Asthma is a significant public health issue worldwide. Australia has one of the highest prevalence rates for asthma in the world, with asthma ranked as one of the top 10 reasons for hospital and general practitioner visits. Repercussions of poorly controlled asthma cost the Australian community up to $720(AU) million annually. Despite efforts made by the National Asthma Council, surveys within Australian settings show that asthma management is not ideal compared with that overseas.

Community pharmacists are in a unique position to help patients manage chronic illness in view of their expertise, their regular contact with patients, and their accessibility. Disease management programs are one of the clinical services being offered by pharmacists, and these particularly lend themselves to chronic conditions, such as asthma and diabetes. Underpinning these new trends in the practice of pharmacy is the philosophy of pharmaceutical care that calls for pharmacists to take responsibility for patients’ clinical and humanistic outcomes.
In various studies across the world, pharmaceutical care–based service provision for people with asthma has been shown to improve asthma-related outcomes in patients.\textsuperscript{8-12} No specialized community pharmacy models for asthma care based on concepts such as pharmaceutical care, disease state management, or national consensus guidelines had been evaluated previously in Australia. With these issues in focus, this project aimed to develop, implement, and evaluate an asthma care model for use in community pharmacy settings in Australia that would answer the societal need for improved asthma management.

Methods

All methods had the approval of the Human Ethics Committee of the University of Sydney. The project was undertaken in 3 distinct stages, commencing in November 1997 and terminating in May 2001.

STAGE 1: QUALITATIVE

The first stage consisted of a needs analysis conducted through semi-structured interviews with community pharmacy practitioners to gauge their current role in asthma management and future options they envisaged. The feedback from pharmacists in the first stage identified various barriers such as lack of training, resources, time, mechanism of interprofessional collaboration, and patient awareness of services, which were addressed during the development stage while designing the asthma care model.\textsuperscript{14}

STAGE 2: DEVELOPMENT

This stage consisted of developing and evaluating an asthma care model. At the end of this stage, the researchers finalized the asthma care model to be implemented and evaluated.

Asthma Care Model

This model consisted of 2 elements: a training element, which was developed using principles of adult learning, and a service element, which consisted of defining the processes for the proposed specialized asthma service.

The Australian Six–Step Asthma Management Plan developed and disseminated widely by the National Asthma Council to both healthcare professionals and the general public was chosen as the framework for the asthma care model.\textsuperscript{14} The 6-step plan consists of the following factors:

1. assessment of patient’s asthma severity,
2. achievement of best lung function,
3. maintenance of best lung function through avoidance of triggers,
4. maintenance of best lung function through optimal medications,
5. provision of a written action plan, and
6. education and regular review.

Within the training element of the asthma care model, self-study manuals addressing the 6 steps above were prepared and sent to pharmacists. Following a period of self-study, pharmacists were invited to attend a 2-day workshop.

The service element of the asthma care model consisted of pharmacists:

1. seeing patients on an appointment basis,
2. conducting an individualized needs analysis framed around each of the 6 steps,
3. conducting interventions to address needs that emerged through individual analysis,
4. documenting interventions delivered and outcomes measured,
5. collaboratively setting goals with the patient for the next visit.

6. monitoring patients at 1 month, 3 months, and 6 months after the initial intervention visit, and
7. collaborating with other healthcare practitioners involved in the asthma care of the patient.

For each patient, a file with the 4 designated visits was provided to the pharmacists. Diaries designed for peak flow and medication usage records were provided to patients and completed by them for 15 days (this provided sufficient peak flow data while not being overly onerous for patients) before each visit. Patients brought their medication and devices for a device usage assessment at each visit.

STAGE 3: IMPLEMENTATION AND EVALUATION

A parallel, controlled, repeated-measures design was used to implement the model (Figure 1).

Pharmacist Recruitment

An area for conducting the intervention was selected on the basis that it had a cohesive pharmacist’s association and general practitioners who were supportive of the notion of pharmacy-based asthma services. Another geographically distinct area, which matched the intervention in terms of both general and asthma-related demographics, was chosen as the control.\textsuperscript{19} In the intervention area, pharmacists were recruited by approaching the local pharmacist’s association. In the control area, as no such association existed, pharmacists were recruited using mixed methods such as cold-calling, personal contacts, and using a personal approach.

