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Can pharmacists influence the health-related quality of life of patients with asthma?
The New Zealand Pharmaceutical Care experience

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هل يمكن للصيدلي التأثير على النواحي الصحية لحياة مرضى الربو: تجربة صيادلة نيوزلندة

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الملخص: الهدف: تقييم تأثير العناية العقارية بالربو وتحديد النتائج الصحيةمن الأستجواب المتعلق لمرضى الربوكمؤشرات للنجاح. **الطريقة:** تم تجميع ٦٢ فردا من مرضى الربو البالغين(١٧عاما وأكبر) من منطقتين ريفيتين في نيوزلندا وقُسموا إلى مجموعتين لتقديمهم إلى الخدمة العقارية. عمل المرضى المعنيين كعينة ضابطة لأنفسهم قبل الحصول على خدمة الصيادلة. وقد تم تشخيص الربو للمرضى قبل ستة أشهر من عملية جمعهم وكان للربو أعراضا واضحة لم يتم السيطرة عليها بصورة مثالية قبل ذلك. **النتيجة:** لوحظ تحسن كبير من خلال نتيجة استبيان نوعية حياة مرضى الربو بعد تقديم الخدمة وقد تمكن الصيادلة من ايجاد الحل لأكثر من ٤٠٠ مشكلة لها علاقة بالعقار. **الخلاصة:** تدل النتائج أنه بوجود التدريب المناسب يمكن لصيادلة نيوزلندا مساعدة مرضى الربو في الحصول على نوعية حياة أفضل. هذا البحث سيساعدعلى تقديم الخدمات السريرية في بلدان أخرى لمرضى بحالات أخرى تتطلب مراقبة مستمرة.

ABSTRACT. ***Background:*** The newly emerging practice of Pharmaceutical Care requires that pharmacists take responsibility for the outcomes of drug therapy. Improvement in Quality of Life (QoL) represents the final outcome of the care process and indicates the success of interventions. ***Objectives:*** To assess the impact of a Pharmaceutical Care specialist asthma service provided by community pharmacists to a sample of patients with asthma, the outcome indicators being changes in health status and QoL. ***Method:*** Sixty-two adult asthma patients (17 years and older) living in two rural regions of New Zealand, were segregated into two groups for phased introduction to the service. The patients acted as their own controls before they received the pharmacists' service. They had been diagnosed with asthma at least six months previously, and their asthma was symptomatic and not considered optimally controlled prior to the study. ***Results:*** There was significant improvement in asthma-related QoL (as measured by the Asthma Quality of Life Questionnaire) following introduction of the service, and pharmacists were able to identify, prevent or resolve over 400 drug-related problems. ***Conclusion:*** The results suggest that with appropriate training and support, New Zealand pharmacists can help asthma patients achieve greater quality of life. This research has implications for the introduction of Pharmaceutical Care services in other countries and for patients with other conditions who require ongoing management.

Key words: Pharmaceutical Care, Quality of Life, asthma, pharmacists,

There is compelling evidence that asthma morbidity and mortality has increased worldwide, representing a challenge to healthcare providers.[1,2] Consequently, clinical services are sought to help patients manage their conditions effectively. In recent years, New Zealand pharmacists have formally embraced the internationally recognised practice of *Pharmaceutical Care*, and New Zealand has now probably the largest number of Pharmaceutical Care trained pharmacists per capita in the world.[3,4]

In a widely publicised article, Hepler and Strand defined the process of Pharmaceutical Care as 'the responsible provision of drug therapy intended to achieve definite outcomes that will improve a patient's quality of life.'[5] This definition suggests that, as healthcare professionals, pharmacists take responsibility for the outcomes of drug therapy by adopting an active role in patient management.

As the ultimate goal of drug therapy should be to improve the patient's health-related quality of life (QoL), it

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is imperative to assess the impact of medical interventions on QoL.

While considerable evidence exists demonstrating the worth of Pharmaceutical Care on a variety of patient outcomes, little has been provided on the impact of Pharmaceutical Care on QoL as an end-point in the healthcare process. For example, Fischer *et al* suggested that Pharmaceutical Care appears to increase the information given to patients about medications, promote more effective self-administration of medications by encouraging patients to use systematic reminders, and increase awareness of medication side effects.[6]

In another study, patients receiving Pharmaceutical Care reported receiving more information about asthma self-management, were more likely to monitor peak flow readings, and had increased satisfaction with care.[7] Munroe and colleagues reported that pharmacists' interventions in a community pharmacy-based disease management model substantially reduced monthly healthcare costs in patients with hypertension, hypercholesterolaemia, diabetes, and asthma.[7] More evidence is needed on the impact of Pharmaceutical Care on subjective outcomes, specifically QoL.

