# 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

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**OBJECTIVES:** Despite advances in recent years, asthma morbidity and mortality have been noted to be on the increase in the past decade. The present study examined the failures and recommendations of past studies and introduced a new milieu for asthma care – the community pharmacy. The study incorporated a care protocol with the important ingredients of asthma education on medications, triggers, self-monitoring and an asthma plan, with pharmacists taking responsibility for outcomes, assessment of a patient's readiness to change and tailoring education to that readiness, compliance monitoring and physician consultation to achieve asthma prescribing guidelines.

**METHODS:** Thirty-three pharmacists in British Columbia, specially trained and certified in asthma care, agreed to participate in a study in which experienced pharmacists would have asthma patients allocated to enhanced (pharmaceutical) care (EC) or usual care (UC). Pharmacists less experienced were clustered by geography and had their pharmacies randomized to two levels of care; each pharmacy then had patients randomized to EC versus control, UC versus control or EC versus UC depending on their pharmacy randomization. Six hundred thirty-one patients provided consent, of which 225 in EC or UC were analyzed for all outcomes. Patients were followed for one year.

**RESULTS:** Compared with patients in the UC group, the results of those in the EC group were as follows: symptom scores decreased by 50%; peak flow readings increased by 11%; days off work or school were reduced by approximately 0.6 days/month; use of inhaled beta-agonists was reduced by 50%; overall quality of life improved by 19%, and the specific domains of activity limitations, symptoms and emotional function also improved; initial knowledge scores doubled; emergency room visits decreased by 75%; and medical visits decreased by 75%. A patient satisfaction survey revealed that the population was extremely pleased with their pharmacy services. Cost analysis reinforces the EC model, which is more cost effective than UC in terms of most direct and indirect costs in asthma patients.

**CONCLUSION:** Specially trained community pharmacists in Canada, using a pharmaceutical care-based protocol, can produce impressive improvements in clinical, economic and humanistic outcome measures in asthma patients. The health care system needs to produce incentives for such care.

**Key Words:** *Asthma care protocol; Asthma education; Pharmacists*

## BC Community Pharmacy Asthma Study : étude sur les résultats cliniques, économiques et holistiques d'un protocole de soins relatifs à l'asthme, appliqué par des pharmaciens communautaires spécialement formés à cet effet en Colombie-Britannique

**OBJECTIF :** Malgré les progrès réalisés au cours des dernières années, la morbidité et la mortalité liées à l'asthme semblent s'être accrues pendant la dernière décennie. La présente étude a porté sur les échecs et les recommandations contenues dans des études passées ainsi que sur l'ajout d'un nouveau milieu de soins pour l'asthme, soit la pharmacie communautaire. Y était greffé un protocole de soins comportant un volet éducatif important sur les médicaments, les facteurs déclenchants et l'autosurveillance; les pharmaciens, pour leur part, étaient responsables des résultats, de l'évaluation de la réceptivité des patients à l'égard des modifications et de la personnalisation de l'éducation en fonction de cette réceptivité, de la surveillance de l'observance thérapeutique et des consultations auprès des médecins pour respecter les lignes directrices en matière de prescription pour l'asthme.

**MÉTHODE :** Trente-trois pharmaciens en Colombie-Britannique, diplômés en soins de l'asthme après avoir reçu une formation particulière, ont accepté de participer à une étude dans laquelle des pharmaciens chevronnés se voyaient attribuer des patients asthmatiques pour la prestation de soins courants (SC) ou de soins (pharmaceutiques) valorisés (SV). Les pharmaciens ayant moins d'expérience ont été regroupés en région géographique et leurs pharmacies ont été réparties au hasard en deux niveaux de soins; ensuite, chaque pharmacie a reçu des patients répartis à leur tour au hasard en deux groupes suivant la sélection de la pharmacie : SV ou témoins, SC ou témoins ou encore SV ou SC. Au total, 631 sujets ont fourni un consentement, et 225 d'entre eux appartenant aux groupes de SV ou de SC ont fait l'objet d'une analyse globale. Les patients ont été suivis pendant un an.