Pharmacists in the control area were not offered any training, whereas in the intervention area, the asthma care–training program was implemented. Neither group was offered any remuneration. In the intervention area, the research team used marketing tools to aid the process of patient recruitment and also established interprofessional networks involving the Division of General Practice, asthma educators at the local hospital, the local asthma working group, and schools. The implementation was carried out between June 2000 and May 2001.

Patient Recruitment

Using an improvement of 25% in proportion of patients owning an action plan from a reported baseline of 43%, 95% confidence intervals, and a power of 90%, 40 patients were required in each group. Allowing

![Figure 1. Research design. Arrows indicate data comparison points.](image-url)
for a patient dropout rate of 20%, it was estimated that at least 50 patients would be needed in each group. It was proposed that 10 pharmacists would be requested to recruit a minimum of 3 patients each.

Inclusion criteria included patients with a previous diagnosis of asthma who used bronchodilator medications > 3 times a week, those with frequent acute attacks, or those with general concerns about their asthma.

Children < 12 years of age, patients with other major disease (eg, lung cancer, chronic obstructive pulmonary disease, AIDS), or terminally ill patients were excluded.

**Evaluation**

The ECHO (economic, clinical, and humanistic outcomes) model was used to evaluate the quality of service delivered. Outcomes measured are indicated in Table 1. Outcomes measured only in the intervention group consisted of peak flow indices, mean daily dose of medications, risk of nonadherence, device techniques, willingness to pay, and satisfaction with service. Outcomes compared between the control and intervention groups consisted of asthma severity score, medication profiles, action plan ownership, asthma-related quality of life, perceived control of asthma, asthma-related knowledge, and hospitalization events. The medication usage profile of patients was used to calculate the costs of medications being used. The costs were based on the Pharmaceutical Benefits Scheme listed price for each drug and were worked for each microgram per milligram of the drug used on a daily basis. (The Pharmaceutical Benefits Scheme is a government initiative to subsidize costs of drugs for consumers so that consumers do not pay above a copayment threshold, regardless of the cost of medication. This cutoff is different for different consumers, such as pensioners and war veterans.) Also, as the Report on Cost of Asthma in Australia calculated costs associated with mild, moderate, and severe asthma, these figures were used to determine changes in cost consumption wrought by changes in overall severity in the intervention group.

A service audit was conducted through observation of pharmacists using the asthma care model with recruited patients, and immediate feedback was offered to the pharmacist by the observing researcher.

**DATA ANALYSIS**

For all outcome variables, normality tests were conducted using the Kolmogorov–Smirnov test. For normally distributed variables, pretest–posttest comparisons were conducted using the paired Student’s t-test for 2 variables, and repeated measures tests were used to check for differences in means between ≥ 3 variables. For comparisons between independent groups (intervention group vs first and second control group), the Student’s t-test for independent samples or a one-way ANOVA was carried out. The Friedman’s test was used for variables that were not normally distributed. Data from 2 independent groups were compared using the Kruskall–Wallis or Mann–Whitney U test. Proportional data were analyzed using the χ² test. A 2-tailed, 5% (0.05) level of significance was used for all statistical procedures.

**Results**

**STUDY SAMPLE**

In the intervention area (Illawarra region of New South Wales, Australia), 12 pharmacists completed the study. Fifty-two patients were recruited in the intervention site, with 39 completing the 6 months as stipulated in the project protocols (75% retention rate). Twenty patients were recruited in the control area (Blue Mountains region of New South Wales) by 7 pharmacists (first control group). As the rate of recruitment and retention of control patients was found to be very low, a second group of 28 patients (second control group) was recruited by another 6 pharmacists at a time point that coincided with the postservice data collection in the intervention group.

**PHARMACIST’S ASTHMA CARE MODEL INTERVENTIONS**

Intervention pharmacists delivered a mean of 747 interventions across 3 visits (~14 pt.) and spent a total mean time of 96.4 minutes per patient. Of this, pharmacists spent an average of 56.6 minutes per patient at the first visit, 18.8 minutes per patient at the second visit, and 21.1 minutes per patient at the third visit.

