Journal of Clinical Pharmacy and Therapeutics (2003) **28**, 395–402

Asthma management by New Zealand pharmacists: a pharmaceutical care demonstration project

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SUMMARY

Background: **Pharmaceutical care services became recognized in New Zealand in the mid-1990s, albeit with limited evidence of the acceptability and effectiveness of the model. An asthma-specific pharmaceutical care service was trialled in southern New Zealand, based on a 'problem–action–outcome' method, with pharmacists adopting a patient-centred, outcome-focused approach with multidisciplinary consultation.**
Objective: **To report on the implementation and outcomes of a specialist asthma service offered by community pharmacists.**
Design: **Pharmacists in five pharmacies, servicing predominantly rural, established clientele, received training in the asthma service and research documentation. Ten patients per pharmacy were recruited in each year (years 1 and 2) of the study. The patients were entered into the study in cohorts of five per pharmacy twice yearly, with year 2 mirroring year 1. The phase-in design minimized the impact on the pharmacists. The patients acted as their own controls. All patients received individualized care and had approximately monthly consultations with the pharmacist, with clinical and quality of life (QoL) monitoring.**
Results: **A total of 100 patients were recruited. On average, 4·3 medication-related problems were identified per patient; two-thirds of them were compliance-related. The most common interventions were revision of patients' asthma action plans, referral and medication counselling. Clinical outcomes included reduced bronchodilator use and improved symptom control in around two-thirds of patients. Asthma-specific QoL changes were more positive and correlated well with clinical indicators.**
Conclusion: **Further research is warranted to integrate this service into daily practice. Clinical outcomes were generally positive and supported by QoL indicators. Characteristics of New Zealand practice and this sample of pharmacies may limit the generalizability of these findings.**

Keywords: **asthma, community pharmacy, outcomes, pharmaceutical care, quality of life, specialist service**

INTRODUCTION

Evidences which indicate an increase in asthma morbidity and mortality worldwide (1), present a challenge to health care providers (2). In response to this, various models for asthma management services by health professionals have been tested internationally. Common features of these services include educational interventions for patients, self-management through monitoring of peak expiratory flow rates (PEFR) and questionnaires to gauge symptom severity, quality of life (QoL) and satisfaction (3–6).

A review of 18 asthma self-management intervention studies concluded that significant achievement is possible in asthma knowledge, patient perceptions, psychological status, medicines use behaviour, behaviour relating to environmental triggers, symptoms and functioning and usage of health care resources (3). These represent the key outcome measures for asthma management programmes. The study design was discussed as a challenge, particularly considering the influence of social environments on asthma control, and more research is warranted in this area along with the development of standardized measures and tests of theory-based interventions (3).

Received 18 February 2003, Accepted 19 August 2003
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A controlled study in Germany tested the impact of a 5-day standardized clinical asthma training programme in groups of 25–29 children and their families (4). The training, with monthly follow-up for 6 months, was found to be more effective than training without follow-up and no training. The outcomes were measured by questionnaire, including measures of self-management, coping and anxiety. However, improvements in lung function and the number of sick days did not remain significant at 1 year after the intervention. This study demonstrates the potential impact of ongoing contact between asthma patients and educators, following an intervention based on group education rather than individualized consultation.

Individualized asthma education was the subject of a study conducted in The Netherlands (5). A feedback instrument helped to determine the information needs of the patients. The researchers measured the resulting information exchange between general practitioners and patients, along with patient satisfaction, for over 6 months. A significant increase in patient satisfaction and decrease in information needs were found in the study patients.

In the community pharmacy setting, Finnish researchers have applied therapeutic outcomes monitoring principles in an intervention that consisted of education, counselling and outcomes monitoring (6). The sample of four pharmacies recruited a total of 28 adult patients deemed to have asthma management problems. The patients acted as their own controls, with measurements of knowledge and attitudes at baseline and at 12 and 24 months post-intervention. The findings were generally positive. Although asthma control measures (such as PEFR) were not reported, this study presents a design that may be applied to other populations.

