times**
- 6 Unable to sleep because of asthma**

2. On average, during the past week, how bad were your asthma symptoms when you woke up in the morning?

- 0 No symptoms**
- 1 Very mild symptoms**
- 2 Mild symptoms**
- 3 Moderate symptoms**
- 4 Quite severe symptoms**
- 5 Severe symptoms**
- 6 Very severe symptoms**

3. In general, during the past week, how limited were you in your activities because of your asthma ?

- 0 Not limited at all**
- 1 Very slightly limited**
- 2 Slightly limited**
- 3 Moderately limited**
- 4 Very limited**
- 5 Extremely limited**
- 6 Totally limited**

4. In general, during the past week, how much shortness of breath did you experience because of your asthma ?

- 0 None**
- 1 A very little**
- 2 A little**
- 3 A moderate amount**
- 4 Quite a lot**
- 5 A great deal**
- 6 A very great deal**

5. In general, during the past week, how much of the time did you wheeze?

- 0 Not at all**
- 1 Hardly any of the time**
- 2 A little of the time**
- 3 A moderate amount of the time**
- 4 A lot of the time**
- 5 Most of the time**
- 6 All the time**

6. On average, during the past week, how many puffs of short-acting bronchodilator (eg. Ventolin) have you used each day?

- 0 None**
- 1 1-2 puffs most days**
- 2 3-4 puffs most days**
- 3 5-8 puffs most days**
- 4 9-12 puffs most days**
- 5 13-16 puffs most days**
- 6 More than 16 puffs most days**

ACQ ©

Juniper E, O'Byrne P, Guyatt G, Ferrie P, King D. Development and validation of a questionnaire to measure asthma control. Eur Respir J 1999;14(4):902-907.

Appendix 7

Pharmacist Newsletters



The University of Sydney

Community Pharmacy Asthma Self-Management Program

PROJECT UPDATE - JANUARY, 2005

Greetings Community Pharmacists!

We are now more than half way through our project. Lorraine has been visiting pharmacists and collecting data. A big *thank you* to you all for your recruitment of patients and such accurate collection of data! As promised, we have some preliminary results for you. The attached pages outline some of the socio-demographic data regarding our patients. Our typical patient is female, who is about 52 years old, has a job, whose asthma onset occurred in early adulthood, has had an asthma review by her GP in the last 12 months, but does not have a Written Asthma Action Plan. She is also more likely than not to engage in regular exercise (walking). However, as you will see from the stats there is a wide variability amongst patients within each of these factors.

Final Visits Are Coming Up!

For many of you final visits will be taking place over the next few months. This is a time when motivation can sometimes wane a little (not only for patient but also for pharmacist!). Please don't hesitate to

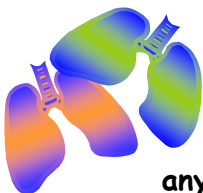
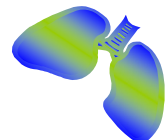
impact of the service you are delivering. Importantly, this is what we will send to the Pharmacy Guild to use in its discussions with the Federal Government.

A Gift For You

Many of our pharmacists have commented that one of the difficulties with patient adherence to asthma medications (particularly preventers) is that patients are not aware of the long-term damage to lung tissue which can occur when adherence is poor. We have enclosed a laminated picture of a normal and inflamed bronchus which we hope you will find helpful in your discussions with your patients.

Until next time,

*Lorraine (Tel: 9036 5437)
and Sinthia (Tel: 9351 5818)*



contact
Lorraine or
Sinthia if

any problems arise or you would like some extra help. Once all the data is in we can provide you with more substantial information regarding the



RECRUITMENT UPDATE - 23 AUGUST, 2004

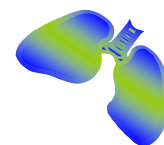
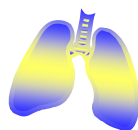
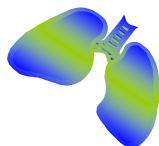
Greetings Community Pharmacists!