**RÉSULTATS :** Voici les résultats enregistrés dans le groupe de SV par rapport à ceux enregistrés dans le groupe de SC : diminution de 50 % des scores relatifs aux symptômes; augmentation de 11 % du débit de pointe; diminution du nombre de jours d'absence du travail ou de l'école de 0,6 jour/mois; diminution de 50 % de l'utilisation de bêta-agonistes en aérosol; amélioration de 19% de la qualité de vie en général; diminution de la limitation des activités ainsi que des symptômes et amélioration de l'adaptation affective; doublement des scores relatifs aux connaissances initiales; diminution de 75 % des consultations à l'urgence ainsi que des consultations en cabinet. Une enquête sur le degré de satisfaction a révélé que les patients étaient très satisfaits des services reçus à la pharmacie. Par ailleurs, l'analyse des coûts favorise le modèle de SV qui s'avère plus rentable que le modèle de SC en ce qui concerne la plupart des coûts directs et indirects chez les patients asthmatiques.

**CONCLUSION :** Les interventions des pharmaciens communautaires au Canada qui appliquent un protocole de soins pharmaceutiques après avoir suivi une formation particulière sur l'asthme peuvent donner des résultats impressionnants des points de vue clinique, économique et holistique. Le système de soins de santé a besoin de stimuler ce genre de soins.

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With the availability of improved medications, clinical practice guidelines (1-3) and plentiful information on asthma, one would expect the morbidity and mortality of the disease to decrease, but authors in the previous decade have noted an apparent increase (4,5). Furthermore, asthma education has been found to be disappointing by a variety of professionals in terms of its influence on outcomes measures in asthma. These programs generally increase knowledge and self-management skills, but only a minority of them show any reduction in asthma-related morbidity (6). The successful ingredients appear to be self-management and, especially, a written action plan (7).

Previous studies have identified a number of problems associated with poor outcomes – these include noncompliance (8), improper inhaler technique (9-11), ignorance of guidelines (12), poor follow-up, inadequate use of corticosteroids (13) and poverty (14,15). There is evidence that pharmacists in dedicated care programs can influence outcomes (16-21). Several American studies involving pharmacists in hospitals or outpatient clinics have shown altered outcomes. A recent protocol (22) has been published for pharmaceutical care in asthmatic outpatients. Its use in a recent study showed significant change only in peak expiratory flow rates (PEFRs); the pharmacists were not specially trained and their compliance with the protocol was meagre (23). One small Finnish study (24) has been performed in community pharmacies, with impact reported on a few outcome measures. Another small Maltese study (25) showed that a community pharmacy-based asthma education and monitoring program impacted on quality of life (QoL), pulmonary function, inhaler technique and number of hospitalizations.

One group of British Columbia (BC) pharmacists from the Health Outcome Pharmacies (HOP) cooperative who had been trained in offering an advanced level of care – called 'pharmaceutical care' – expressed interest. In addition, they had all been trained in the pharmaceutical care of asthma (certified after a weekend of training with prereading, an 80% requirement on examination and three submitted post-weekend cases). Further, many of the group had also been certified as asthma educators. Thus, through their specialized asthma education, this group was in a favourable position to improve health and economic outcomes in asthma care. Moreover, their accessibility in the community, their ability to intervene comprehensively (including taking responsibility to communicate with physicians and other care providers), as well as their program of patient assessment, education on self-management and follow-up, provided a potentially unique advantage.

This study aimed to demonstrate a significant difference in clinical, economic and QoL outcomes in asthma patients who received enhanced pharmaceutical care (EC) versus those who received usual care (UC). One of the goals of pharmaceutical care is to involve the patient in his/her therapy and provide sufficient support for self-management. The study aimed to demonstrate that such care would change patient behaviour such that they would be able to control their asthma rather than be controlled by their asthma.

## PATIENTS AND METHODS

The study was offered to all members of the HOP cooperative in BC. One group of 11 HOP pharmacists already involved in asthma education was 'grandfathered', such that their patients were randomized centrally to receive either EC or UC. The other 22 pharmacists were clustered in pairs by geographic similarity and then were assigned per pair by coin toss to enrol patients (A) for EC or as controls, the latter division decided by centrally performed patient randomization, or (B) for UC or as controls, by central randomization. Pharmacists were paid $75 for each patient enrolled in UC and $300 for each patient enrolled in EC.

### The protocol

Asthma patients, particularly those whose asthma was uncontrolled (26), were recruited in the local community by each pharmacist. Methods included store notices, communication with local physicians and clinics, and information provided by BC Pharmacare. Once recruited, the patient was asked to make an appointment with the pharmacist, who explained the study and sought consent. Diagnosis was confirmed with their physician.