Pharmaceutical care is a model for patient management also based on therapeutic outcomes, but with an emphasis on improving patients' QoL. Other key features of pharmaceutical care require pharmacists to work proactively in collaboration with the patients themselves and other health professionals, with documentation and ongoing patient monitoring to achieve therapeutic goals, and to take responsibility for the outcomes of drug therapy (7). The model originated from Minnesota, and quickly gained international credibility. New Zealand pharmacists embraced the practice, and New Zealand has now achieved what could be considered the highest number of pharmaceutical care-trained pharmacists per capita in the world (8, 9). This uptake demanded research in the integration of the service into daily pharmacy practice, and, importantly, its outcomes. As the ultimate goal of drug therapy should be to improve the patient's health-related QoL, the key outcomes to be measured include both clinical and QoL impact of the pharmacists' interventions.

The pharmaceutical care model is intended for patients with any disease state(s), but in response to the need to demonstrate its effectiveness, single disease states, such as asthma, have been the focus of international studies. Asthma-specific pharmaceutical care services have resulted in patients receiving more information about asthma self-management, increased likelihood of monitoring PEFR and increased satisfaction with care (10). Economic savings have also been reported (11). Difficulties exist with the lack of validated outcome measures, and particularly in developing suitable experimental methods in a community pharmacy setting whereby the use of control patients and crossover designs introduces logistic challenges.

AIMS

The focus of this study was the practical implementation of Hepler and Strand's pharmaceutical care model in New Zealand. Asthma was chosen as the model for demonstration purposes, as its prevalence, management protocols and outcome measures are well defined.

Specific objectives were to report on the clinical and QoL outcomes of a specialist asthma pharmaceutical care service in a sample of community pharmacies in New Zealand.

METHOD

Study pharmacies

Five community pharmacies in the Southland and Otago provinces of New Zealand were chosen for the study. These pharmacies were selected for their

convenience to the research centre and stability of their clientele, with most patients using the same pharmacy and general practitioner. The localities are predominantly rural, supported by mixed industry and primary production. One of the pharmacists had previous experience with practice specialization and research.

The pharmacists were trained in specialist asthma management and the study methods in two weekend workshops, which were supplemented by reference materials. The second training session focused on integrating the specialist asthma training into the service, using real asthma patients.

Patient recruitment

The study used patients as their own controls, before and during the pharmacists' service. This is consistent with other pharmacy-based research (6). A crossover experimental design was not feasible because of the probable contamination of patient groups in this rural setting, and the learning effect of educational components of the intervention. There was no matched locality, because of the need for close contact between the study pharmacies and the study centre.

A phase-in design was implemented to minimize burden on the study pharmacists, as the pharmaceutical care service represented a significant deviation from normal practice of the pharmacies. Initially, pharmacists recruited a pool of patients, from whom the researchers selected those for recruitment, based on potential need for intervention, clarity of the diagnosis, and age, gender and ethnic representation. Ten patients were identified for each of the five pharmacies for each year (years 1 and 2) of the study, totalling 100 patients. The 10 patients per pharmacy were phased in five at a time, twice per year.

The pharmacist–patient interviews took place approximately every month throughout the service. Year 2 was a repeat of year 1, with an option for pharmacists to continue consultations with their year 1 patients on an 'as needed' basis.

The pharmacists were reimbursed for their services by contracting individually with the local Health Funding Authority.

CPC® Asthma Management Service

The specialist service consisted of five elements, reflecting the CPC® model (7): (a) patient consultation, (b) systematic assessment, (c) care planning, (d) patient education, recommendations and referrals, and (e) monitoring and follow-up.

Initial consultations lasted for 40–60 min, whereas follow-ups took 15–20 min. The documentation was electronic, using dedicated Cognicare® software licensed in New Zealand from the United States.

Outcome measures

The patients completed daily diaries that incorporated twice-daily peak flow readings and symptom assessment, which included wheezing, night-waking, activity limitation, asthma triggers, sick days, health-care utilization and medication use. These were monthly diaries, reviewed by the pharmacist at each visit, before analysis by the researchers.

The researchers collected baseline asthma control data prior to the patients' entry into the study. This was based on a 1-week recall of symptoms, medication taken and use of health services. These clinical data were derived from a wide range of published sources (12). PEFR was not measured prior to the pharmacists' intervention, so as to avoid contamination of outcome measures if patients were not already performing these readings.

The researchers also collected QoL data from patients, using both the generic Short Form-36 (SF-36) (13) and asthma-specific Asthma Quality of Life Questionnaire (AQLQ) (14), contributing to the validation of the AQLQ in New Zealand. The eight health domains of the SF-36 were summarized and reported as Physical and Mental Component Summaries (PCS and MCS, respectively) (15). Minor changes in the list of activities attached to the AQLQ were made, in consultation with the questionnaire's developer in Canada, so that the patient-selected activities were 'compatible' with the New Zealand population (for example, ice hockey replaced with rugby). Only QoL data pertaining to the adult population will be reported here. The use of both generic and asthma-specific questionnaire has been advocated to capture both

general estimates of asthma burden and specific changes to QoL (16).