This paper outlines the findings of a Pharmaceutical Care specialist asthma service conducted as a demonstration project by the pharmacists in New Zealand. Although the paper does not provide data pertaining to the impact of the service on economical outcomes, the research has implications for other countries faced with rising secondary care costs due to asthma and other chronic conditions.

METHODS

The aim of the study was to assess the health-related and QoL outcomes in a group of asthma patients receiving a pharmacy-based asthma management service.

This study was conducted in five community pharmacies in Otago/Southland regions of New Zealand over a two-year period. The School of Pharmacy, University of Otago, co-ordinated the study, which was funded by the Health Funding Authority with support from GlaxoWellcome New Zealand Limited. The study was approved by the local ethics committee and patients gave informed written consent to participate.

In consultation with the patients' general practitioners, who were kept informed about the aims and progress of the study, pharmacists from the five pharmacies recruited 20 medically-diagnosed asthma patients each. Inclusion criteria were that (i) the patients had been diagnosed with asthma at least six months previously, (ii) their asthma was symptomatic and not optimally controlled, and (iii) they did not suffer other co-morbidity. The latter criterion was based on the assumption that other chronic conditions could interfere with health outcomes measured, including the patient's QoL, and could make it difficult to identify the effect of the intervention on asthma. However, to simulate real-life situations, it was decided that if a concomitant condition were identified during the study, the patient continued participation. Prior to the study, the status of the patients' asthma was estimated by subjective self-assessment and by the frequency of visits to collect asthma medication.

The patients were phased into the study in groups of 5 per pharmacy for stepwise introduction to the service. This avoided the pharmacies being overwhelmed by large numbers of patients at one time, and allowed variable baseline measurement periods for the pre- and post-intervention measures.

Based on a preliminary rating of asthma that used input from patients and their pharmacists, the patients were divided into two groups. While all patients recruited had what appeared to be *poorly controlled* asthma, Group 1 included patients whom the research team felt were in need of immediate intervention. The study design dictated that Group 1 receive the intervention first. It was considered unethical to deny these patients the opportunity for immediate care.

At baseline (T1), face-to-face interviews were conducted with all the patients. Data collected included QoL, specific symptoms, utilisation of health services, and beta-agonist ('reliever' medication) use. Group 1 patients then underwent a one-month run-in period during which standard phar-

Table 1. *Classification of Medication-Related Problems*

Class	Description/examples
Choice of medication/dose	Includes items needed but not prescribed, items prescribed but not needed, duplication of therapy, dose too high or too low
Adverse drug reactions	Any adverse drug reaction or drug interaction experienced by the patient, or for which the patient was at risk
Device	Inappropriate/incorrect choice or use of dosage form or device, route of administration, duration of administration
Compliance	Non-compliance or poor compliance due to factors such as poor understanding of reasons for use of medicine, poor inhaler technique, lack of an Asthma Action Plan
Miscellaneous	Problems that could not be readily classified, e.g. smoking

macy services were delivered (prescription-related counselling, basic monitoring, advice on request). Immediately after the run-in period, the service was introduced to Group 1. Group 2 continued their run-in period for another four months, during which they received no intervention.

Only the data pertaining to adult patients (aged 17 years and over) in Groups 1 and 2 (year 1 of the study) are covered in this review.

Patient training in both asthma management and the provision of the service was provided by the staff from the School of Pharmacy, University of Otago, in co-ordination with other specialists. Specific material was provided on asthma presentation, aetiology, diagnosis, treatment protocols, therapies, devices, monitoring and features in special populations, such as children and pregnant women. An asthma educator attended the three training sessions.

Pharmacists initiated the service by arranging interviews with their patients at monthly intervals or as needed. The process was based on the guidelines of Strand *et al,* given below.[9]

1.*Patient consultation*

At this initial step, pharmacists elicit information on the patients' asthma and other relevant history, including their concerns and understanding of their condition and their medication. The pharmacist also performs peak flow measurements, acquires the medication history, contacts other health professionals where necessary, checks compliance with asthma medication standards including inhaler technique, and documents the data using the software 'Cognicare'®, a window-based pharmaceutical care program designed for point-of-care cognitive services provision.