UC involved an initial interview with the patient to complete a symptom, drug utilization and knowledge assessment. The patient was also taught proper inhaler technique, and the pharmacist answered any questions the patient had about asthma or the project. Study duration was established as 12 months normally, with no less than nine months as acceptable. Patients were asked to complete a monthly asthma calendar/diary; this is the instrument in which patients recorded their PEFRs (if done), twice daily QoL on a one to five scale, their medical, emergency room (ER) or hospital visits, and days off from school or work. As well, patients were given a before and after study asthma QoL determination (27), as well as a pharmacy client survey approximately midway through the study. The survey included 15 questions on a five-point scale. The survey is a composite of other surveys on pharmaceutical care and had been tested in an Ottawa, Ontario population. A PEFR was recorded at the patient's first visit and at the end of the study period. A second interview occurred at the end of the study to assess symptoms, drug utilization and knowledge. The frequency of care in the UC group was determined by the patient's needs for prescription refills. The patients were also asked to submit their calendars and seek new ones after one month, and then quarterly to the end of the study. Patients were followed minimally for nine months, after which, for ethical reasons, they were permitted to opt for EC for a minimum of nine months. Essentially, UC involved what most patients receive in a pharmacy, plus the recording of results for the study.

EC involved soliciting all of the UC information plus the teaching of asthma self-management as outlined in the HOP Asthma Care Module (28). This involved instruction on the basic concepts of the disease, the medications being used and trigger identification and avoidance, as well as the development of the asthma action plan. In addition, the use of a peak flow meter was taught, calendars/diaries were provided and the patient asked to record PEFRs regularly for the course of the study period. Also, spacer devices were used by all patients requiring them for better utilization of their medications. Care in the EC group involved appointments of approximately one hour in length with a pharmacist in a private counselling area every two to three weeks for at least

three appointments, and then follow-up appointments at least every three months for the remainder of the study. Patients could request additional appointments or could see the pharmacist intermittently for short sessions without an appointment. An initial assessment of 'readiness for change' was completed using the Transtheoretical Model of Change (29) and patients were reassessed at each appointment. Education did not begin until the patient was in 'contemplation' stage, and the new strategies were not begun until the patient was in 'preparation' stage.

EC patients received 'pharmaceutical care'; thus, EC may be summarized as:

- pharmacist assesses readiness to change and adjusts initiation date
- pharmacist provides education on disease, helps identify triggers and works with patient to develop action plan
- patient participates in all decisions
- patient monitors own therapy (PEFRs, using calendar/diary)
- pharmacist takes responsibility for outcomes
- pharmacist promotes evidence-based care
- pharmacist-patient interaction based on appointment and occurs in private consultation area
- physician informed or consulted regarding all results and interventions

'Controls' were patients who did not have any special intervention. No special measurements or interventions were made except when, in the opinion of the pharmacist, they were needed. These patients were identified for purposes of study by the BC Ministry of Health.

Recruitment began on February 23, 1999 and continued until September 15, 1999.

### Statistical methods

All paper records were converted to computer in an SPSS for Windows 8.0 (SPSS, USA) statistical format, and confidentiality was protected by similar coding. For the majority of the data, the information of interest was the mean change from first to last time of assessment. These changes were assessed within each of the UC and EC groups, and the changes were also compared between the UC and EC groups. The effectiveness of UC and EC are reflected in the within-group differences, and any superiority of EC over UC is reflected in the between-group comparisons. Paired *t* tests were used to determine whether the within-group differences were statistically significant, and independent group *t* tests were used to compare the changes between groups. The number of physician visits, ER visits and hospitalizations were compared for a one-month period at the end of the study.

## RESULTS

Twenty-seven pharmacies and thirty-three pharmacists were accepted and committed to participate in the study. Subsequently, one pharmacy closed, four pharmacists moved, four pharmacists were unable to recruit patients and several others dropped out, unable to commit the time required. Only 18 pharmacies and 20 pharmacists completed the study and were able to submit data on one or more patients.

Seven hundred seven patients were recruited to the study, of which 631 completed the consent process, with diagnosis confirmed by their physician. Of these, 242 were recruited by 'grandfathered' pharmacies, with subsequent random assignment of 121 patients to EC and 121 patients to UC.

In pharmacies randomized to EC or controls, 175 patients were recruited overall – 70 were randomly assigned to EC and 105 were randomly assigned to the control group.

Finally, in pharmacies randomized to UC or controls, 214 patients were recruited overall – 93 were randomly assigned to UC and 121 were randomly assigned to the control group.