Sinthia and I thought it would be a good idea to let you see how we are going with recruitment and how close we are to our target. A big thank you to all of you - we appreciate your efforts! We are aiming for 120 patients to be recruited overall. As you can see from the table below for some pharmacists this has been an uphill battle. For others, it has been an easier task. There are many reasons for this. If you are one of those who are experiencing difficulties, please don't give up!! Our experience from other projects tells us that persistence is

what wins the day. We have many stories of pharmacists experiencing repeated knockbacks from patients and then out of the blue have four or five patients agree to take part. It's really important that we get as close to our target as possible so that our results are meaningful. We can achieve our target if everyone recruits 5 patients. Lorraine will stay in touch and can discuss some strategies with you for improving recruitment. If there is anything else we can do to help please let us know.

All the very best to you, Sinthia and Lorraine

Gp A Pharmacists	No. Recruited	Gp B Pharmacists	No. recruited
#1	5	#1	4
#2	4	#2	5
#3	4	#3	>5
#4	5	#4	3
#5	1	#5	5
#6	0	#6	4
#7	5	#7	0
#8	3	#8	2
#9	>5	#9	1
#10	1	#10	0
		#11	0





The University of Sydney

Community Pharmacy Asthma Self-Management Program

PROJECT UPDATE - OCTOBER, 2004

Greetings Community Pharmacists!

As we are now a few months into the Asthma self-management project a project update is timely. Recruitment of participants to your service has been good and our numbers are looking very healthy. Sinthia and I would like to thank you for your efforts so far.

One of the expected outcomes of this project is that robust evidence can be provided to the Pharmacy Guild (and hence, the Government) that supports a remunerated service being provided for community pharmacy based asthma care. We are approximately one third of the way through the project and your continued help and support is very much appreciated.

Lorraine has been visiting pharmacies and collecting data. This information will be entered into the database and some preliminary results will soon be available. We look forward to sharing this with you!

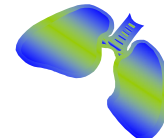
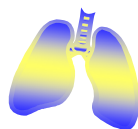
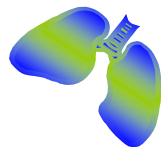
Visit 2 is coming up

Over the next month or so many of you will begin the second round of appointments (Visit 2) with your participants. Here are some tips for making this happen in a busy pharmacy:

- ★ ask your Pharmacy Assistant to contact your participants to make an appointment
- ★ put a note in your diary to contact your participants
- ★ put up a reminder somewhere prominent to speak to your participants next time they come in for their medications about arranging their next visit

Until next time,

Sinthia and Lorraine





PROJECT UPDATE - OCTOBER, 2004

Greetings Community Pharmacists!
As we are now a few months into the Asthma self-management project a project update is timely. We are still recruiting so if you have anyone interested please sign them up! Sinthia and I would like to thank you for your efforts so far.

Apart from the benefits of this service for your patients we hope there are also benefits for you! The feedback we get from other participating pharmacists is that they gain -

- * *Professional self esteem*
- * *Exposure to specialisation models*
- * *Continuing education*
- * *Patient perception as a "specialist"*
- * *A template for other services you may wish to provide*
- * *Collaborative networks with other health care professionals*
- * *Helping to ensure that this service in future will be standard pharmacy practice and government-remunerated.*

We are approximately one third of the way through the project and your continued help and support is very much appreciated. Lorraine has been visiting pharmacies and collecting data.

This information will be entered into the

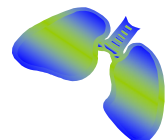
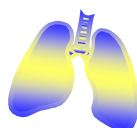
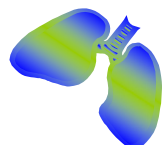
database and some preliminary results will soon be available. We look forward to sharing this with you!