2.*Assessment*

At this stage, the pharmacist assesses the patient's entire therapy, seeking potential or actual medication-related problems, such as overuse of bronchodilators ('reliever' medicines), under-use of inhaled corticosteroids ('preventer' medicines), and poor inhaler technique [Table 1].

3.*Care Plan*

Based on the findings of steps 1 and 2 the pharmacist develops a plan to eliminate or minimise medication-related problems and maximise desired outcomes. This may involve written recommendations and an Asthma Action Plan based on peak flow readings and symptom diaries.

4.*Patient education, recommendation and referral*

The pharmacist provides individualised education to the patient on drug therapy and usage of medication, and demonstrates inhaler technique and the ways to identify and avoid asthma 'triggers'. If necessary, the pharmacist refers the patient to a general practitioner for specific assessment and management.

5.*Patient monitoring and follow-up*

Monitoring enables the pharmacist and the patient to assess the progress towards therapeutic goals, and assures that new medication-related problems are avoided, and that the outcomes are evaluated and documented. Both prevention and resolution of medication-related problems are a focus of the service.

The medication-related problems were categorised for descriptive analysis. The classification system was based on a widely used United States system, with emphasis on asthma management.[10]

INSTRUMENTS

Quality of Life Measures

Two questionnaires were used to quantify quality of life (QoL): the *Short Form-36* (SF-36) and the *Asthma Quality of Life Questionnaire* (AQLQ).[11,12]

The SF-36 is a general health questionnaire used internationally and previously validated for use in New Zealand. It has eight domains of health that are generally summarised into Physical and Mental Component Summaries (PCS and MCS, respectively).[13] The responses are transformed to a scale of 0–100, where 0 denotes extreme impairment and 100 no impairment.

The AQLQ is an asthma-specific QoL questionnaire, which has 32 items that address QoL in four domains: *activity limitation*, *symptoms*, *emotional function*, and *environmental stimuli.* The response options are on a seven-point scale, where 1 indicates maximal impairment and 7 indicates no impairment. The participants are shown their previous answers before they give their new responses to the same questions (an 'informed response' strategy). Responses to the AQLQ were analysed as the mean for the overall AQLQ and its separate domains.

Self-completed Asthma Symptoms Diary

The patients were asked to keep daily diaries documenting their asthma symptoms and peak flow monitoring record, based on the variables and scales used in existing asthma diaries.[14] Diaries were brought to the pharmacist at each subsequent appointment.

Statistical Analysis

Quantitative data for analysis included general and asthma-specific QoL data at baseline (T1) and following four months of provision of the service (T2). The significance of change in QoL at T2 was expressed using analysis of variance, and

p<0.05 was considered statistically significant. The magnitude of the post-intervention change in scores was assessed by calculating the Effect Size of the overall and individual domain scores. Effect Size was calculated by dividing the change in the mean scores from baseline (T1) to follow-up (T2) by the standard deviation of the score at baseline.[15] An Effect Size of 2 was considered small, 4 moderate and 8 large.[16]

The outcomes of medication-related problems and asthma symptoms were expressed qualitatively using the documentation system available, and detailed results have been published elsewhere.[3]

Table 2. *Baseline (T1) characteristics of Group 1 and Group 2 patients (n=62)*

Characteristic	Group 1 (n=34) Mean (SD)		Group 2 (n=28) Mean (SD)		p
Age (years)	46.1	(17.9)	44.5	(17.4)	0.36
Asthma duration (years)	21.1	(13.2)	19.7	(14.7)	0.35
Severity*	6.6	(01.1)	6.1	(0.7)	0.22
Overall AQLQ	4.8	(0.9)	4.9	(0.9)	0.38
SF-36: PCS	48.5	(11.7)	50.2	(10.3)	0.28
SF-36: MCS	41.6	(9.3)	45.1	(10.5)	0.08

* *Expressed as the mean Composite Severity Index (0–12 point score, 0 indicating severe asthma)*

RESULTS

Of the 63 adult asthmatics (27 males) recruited, one withdrew for personal reasons. Demographics of the patients and their QoL status at baseline (T1) are shown in Table 2. In summary, there were no significant differences between the two groups in their mean age, asthma duration, asthma severity, asthma-specific QoL, and general QoL as measured by the PCS and the MCS.

QUALITY OF LIFE

Table 3 shows the change in QoL of Group 1 after receiving the service for four months. With the exception of the environmental domain, all domains of the AQLQ, including the overall AQLQ, indicated different levels of statistically significant changes at T2 with a corresponding Effect Size.

Neither the PCS nor the MCS of the SF-36 indicated significant change at T2 (p=0.615, and 0.117, respectively).