Data analysis

Medication-related problems were categorized for analysis. The categories used (Table 1) were based on a system widely used in the United States (17), with emphasis on the categories of greater relevance to asthma management. To explore QoL, data gathered from the total sample were divided into two groups. Group 1 patients comprised those who had received 4 months of pharmaceutical care. Group 2 patients were those who had received traditional pharmacy services for 4 months (pre-intervention only). QoL questionnaires were interviewer-administered at baseline (T1) and 4 months later, to both groups (T2). Significance of QoL score changes at T2 were expressed by using analysis of variance, and $P < 0{\cdot}05$ was considered to be statistically significant. The magnitude of post-intervention change was analysed using the effect size formula which translates the before and after changes into a standard unit of measurement, and was calculated by dividing the change in mean scores from baseline (T1) to follow-up (T2) by the standard deviation of the score at baseline (18). An effect size of 2 was considered small, 4 moderate and 8 large (19).

Table 1. Classification of medication-related problems

Major category	Subcategories
Choice of medication/dose	Items needed but not prescribed Items prescribed but not needed Duplication of medications Dose too high or too low
Device	Inappropriate or incorrect choice or use of dosage form or device Route of administration Scheduling or duration of administration
Compliance	Non-compliance or poor compliance with prescribed medications Poor inhaler technique Lack of an asthma action plan, etc.
Adverse drug reactions/ drug interactions	Documented/suspected adverse reactions Drug interactions
Miscellaneous	Smoking Problems with non-asthma medication, etc.

RESULTS

Patient characteristics

Of the final sample of 100 patients, 34 were aged below 17 years. Maori patients ($n = 9$) were representative of this district; however, these were mainly children, and other ethnic groups were under-represented.

Fifty-four patients were diagnosed asthma in the previous 10 years, although 18 patients had been diagnosed more than 30 years earlier. When related to age, most patients (28%) had lived with asthma for more than 80% of their lives. Only 25 patients were using an Asthma Action Plan prior to the study.

Clinical results

An average of 4·3 medication-related problems were identified per patient. Sixty-six per cent of all medication-related problems (285/431) were classified as 'compliance-related', whereas 19·3% ($n = 83$) related to choice of medication or dose, 10·7% to choice of device, 2·6% ($n = 11$) to adverse drug reactions or drug interactions, and 1·4% to other problems. The five pharmacies were responsible for between 41 and 140 interventions each.

All 100 patients received some form of intervention. Nearly three-quarters ($n = 72$) received a new or revised Asthma Action Plan or recommenced using their existing plan, as a result of the CPC® service. Forty-nine patients were referred to another health professional (general practitioner, respiratory specialist or asthma educator) for further attention, usually with some recommendation about the choice of medication or device.

Within 6 months of the initial consultation with the pharmacist, 70% of patients were estimated to have had between one-quarter and three-quarters of their medication-related problems resolved. Regarding medication use, bronchodilator use was

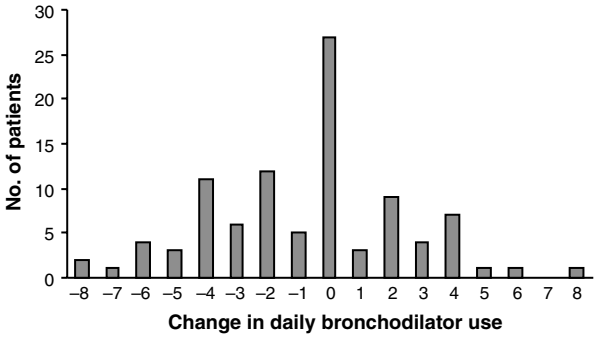

Fig. 1. Change in bronchodilator use (post- minus pre-intervention).