A total of 291 goals were set by the patients and pharmacists across all of the visits (5.7 pt.). Of these, 160 goals were set at the first visit (3.1 pt.), 81 goals were set at the follow-up visit one month after the initial interview (2.0 pt.), and at the final visit, 50 goals were set (1.3 pt.). The majority of these goals

<table>
<thead>
<tr>
<th>Measure</th>
<th>Type of Measure</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity</td>
<td>clinical, economic</td>
<td>score obtained from pt. report on frequency symptoms, score range 1–3²; figures reported for costs associated with severity type² used to calculate cost-savings through severity changes</td>
</tr>
<tr>
<td>Hospitalization in last 6 mo</td>
<td>clinical, economic</td>
<td>pt. report on number of hospital visits in last 6 mo; economic analysis based on total hospital days compared between all pts. 6 mo before and 6 mo during intervention³</td>
</tr>
<tr>
<td>Peak flow index</td>
<td>clinical</td>
<td>pt. peak flow diary record, worked as minimum/maximum peak flow over 15 days×100¹⁸</td>
</tr>
<tr>
<td>Medication profiles</td>
<td>clinical, economic</td>
<td>proportion of all pts. on a particular class of drugs; costs based on government-listed prices</td>
</tr>
<tr>
<td>Risk of non-adherence</td>
<td>clinical</td>
<td>an overall score (0–11) obtained based on a validated questionnaire (Brief Medication Questionnaire)²⁷ relating to pts.; risk of nonadherence administered by the pharmacist</td>
</tr>
<tr>
<td>Defined daily doses</td>
<td>clinical</td>
<td>pt. self-report on doses of each medication used over the past week, converted to mean daily dose for each medication</td>
</tr>
<tr>
<td>Inhaler technique</td>
<td>clinical</td>
<td>pharmacist recorded pts.’ usage score as either satisfactory (100% correct) or unsatisfactory based on checklists provided</td>
</tr>
<tr>
<td>Action plan ownership</td>
<td>clinical</td>
<td>pharmacist recorded whether pt. owns an action plan</td>
</tr>
<tr>
<td>Quality of life</td>
<td>humanistic</td>
<td>pre- and postservice-validated questionnaire with 20 items scaled 0–80 (0 best, 80 worst)²²</td>
</tr>
<tr>
<td>Perceived control of asthma</td>
<td>humanistic</td>
<td>pre- and postservice-validated questionnaire with 11 items scored 11–55²³</td>
</tr>
<tr>
<td>Knowledge about asthma</td>
<td>humanistic</td>
<td>pre- and postservice-validated questionnaire, 31 true/false responses, scored 0–31²⁴</td>
</tr>
<tr>
<td>Pt. satisfaction, willingness to pay, pharmacist satisfaction</td>
<td>humanistic</td>
<td>telephone interview using questionnaire adapted by researchers from a validated pt. satisfaction questionnaire, willingness-to-pay questions using a 2-tiered approach,²⁵ and a debriefing meeting held with pharmacists after project completion</td>
</tr>
</tbody>
</table>
(45%) related to medication usage, followed by non-ownership of written action plans (25%), trigger avoidance issues (15%), lack of regular review (12%), and issues of asthma control (3%).

**COMPARABILITY BETWEEN INTERVENTION AND CONTROL GROUPS**

Demographic data were initially compared between the first control group (n = 22) and the preservice intervention group (n = 52). The second control group (n = 28) was compared with the postservice intervention group (n = 39), which was a subset of the preintervention service group (ie, pts. who completed the service at 6 mo). The groups were similar in terms of pharmacy characteristics, including average number of daily prescriptions dispensed (p = 0.86) and average number of staff employed (p = 0.57). There were no significant differences with respect to pharmacist characteristics such as age (p = 0.51), gender distribution (p = 0.11), or pharmacy ownership (p = 0.06).

In terms of patients, when the 3 samples were analyzed as 3 independent samples (ie, the first and second control groups and the preservice intervention group), there were no differences in the groups with respect to age (p = 0.16), age at formal diagnosis of asthma (p = 0.92), gender (p = 0.63), family history of asthma (p = 0.86), or occupational profiles (p = 0.46). This was also the case for most asthma management profiles (Table 2). When the 2 control groups were compared, quality of life was the only humanistic parameter that was different between the 2 groups (p = 0.003), while the other 2 parameters, perceived control and knowledge, were not significantly different (p = 0.66 and 0.80). Thus, it was concluded that the 3 groups were mostly comparable.