The AQLQ scores of Group 2 patients were also measured at T2, at which time, this group were still receiving their baseline service (Table 4). Apart from the Activity domain (p = 0.010), all domains of the AQLQ indicated small, non-significant improvements.

Again, general health, as measured by the PCS and the MCS, did not show significant difference at T2 in both the groups of patients.

Table 3. *Change in AQLQ Scores (Group 1 patients, n=34)*

Domain	T1* (SD)	T2** (SD)	Paired Difference T2–T1 (SD)	p (t-test)	ES#
Activity	4.8 (0.8)	5.1 (1.2)	0.3 (0.9)	0.05	0.3
Symptoms	4.5 (1.1)	4.9 (1.2)	0.4 (0.9)	0.01	0.4
Emotional	4.7 (1.4)	5.1 (1.4)	0.4 (1.0)	0.01	0.3
Environmental	5.1 (0.9)	5.3 (1.0)	0.1 (1.0)	0.21	0.1
AQLQ-overall	4.8 (0.9)	5.1 (1.0)	0.3 (0.8)	0.02	0.4

* *Mean score at baseline*
** *Mean score at first follow-up (four months of the Pharmaceutical Care service)*
\# *Effect Size: indicates magnitude of change (2: small, 4: moderate, 8: large)*

Table 4. *Change in AQLQ Scores (Group 2 patients, n=28*

Domain	T1* (SD)	T2** (SD)	Paired Diff. T2-T1 (SD)	p (t-test)	E.S#
Activity	4.7 (1.1)	5.3 (1.17)	0.6 (1.1)	0.01	0.5
Symptoms	4.6 (1.1)	5.0 (1.13)	0.3 (1.2)	0.15	0.3
Emotional	5.0 (1.2)	5.2 (1.03)	0.2 (1.3)	0.40	0.2
Environmental	5.2 (1.1)	5.3 (1.01)	0.1 (0.8)	0.62	0.1
AQLQ-overall	4.9 (0.9)	5.2 (0.96)	0.3 (0.9)	0.09	0.3

* *Mean score at baseline*
** *Mean score at first follow-up (four months of the Pharmaceutical Care service)*
\# *Effect Size: indicates magnitude of change (2: small, 4: moderate, 8: large)*

OTHER OUTCOMES

While the current study design specifically addressed changes in QoL in the two groups, other outcomes were collated and analysed in a more quasi-experimental and qualitative manner in the whole sample. Individual case studies were used to provide evidence for the potential effectiveness of the service in different outcomes.[3]

A total of 431 medication-related problems were identified by the pharmacists, and all were documented using the designated computer software. There was no important difference between the groups, as these issues had been identified in the initial interview. On average, 4.3 medication-related problems were detected per patient, although the range was wide (between 1 and 6 per patient). About half of

Table 5. *Examples of problems faced by pharmacists providing Pharmaceutical Care*

Simple Problems*	Complex Problems**
Poor patient understanding of their condition	Changing the patient's behaviour (e.g. improving compliance)
Under-use of preventer	Complications due to co-morbid conditions
Overuse of reliever	Difficulty in avoiding environmental stimuli and triggers (pollen, weather, pets)
Poor inhaler technique	Patients using non-prescribed medications
Lack of an Asthma Action Plan	Inability or unwillingness to stop smoking
Poor understanding of the benefit and use of peak flow meter	

* *Problems that might be addressed by educating and counselling*

** *Problems warranting longer and more intensive Pharmaceutical Care or referral to GP or specialist*

the patients recruited had approximately half of their medication-related problems resolved within the first six months of receiving the service. Ten patients had at least 75% of their problems resolved. The pharmacists found out that while some problems were easy to resolve with simple interventions, others were more complex, some warranting referral to the general practitioner for more specific management. Table 5 gives examples of the simple and complex problems faced by the pharmacists. .

The medication-related problems were classified as per the Hepler and Strand model, and about two-thirds were of 'compliance/understanding' type, such as overuse of bronchodilators and under-use of corticosteroids.[10] The remaining problems were mostly related to choice of devices and adverse drug effects. Choice of the drug did not feature highly, indicating that in most cases the choice of treatment was correct, but the patient did not know how to use the medication properly, or had chosen not to use it. All patients received some kind of intervention, including revision of Action Plan, referral to the GP, and/or further counselling or education.

DISCUSSION

This study provided data that suggest that motivated and well-trained pharmacists can influence asthma-related outcomes in the community, with improvement in asthma-related QoL.