Overall, 191 patients were randomly assigned initially to EC, 214 to UC and 226 to control. Another 44 patients crossed over from UC to EC for a total of 235 patients. Of these, 88 patients dropped out and another 27 had insufficient data submitted; thus, there was a total of 119 patients who completed EC. Of the 214 patients in UC, 95 dropped out and another 14 had insufficient data submitted, for a total of 105 completed patients.

Dropouts occurred because of patients failing to keep appointments, patients changing pharmacies to avoid completing forms, patients not completing final QoL forms and patients otherwise not cooperating in data collection. Three patients died during the study of causes unrelated to asthma.

Of the 224 qualifying patients in EC or UC, there were 44 male and 75 female patients in EC, and 39 male and 66 female patients in UC, for an overall total of 37% males and 63% females. The average age was 48 years, with a range from seven to 84 years.

Because the patient allocation methods varied, preliminary analysis of all outcomes was performed to determine differences between the UC groups allocated by patient random assignment or pharmacy randomization. Comparing terminal with initial differences for symptom scores, PEFRs and ER visits, no significant differences were found using F-tests done on the Type III sums of squares. No differences were found for any outcome between the two differently randomized EC or UC groups. Therefore, for the analysis presented here, all of the EC results are combined, as are all of the UC results.

### Outcome measures

Table 1 summarizes the findings for all of the outcomes measures, comparing the initial measurement with the final measurement and determining statistical significance of the difference.

### PEFRs

PEFRs were taken minimally at the beginning and at the end of the study period for both UC and EC patients. A highly significant improvement in mean PEFR was observed in the EC group, and virtually no change was seen in the UC group. The difference between these two changes was approximately 11% and was highly significant. Daily PEFRs recorded by some patients (45 patients in EC group and seven patients in the UC group) are shown in Figure 1; it shows the same difference with much more variation for the UC group.

**TABLE 1**
**Differences between first and final visits for the major outcomes measured**

| Measure | Group | Initial | Final | Difference P within group | Difference P between group |
|---|---|---|---|---|---|
| Peak expiratory flow rate | UC | 344.1 | 351.9 | 0.9780 | **0.0002** |
| (L/min) | EC | 349.4 | 383.4 | **0.0001** | |
| **Symptoms: Total and individual (on 0 to 3 scale)** | | | | | |
| Cough | UC | 1.295 | 0.974 | **0.0055** | **0.0113** |
| | EC | 1.280 | 0.585 | **0.0001** | |
| Wheeze | UC | 1.080 | 0.922 | 0.1346 | **0.0028** |
| | EC | 1.093 | 0.492 | **0.0001** | |
| Shortness of breath | UC | 1.205 | 1.156 | 0.7244 | **0.0000** |
| | EC | 1.331 | 0.619 | **0.0001** | |
| Chest tightness | UC | 0.909 | 0.753 | 0.0767 | **0.0018** |
| | EC | 1.025 | 0.453 | **0.0001** | |
| Phlegm production | UC | 1.159 | 1.013 | 0.1833 | **0.0046** |
| | EC | 1.169 | 0.697 | **0.0001** | |
| Heartburn | UC | 0.568 | 0.545 | 0.5826 | **0.1608** |
| | EC | 0.534 | 0.310 | **0.0029** | |
| Nocturnal awakenings (n) | UC | 1.898 | 1.608 | 0.2438 | **0.0103** |
| | EC | 2.186 | 0.701 | **0.0001** | |
| Nasal symptoms | UC | 1.350 | 1.237 | 1.0000 | **0.0009** |
| | EC | 1.463 | 0.707 | **0.0001** | |
| Symptom total | UC | 1.058 | 0.928 | **0.0494** | **0.0000** |
| | EC | 1.081 | 0.531 | **0.0001** | |
| **Knowledge scores: Total and individual** | | | | | |
| Knowledge assessment – | UC | 8.697 | 14.602 | **0.0001** | **0.0000** |
| Total score (out of 21) | EC | 9.125 | 19.649 | **0.0001** | |
| Asthma's effect on lungs | UC | 0.638 | 1.386 | **0.0001** | **0.0004** |
| (out of 2) | EC | 0.714 | 1.930 | **0.0001** | |
| Medications (out of 10) | UC | 4.464 | 7.170 | **0.0001** | **0.0000** |
| | EC | 4.650 | 9.419 | **0.0001** | |
| Asthma control (out of 7) | UC | 2.217 | 4.310 | **0.0001** | **0.0058** |
| | EC | 2.692 | 6.404 | **0.0001** | |
| Peak flow monitoring | UC | 1.500 | 1.850 | **0.0062** | 0.5433 |
| (out of 2) | EC | 1.382 | 1.956 | **0.0001** | |
| **Drug utilization: Doses per day** | | | | | |
| Beta-agonists | UC | 3.576 | 2.884 | 0.7636 | **0.0082** |
| | EC | 3.962 | 1.944 | **0.0001** | |
| Corticosteroids | UC | 2.503 | 2.400 | 0.5904 | 0.6309 |
| | EC | 2.428 | 2.367 | 0.8451 | |
| **Asthma quality of life scores by Juniper questionnaire (on a 1 to 5 scale)** | | | | | |
| Activity limitation | UC | 4.259 | 4.445 | **0.0385** | **0.0013** |
| | EC | 4.352 | 5.133 | **0.0001** | |
| Symptoms | UC | 4.407 | 4.591 | 0.1012 | **0.0001** |
| | EC | 4.230 | 5.330 | **0.0001** | |
| Emotional function | UC | 4.322 | 4.504 | 0.1834 | **0.0001** |
| | EC | 4.383 | 5.378 | **0.0001** | |
| Environment factors | UC | 3.951 | 4.060 | 0.2946 | **0.0740** |
| | EC | 4.212 | 4.692 | **0.0027** | |
| Total score | UC | 4.234 | 4.400 | 0.0775 | **0.0001** |
| | EC | 4.294 | 5.133 | **0.0001** | |
| **Days off of school or work in previous month (n)** | | | | | |
| Days off | UC | 1.803 | 1.442 | 0.1187 | 0.5688 |
| | EC | 0.973 | 0.402 | 0.0788 | |
| **Emergency visits in previous month (n)** | | | | | |
| Emergency visits | UC | 0.377 | 0.213 | 0.1567 | 0.4757 |
| | EC | 0.165 | 0.043 | **0.0342** | |
| **Hospitalizations in previous month (n)** | | | | | |
| Hospital visits | UC | 0.143 | 0.160 | 0.8491 | 0.9396 |
| | EC | 0.123 | 0.078 | 0.7164 | |
| **Medical visits in previous month (n)** | | | | | |
| Medical visits | UC | 1.429 | 1.730 | 0.6949 | **0.0445** |
| | EC | 1.328 | 0.386 | **0.0062** | |