**CLINICAL OUTCOMES**

**Asthma Severity Score**

Statistically significant differences in mean severity scores were found between the intervention group at final visit (1.6 ± 0.7) compared with baseline severity scores for the first (2.7 ± 0.7) and the second (2.4 ± 0.5) control groups (p < 0.001). In the intervention group, there was also a significant difference in the mean severity score between baseline (2.6 ± 0.5) and the final visit (p = 0.001), as well as in the severity score between baseline and the second visit (1.7 ± 0.6; p = 0.003) conducted one month after the baseline visit.

**Peak Flow Index**

This was measured only in the intervention group. The peak flow index improved significantly from a baseline of 82.7% ± 8.2% to 87.4% ± 8.9% at the last visit (p < 0.001).

**Medication Profile**

In the intervention group, there was a significant decrease in the mean daily dose of salbutamol between baseline (374.8 ± 314.8 µg) and final visit (198.5 ± 196.9 µg; p = 0.01) and a significant increase in the mean daily dose of Seretide (a device containing salmeterol and fluticasone) between baseline (600.0 ± 0.0 µg) and the final visit (933.3 ± 250.0; p = 0.008). The proportion of patients using reliever medication alone changed from 9.6% to 1.9% (p < 0.001), the proportion of patients using both reliever and preventer medications decreased from 50% to 28.8% (p < 0.001), and the number of patients on an ideal profile of reliever, preventer, and symptom controller medication increased from 7.7% to 28.8% (p < 0.001).

An independent group’s comparison between the 3 groups (first control, second control, postservice intervention) was carried out to test for differences between proportions of patients using relievers and preventer medica-
HUMANISTIC OUTCOMES

There was a statistically significant improvement in perceived control of asthma and asthma-related knowledge scores in the intervention group compared with the control group between baseline and final visit (Table 3). However, as the 2 control groups were not comparable in terms of quality of life, it may be inferred that there was a statistically significant improvement in the quality of life in the intervention group only, both pre- and postservice (40.6 ± 14.3 vs 19.0 ± 13.5; p < 0.001). When the postservice intervention group was compared with respect to action plan ownership with both control groups, there were significant differences in the 3 groups (p < 0.001).

Patient Satisfaction

Out of 30 patients interviewed, most patients felt generally very satisfied with the service they had received from their pharmacists, rated the quality of the service highly, and found many aspects useful. They had many positive comments to offer about their pharmacists. When asked whether they would be willing to pay for the service they had received should they be offered similar services in the future, most indicated they would be willing to pay.

Pharmacist Feedback

In a debriefing meeting held with the pharmacists who had participated in the service, pharmacists indicated that they believed delivering the asthma care model services had been a positive learning experience. From that meeting, it emerged that pharmacists recommended greater flexibility and individualization of the elements of the service to patients’ needs for future implementation of the service.

ECONOMIC OUTCOMES

Economic analysis of the data showed that the mean monthly medication costs per patient at baseline were $264.80 (AU) and these were reduced to $253.70 at the end of the intervention. This represented a savings of $11.00 per patient per month, translating to $132.84 annual savings per patient. Hospitalization data collected in the intervention group after the service and 6 months prior indicated a savings of $1.50 per patient per month. Cost-savings due to an overall decrease in severity were estimated to be $8400.10 monthly and $100 801.20 annually for the group of intervention patients who completed the study.

Discussion

The asthma care model developed and implemented within this study is the first of its kind in Australia. Unlike a large number of other models tried elsewhere, this model used a set of nationally accepted consensus guidelines and translated these into a real-life pharmacy setting. The 6-step asthma management plan was used as a framework for training pharmacy practitioners and for delivering and evaluating the service. The asthma care model developed in this study thus represents an example of the systematic use of current best practice guidelines in asthma management in Australia, using a community pharmacy setting.

Patient retention rates of 75% seem consistent with patterns observed in similar studies conducted in community pharmacies. It was interesting that the mean time spent per intervention per visit increased from 5 minutes (first visit) to approximately 20 minutes per intervention per patient at the final visit, indicating that interventions that remained to be delivered by the last visit were perhaps more problematic for patients and pharmacists to resolve. By the final visit, the mean number of interventions per patient per visit dropped from approximately 11 to 1 intervention. Most of the interventions delivered pertained to step
4 (maintain best lung function by using optimal medications) and step 1 (assess asthma severity) of the 6-step asthma management plan.