The pharmacy services in New Zealand are fully computerised, both at the community and the hospital levels. The consequent efficiency in in storage and access of medication histories enables quick identification of patients with medication-related problems, such as those failing to collect repeat prescriptions, and those who collect their bronchodilator therapy but not their inhaled corticosteroid therapy. In the current study, the pharmacists used their computer facilities to identify patients who were potentially suitable for inclusion in the study. Asthma has been chosen in the current study because of its impact on QoL. While it affects all age groups, older asthmatics have reportedly had significantly worse QoL than age- and sex-matched controls, and had more frequent depressive symptoms.[17] During an asthma attack, the patients' functional capacity, and consequently their capability to lead normal daily life, becomes impaired.

Asthma sufferers report a wide range of restrictions due to their condition. These include difficulties in performing housework, time off work, disruption of social life, avoidance of certain foods, and extra expenditure incurred in modifying their environment to suit their condition.[18] Emotional problems such as fear, helplessness, dependence and depression have also been identified as consequence of asthma in addition to physical one such as chronic lung diseases.[19] Therefore the most important goals in asthma management are improving patients' everyday functioning, their emotional and social lives and subjective well-being. Therefore, it would be logical to assume that should a demonstrable improvement in QoL occur, the main objective of this specialist service could be considered achieved.

Pharmaceutical Care services seek to add new dimensions to pharmacy practice, and to re-direct the focus of pharmacists from the product to the individual patient. Structured and focussed processes have enabled the pharmacists participating in this study to realise improvements in daily performance of most patients. This has been demonstrated in the change observed at follow-up (after four months of provision of the service), and evidenced by *Effect Size*, a statistical method that has been widely advocated in biomedical research to quantify magnitude of change.[15] Effect Size has become popular in the social and behavioural sciences, but not so much in medicine.[16] While traditional clinical measures can estimate concrete phenomena related to change in biological functioning, they fall short of quantifying change in health status that have no direct biological meaning, such as anxiety, depression, and QoL limitations. Effect Size measures the magnitude of change or 'the clinically important change' in health status, and not the statisti-

cal significance of the change.[15] The larger the Effect Size, the greater the degree to which the phenomenon under study is manifested. The Effect Size therefore serves as an index of the degree of departure from the null hypothesis. In the current study, a moderate Effect Size was observed in the overall QoL and in the symptoms domain of the patients who received the service. The majority reported significantly fewer asthma symptoms, fewer asthma-related emotional problems, and better performance of daily activities. That these changes occured within a short period, could be due in part to the erratic nature of asthma. However, simple interventions like correction of inhaler technique can lead to dramatic improvement in a short time.[20] Restrictions due to environmental triggers were found to be the most resistant to improvement. Identification and avoidance of asthma triggers remains the best solution for these patients.

The SF-36 Physical and Mental Component summaries did not reflect significant changes in the patients' general QoL. However, the SF-36 taps areas of health that might have only been slightly affected by asthma, while the AQLQ, being specific to asthma, demonstrated greater sensitivity in detecting change.

The participating pharmacists acquired new communication and cognitive skills in their dealings with both patients and other health practitioners. Indeed, the quality of interaction between the patients and their health professionals should determine to a large extent whether the desired outcomes are achieved. For example, the patient's understanding of the importance of treatment influenced compliance more positively than the presence of perceived side effects, which again reflects the importance of communication with the patient.[21] Good communication, improved education, and tailoring therapy to the individual needs of the patient are all considered to improve asthma outcomes.[22] In cases of mild asthma, rigid adherence to long-term daily peak flow measurement without taking into account the individual needs, does not appear to improve outcomes.[23,24]

As part of the intervention, medication-related problems were identified and acted upon. Results related to medication-related problems were reported in a more qualitative manner, and a brief cross-section of these has been provided in the current article, where the emphasis is more towards the impact of the service on QoL. The study also provided insight into the applicability of the Pharmaceutical Care service, and the difficulties faced by the pharmacists involved. These have also been reported elsewhere.[3]

Finally, while the sample size recruited might appear small, this sample size is of the same order as used in other QoL studies and was based on calculations reported by Guyatt *et al* using the Responsiveness Index approach.[25–26,27]

CONCLUSION

The pharmacist's role and place in the healthcare structure has changed, and new opportunities have emerged. Results from this study provide evidence that through providing structured, co-operative, patient-oriented Pharmaceutical Care, pharmacists can help asthma patients achieve desired health outcomes.

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