*Differences in bold indicate statistical significance. EC Enhanced care; UC Usual care*

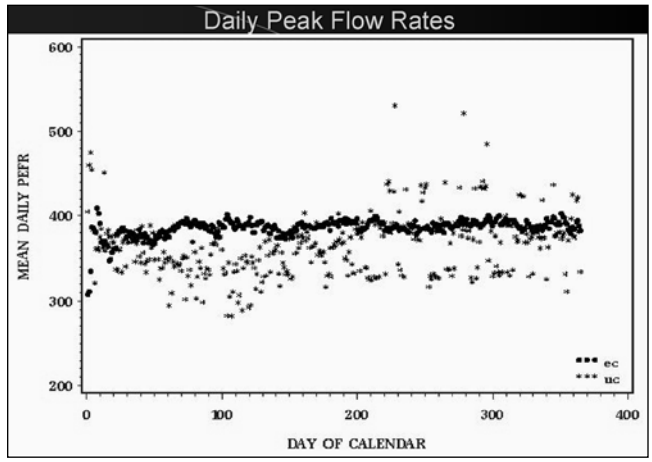


**Figure 1)** *Recorded peak expiratory flow rate (PEFR) results for 45 enhanced care (ec) and seven usual care (uc) patients*

### Symptom scores

Pharmacists recorded the symptom scores at the beginning and end of the study period. Analysis was performed on the most common symptoms only (dyspnea, cough, wheeze, chest tightness, phlegm production and nasal symptoms). Symptoms were scored as follows: 0 = no symptoms; 1 = a few symptoms; 2 = a lot of symptoms; and 3 = worst ever symptoms. A total symptom score (excluding nocturnal awakenings, because this was not on the same scale) was also calculated on each occasion. Because symptoms were expected to diminish in severity, the differences were expressed as last minus first. These differences were then compared between the UC and EC groups.

Mean scores for cough and the symptom total improved significantly in both groups, whereas the remainder of symptoms improved in the EC group only. For all individual symptoms and the total, the improvements were significantly greater in the EC group.

### Knowledge

The patient's knowledge of several aspects of their asthma was measured at the beginning and the end of the study. Total scores were calculated for two questions on asthma's effect on lungs, 10 questions on medications, seven questions on asthma control and two on peak flow monitoring. The total score was based on all 21 questions provided that 50% or more of the questions for each section had been answered. When less than the maximum but more than 50% of the questions were answered, the total was prorated.