Pharmacists had some difficulty in conducting the collaborative goal setting. This is understandable since, prior to the commencement of the project, these pharmacists had been in a transactional mode with their asthma patients. Activities like collaborative goal setting necessitated switching to an entirely different mind set: that of the so-called therapeutic alliance. Even though the pharmacists had initial problems in collaborative goal setting at the initiation of the study during their site audit, they seemed to have overcome these by the end of the project, as evidenced by the fact that 291 goals had been identified across the 3 visits, producing an average of 5.7 goals (issues to be addressed) per patient. These issues would otherwise have probably gone undetected and unaddressed. Successful goal setting undertaken by the intervention pharmacists indicated that they had truly been able to embrace the practice of concordance despite the fact that pharmacists have been shown to have the least favorable attitudes toward concordance compared with other healthcare practitioners.26

While improvements in asthma severity as demonstrated through use of this asthma care model have been established in many other models, not many pharmacy-based asthma care projects have been able to demonstrate improvements in lung function. The peak flow index used in this project is a more robust index18 than simple peak flow measures and has not been used previously within pharmacist care settings. In terms of medication use, results are consistent with those from other pharmacy asthma care research, that is, increase in patient use of preventer medication and decrease in use of reliever medications. Risk of nonadherence, which decreased in this study, was another unique measure that has not been used before in other asthma studies; most projects have looked at patients’ self-reported adherence.5 11

Although written action plans, coupled with regular practitioner review and patient education, are the crux of patient self-management,27 they have not usually been targeted as a focus of pharmacist asthma care provision. Increased ownership of action plans in the intervention patients, which was initiated by the pharmacists, is a strength of this asthma care model. In response to the asthma care model service, there was improvement in the quality of life and asthma knowledge as shown previously,8 10 but we also showed improvement in the perceived control of asthma, which may be an indication of the patient’s ability to self manage. Cost-savings were demonstrated through the lowering of mean severity scores and improvement in medication profiles. Hospital-related cost-savings were also shown; the relatively small value indicates few hospitalizations in the intervention group even before the service.

The asthma care model was cognizant of the needs of practitioners and was developed by taking into account the information obtained during the qualitative stage of the research. Marketing tools were used to enhance patient recruitment, and though an evaluation of the marketing activity of the research team was not a major focus of the study, the results of this endeavor have implications for the future of such service provision through community pharmacies. Sustainability of the model was achieved, as some pharmacists indicated that they had continued to use modified versions of the service protocols with other patients after the project. These pharmacists were not paid to deliver the asthma care model services, during or after the research, this indicates that they may be a rather special group of highly motivated, leading-edge practitioners.

From a research perspective, the study does not meet the standards of a rigorous, randomized control design. The sample sizes were small; therefore, the results may not be representative of the population of asthmatics. Due to difficulties in patient recruitment, the same control group could not be followed through the study and another control group was recruited for comparison with the postservice results from the intervention group. Also, as the pharmacy numbers were quite small, effect size based on pharmacy or pharmacist type could not be demonstrated. As actual costs of the patients’ medications were not documented, exhaustive cost-effectiveness analysis from the consumer’s or government’s perspective could not be carried out.

Summary

This project demonstrated the successful implementation of an asthma care model in community pharmacy. This model was based on the foundations of pharmaceutical care and disease management and used research principles to demonstrate the effectiveness of community pharmacies as a venue for specialized health care for patients and caregivers of people with asthma and the pharmacist as an efficient deliverer of cognitive services for asthma. In Australia, this venue and resource is currently underutilized. Since there is still considerable community morbidity from asthma, the results of the asthma care model should be used to develop systems and resources on a larger scale to help reduce levels of morbidity from asthma in the community.

References

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EXTRACTO

TRASFONDO: Los farmacéuticos se encuentran en una posición única en el sistema de salud para identificar situaciones críticas sobre el manejo de asma en la comunidad. Varios programas han demostrado el beneficio de que un farmacéutico dirija un programa de manejo de asma, sin embargo estos programas no se han realizado en Australia.