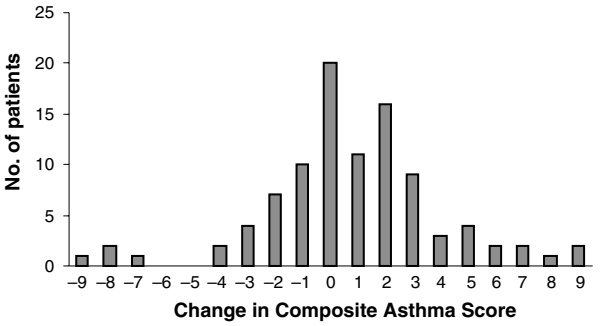

Fig. 2. Change in Composite Asthma Score (post- minus pre-intervention).

reduced over this time in 44 patients, compared with 26 patients requiring additional reliever therapy (Fig. 1).

A Composite Asthma Score was derived for the purposes of summarizing activity limitations, wheeze and cough, with scores ranging from 0 to 12 (12 indicating total absence of symptoms). Analysis of Composite Asthma Scores over 6 months of consultations indicated that 50 patients had a higher (improved) score, whereas 27 experienced worsening of symptoms (Fig. 2).

Daily average PEFR readings over the same time frame indicated that around two-thirds of patients demonstrated at least some improvement in their readings, although this was modest in most cases (Fig. 3).

Quality of life results

Of a total of 66 adult patients (17 years and older), 62 provided QoL data at baseline and follow-up (34 in group 1 and 28 in group 2). The remaining four

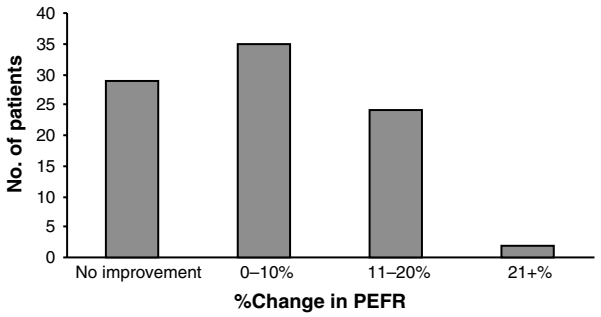

Fig. 3. Change in average peak flow readings (post-minus pre-intervention).

patients withdrew from this part of the study for various personal reasons (work commitment, absence from locality, etc.). Table 2 compares the change in QoL of group 1, after receiving service for 4 months, with group 2 after receiving 4 months of traditional pharmacy service. With the exception of the environmental domain, all other QoL domains of group 1 patients (activities, emotional and overall QoL) indicated different levels of statistically significant changes at T2 with a corresponding effect size. Group 2 scores showed very little change in all AQLQ domains except the 'activity'. Neither the PCS nor the MCS of the general SF-36 showed significant change at T2 (P = 0·61 and 0·12, respectively).

DISCUSSION

Discussion of the methods

The choice of asthma as the model for the specialist service was useful, as the outcome measures were reasonably well established, and adoption of training and practice guidelines was relatively straightforward. Further, relevant QoL instruments were available, albeit unvalidated in this population in the case of AQLQ. Validation of this instrument has been reported elsewhere (20).

As far as possible, patients with comorbidities were excluded from recruitment, to allow for detection of change in their asthma. Upon collection of patient histories, however, other disease states sometimes became apparent (e.g. chronic obstructive airways disease, allergies). The presence of other conditions on patients' management of their asthma should be recognized. The use of both generic and asthma-specific QoL instruments

Table 2. Change in Asthma Quality of Life Questionnaire (AQLQ) scores (group 1, $n = 34$ patients; group 2, $n = 28$ patients)

	Paired difference, T2–T1 (SD)		*P* (*t*-test)		Effect size	
Domain	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Activities	0·3 (0·9)	0·6 (1·1)	0·05	0·01	0·3	0·5
Symptoms	0·4 (0·9)	0·3 (1·2)	0·01	0·15	0·4	0·3
Emotional	0·4 (1·0)	0·2 (1·3)	0·01	0·40	0·3	0·2
Environmental	0·1 (1·0)	0·1 (0·8)	0·21	0·62	0·1	0·1
AQLQ-overall	0·3 (0·8)	0·3 (0·9)	0·02	0·09	0·4	0·3

Effect size express the magnitude of change (2: small, 4: moderate, 8: large).

was appropriate for these situations and this technique is recommended for future research.

The regional location was chosen for its proximity to the research centre and for continuity of pharmacy clientele, but it is recognized that characteristics of this sample may not allow generalization of the findings to other regions of the country or internationally. For this reason, further research in different asthma populations, along with refinement of the study documentation, is recommended. Asthma is also recognized as problematic in northern regions of New Zealand, and it is possible that regional and ethnic differences within the country could influence the nature and effectiveness of the pharmacists' interventions. For example, the study population was underrepresented in Maori, Pacific Island and Asian ethnic groups.