Keeping track of your appointments

When you have a number of patients participating in a project keeping track of who's coming when can be tricky. Here are some tips for making this happen in a busy pharmacy:

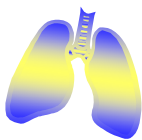
- ★ Make a list of your participants and the dates they are due to see you for each of their visits
- ★ Enlist the help of your Pharmacy Assistant. She/he could contact your participants to make an appointment or to remind them about an upcoming appointment
- ★ Make a note in your diary or on your patient database about upcoming appointments
- ★ Put up a reminder somewhere prominent to speak to your participants next time they come in for their medications about arranging their next visit

*Until next time,
Sinthia and Lorraine*



Appendix 8

Participant Follow-up Survey



TELEPHONE FOLLOW-UP SURVEY

1. What did you think was the aim or purpose of this program?
2. What did the programme do for you personally?
3. Which aspect of the asthma program did you find *most* useful? Why?
4. How did you feel about the length of each visit that you had with your pharmacist?
5. On a scale of 1 to 5 (1=not useful at all to 5=very useful), how useful did you find the following asthma related aspects:

	Not useful at all 1	Not Very Useful 2	Neither Useful Nor Not Useful 3	Useful 4	Very Useful 5
Recognizing/Understanding your asthma symptoms					
When your asthma gets worse, knowing how to change your medications					
Identifying Problems relating to your asthma and prioritizing them					
Setting goals to improve your asthma					
Setting Strategies to achieve goals					
Monitoring goals					
Recognizing/Understanding your asthma triggers					
Using the asthma severity checklist table to monitor your asthma control					
Confidence in managing your asthma					

Overall how would you rate your satisfaction with the asthma service you have received					
--	--	--	--	--	--

6. Now I'd like to ask you about what you think about the asthma workbook that you used during the program. On a scale of 1 to 5 (1=not helpful at all to 5=extremely helpful) how helpful you found the following sections of the workbook.

	Not at all helpful 1	Not very helpful 2	Somewhat Helpful 3	Very Helpful 4	Extremely helpful 5
Medical information about asthma					
Triggers and how to avoid them					
Asthma severity scale					
Setting goals and strategies					

7. Will you continue to use the workbook in the future?

Y N

If yes, which aspect of the workbook will you continue to use?

If no, why?

8. We're also interested to know you much input *you* had in working out what goals and strategies you would use to manage your asthma? Did:

Your Pharmacist set them? You set them? Or did you set them together?

9. How did you feel about this?

10. If a friend/family member of yours had asthma, would you recommend this program to them?

Y ☐ N ☐

11. In what ways do you think the asthma program could be improved?

12. If an asthma program was to run in your pharmacy in the future what would you like it to include?

13. Would you be willing to pay for an asthma service if it was offered as a regular service?

Yes No

If yes, how much would you be willing to pay for the service? \$.....

Well, that is the end of the questions. Thank you very much for your participation in our study!

Appendix 9

Strategies set by Intervention Participants

Appendix

Strategies used by Intervention Participants to achieve goals

Strategies used for <i>Medication Goals</i>	Number
---	--------

Lower dose	1
More exercise	2
Position of medication	2
Use individual prompt to remember dose	4
Timing of dose	2
Go to GP to change dose or medication	5
Take medications as prescribed	4
Use spacer	1

Strategies used for *Triggers Goals*

Go to allergy clinic	1
Wear mask	1
Hot wash bed clothes	1
Increase use of nasal sprays	2
Use saline rinse	2
Use steam-inhaler	1
Watch diet	1
Go to GP	2
Use buteyko technique	1
Relaxation	1
Independence	1
Monitor	1
Avoid triggers	27
Dusting and vacuuming	3
Take medications	1

Strategies used for *Exercise Tolerance Goals*

Take medications before exercise	3
Take medications during exercise	2
Take preventive medication	4
Set schedule to increase exercise	5
Go to GP	1
Walk slower	1

Strategies used for *Asthma Control Goals*

Use saline rinse	2
Use rhinocort	1
Increase exercise	2
Go to see GP/specialist	7
Take medications as prescribed	11
Use Zyrtec	1
Monitor with spirometer	2
Avoid triggers	7
Take time for oneself	1
Reduce stress	1
Stop smoking	1
Take vitamins	2
Attend pulmonary rehabilitation course	1
Go to Naturopath	3
Take deep breaths	1
Use antihistamines	1
Use brondicon	1
Take cough lollies	1
Chew gum	1