OBJETIVO: Medir el impacto, en términos de resultados objetivos clínicos, humanísticos, y económicos, de proveer un servicio especializado de asma a través de farmacias de comunidad.

MÉTODO: Se utilizó un diseño controlado y paralelo, en el cual se reclutaron 52 pacientes para un programa de manejo de asma con intervenciones del farmacéutico y se compararon con 50 pacientes asmáticos de otra localidad. En el programa de intervenciones, los farmacéuticos se adiestraron y siguieron un modelo de cuidado de asma que incluía 3 visitas de seguimiento por un período de 6 meses. Este modelo fue evaluado en base a resultados clínicos, humanísticos, y económicos.

RESULTADOS: Hubo una reducción significativa en la severidad de la condición en el grupo que recibió las intervenciones, 2.6 ± 0.5 a 1.6 ± 0.7 (p < 0.001) vs. grupo control 2.3 ± 0.7 a 2.4 ± 0.5. En el grupo que recibió las intervenciones, los índices de flujo máximo pulmonar mejoraron de 82.7% ± 8.2 al inicio a 87.4% ± 8.9 (p < 0.001) en la última visita. Además, hubo una reducción significativa en la dosis diaria de salbutamol utilizada por los pacientes de 374.8 ± 314.8 µg al inicio a 198.4 ± 196.9 µg en la última visita (p < 0.015). Hubo una mejoría estadísticamente significativa en el control del asma, de acuerdo a la percepción del paciente, y en el puntaje de preguntas relacionadas al conocimiento de la condición en el grupo que recibió las intervenciones comparado con el grupo control. Se demostró un ahorro anual de $132 844 (dólares Australianos) por paciente en costos asociados al uso de medicamentos y $100 801.20 en el grupo completo, basado en la reducción total de severidad.

CONCLUSIONES: Basado en los resultados de este estudio, parece ser que un modelo especializado de asma ofrece a los farmacéuticos de comunidad oportunidad de contribuir en el mejoramiento del manejo de asma en la comunidad australiana.

Annette Pérez

RÉSUMÉ

CONTEXTE: Les pharmaciens ont une place dans le système de santé qui leur permet de jouer un rôle important dans le traitement de l’asthme en milieu communautaire. Plusieurs études ont démontré les bienfaits de tels programmes gérés par des pharmaciens. Cependant, aucun de ces programmes n’a été évalué en Australie.

OBJECTIF: Mesurer l’impact d’un programme de soins spécialisés en asthme à travers un réseau de pharmacies communautaires sur le plan clinique, humain, et économique.

MÉTHODES: Un essai contrôlé a été réalisé parallèlement dans lequel 52 patients recevant l’intervention et 50 autres patients recevant le suivie habituel a été réalisé à 2 endroits distincts. L’intervention était effectuée par des pharmaciens formés pour prodiguer des soins à une clientèle asthmatique selon un modèle défini. Le modèle a été évalué selon des critères cliniques, humains, et économiques.

RÉSULTATS: Il y a eu une réduction significative de la sévérité de l’asthme dans le groupe ayant reçu l’intervention par rapport au groupe-contrôle (2.6 ± 0.5 a 1.6 ± 0.7 contre 2.3 ± 0.7 a 2.4 ± 0.5, respectivement, p < 0.001). De même, les valeurs de débit de pointe se sont améliorées de 82.7% ± 8.2 à 87.4% ± 8.9 (p < 0.001) entre le début et la fin de la période étudiée. Il y a également eu une diminution significative de la dose totale de salbutamol utilisée de 374.8 µg ± 314.8 à 198.4 µg ± 196.9. Il y a eu une amélioration significative dans la perception du contrôle de l’asthme et dans les scores reliés à la connaissance de la maladie. Les économies attribuées à une diminution de la sévérité de l’asthme ont été estimées à 132 844 dollars australiens en coûts de médicaments par patient et à $100 801 pour l’ensemble du groupe ayant reçu l’intervention.

CONCLUSION: Selon les résultats obtenus, il semble qu’un modèle de soins spécialisés en asthme offert par des pharmaciens en milieu communautaire représente une opportunité pour améliorer le traitement de l’asthme en Australie.

Nicolas Paquette-Lamontagne