The use of an optimal experimental study design was not feasible in a real-life study such as this. Within small communities, the introduction of a 'no service' control would introduce potential contamination in pharmacists unwittingly introducing interventions beyond baseline practice to 'control' patients. It was assumed in this study that patients would remain loyal to their study pharmacies, and that they were not receiving asthma education from sources other than those initiated by their pharmacists. A design feature considered more experimentally sound, for future research, the identification of 'matched' localities elsewhere in the country, provided that contact could be maintained with collaborating research centres for training, support and on-site data collection by the researchers.

The study pharmacists reported that they had enjoyed the challenge of providing a novel specialist service. More research is warranted in adapting this from the demonstration setting into daily practice, with consideration of appointment scheduling, reimbursement and workflow practices. The study documentation and questionnaires were both appropriate and usable, although computerized patient records may not be essential for daily practice. The suggested changes to the AQLQ to allow cross-cultural adaptation require further validation in local populations, although the instrument demonstrated sound reliability and responsiveness.

The data from 100 patients, tracked over 6 months (introduced through a staggered baseline period), permitted limited statistical analysis. As patients acted as their own controls (before and during receipt of the specialist service), within-patient analysis was considered appropriate for the purposes of analysing change. This technique was applied to both the clinical and QoL data, although the more advanced scoring systems in the QoL questionnaires allowed tests for statistically significant differences.

Discussion of the results

There was considerable variation in the number of medication-related problems detected between the five study pharmacies. It is not clear whether this was because of differences in recording or clinical vigilance, or the result of the characteristics of their respective cohorts. One pharmacist who had previous experience in the provision of pharmaceutical care service, was reflected in both the detection of the number of medication-related problems and his role as a 'leader' within the study group.

The majority of patients reported some degree of improvement in their asthma control indicators.

Despite international and methodological differences, this is consistent with the findings of other studies in the influences of educational and clinical services (3–7), at least in the short-term. However, these findings are quite modest overall. The variable nature of the condition, short-term follow-up and impact of other medical conditions are obvious limitations in measuring the outcomes of a service such as this. It must also be recognized that this is real-life research, and despite all efforts, about one-third of the patients showed little or no improvement.

An extended study period would allow analysis of the long-term impact of pharmacists' services on asthma management in the community. It was not intended to prove that pharmacists could 'cure' asthma, or to compare the influence of pharmacists to other health professionals in the management of this condition. The service described here is a collaborative management process, which requires ongoing consultation between the patients and health professionals, and true outcomes may take longer to materialize.

The findings regarding QoL were generally more positive than the short-term clinical findings. QoL scores before and after the intervention demonstrated the burden of the condition on daily life, and also the sensitivity of the QoL instruments in detecting change and the impact of personalized health care services and counselling in a condition such as this. Improvement in different QoL domains after provision of the service was considered to be of special importance as the major objective of the provision of pharmaceutical care is to positively influence daily functioning and well-being. There also appeared to be good correlation between the QoL data and measures of asthma severity, including bronchodilator use and asthma symptoms. These findings are beyond the scope of this article. However, continued use of this battery of documentation is recommended, and should pharmacists be given training in QoL questionnaire administration and analysis, they should be able to manage the recording of these data themselves in daily practice.

The economic impact of the pharmacists' services was not measured, although medication costs were monitored for a subset of patients. Again, extended monitoring of patients would allow relatively uncommon events, such as deaths or emergency care, to become apparent and considered in the potential outcomes.

CONCLUSIONS

The basic principles of the service have potential to be adopted for other conditions. Because of the modest nature of clinical improvements, it is suggested to target future services to those more 'needy' of a pharmacist's intervention, whereas recognizing that there may always be patients who are resistant to intervention. A range of outcome measures is recommended, including humanistic (QoL) outcomes. Issues to be further addressed include integration of permanent services into workloads, enhancing interprofessional relationships and reimbursement in a non-research setting.

This demonstration project has shown that community pharmacists, with training and support, are highly capable of implementing a specialist asthma management service, with largely positive outcomes.

ACKNOWLEDGEMENTS

The authors acknowledge financial support by the Southern Regional Health Authority (New Zealand) and Glaxo Wellcome Limited, and the participation by staff of the five study pharmacies.

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