A significant improvement in knowledge was found between the first and last visits in both groups for all of the domains indicated. With the exception of knowledge of peak flow monitoring, this improvement was significantly greater in the EC group.

### Drug utilization changes

Two principal groups of drugs were analyzed for changes in use – beta-agonist inhalers and corticosteroid inhalers. Again, comparison was made using the mean number of doses used at the beginning of the study and at the end of the study. The results show a significant drop in the number of

beta-agonist doses in the EC group only. No significant changes were noted in the number of corticosteroid doses in either group.

### QoL

The Juniper questionnaire assesses QoL totally and in several specific domains: activity limitation, symptoms, emotional function and environmental stimuli (adult only). Responses are on a seven-point scale, on which one is the worst and seven the best. Significant improvement was evident on all scales for the EC group, but for the UC group, only activity limitation was improved. On all scales, the EC group had a significantly greater improvement than the UC group.

### Daily QoL readings

Figure 2 illustrates results of the average of two daily QoL readings for 43 EC patients and 39 UC patients on a five-point scale (1 = very bad day, 5 = very good day). The curve has some variation throughout the 12 months, with a plateau after approximately 115 days and a peak at approximately 280 days. However, the 19% difference between the EC and UC groups is maintained throughout most of the period.

### Days off from work or school

Patients recorded days off from school or work and reported them to the pharmacist. When comparing the number of days off from work or school in the first month of the study and the last month of the study in the two groups (UC and EC), *t* test analysis indicated that there was no significant decrease in days off between the beginning and the end of the study in the UC group. The apparent improvement of 60% in the EC group was not quite significant.

### ER visits

Patients reported ER visits in the previous month to the pharmacist. *T* test analysis showed a significant reduction in the mean number of ER visits between the first and last pharmacy visits for the EC group only. This reduction is smaller than that in the UC group but still significant because the variability in the difference scores was much smaller in this group.

### Hospitalizations

At the first and last pharmacy visit, patients reported the number of days in hospital in the previous month. No significant differences were found between hospitalizations in either group.

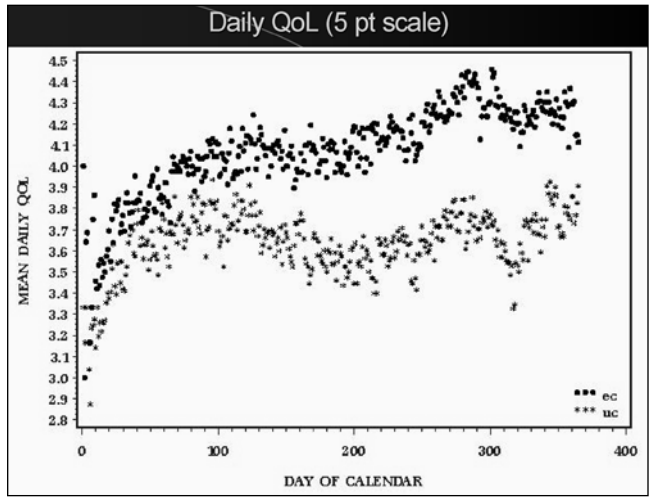


**Figure 2)** *Recorded results of the average of two daily quality of life (QoL) ratings (range 1 to 5) in both the enhanced care (ec) group (n=43) and the usual care (uc) group (n=39)*

### Visits to doctor

Medical visits were also analyzed. Pharmacists recorded the number of medical visits in the previous month on the first and last visits. *T* test analysis showed a significant reduction in the number of physician visits between the first and last pharmacy visits in the EC group only, from 1.33/month to 0.39/month. In fact, the number of physician visits increased between the first and last dates in the UC group. The differences between the two groups were significant.

### Pharmacoeconomic aspects

The literature suggests that pharmacists' intervention in asthma care tends to increase medication costs (due to the increased use of anti-inflammatory drugs) and to decrease medical costs of visits (office, ER and hospital), for an overall net savings to the health care system (16,19,20,30,31). A cost comparison for the present study is illustrated in Table 2. The extra pharmacists' fees are more than compensated by the savings in ER visits, medical visits, hospitalizations and days off from school or work. Indeed, costs are more than halved by the EC option.

### Patient client survey

One hundred ninety-six replies were received out of 405 surveys sent, for a response rate of 48%. Both UC and EC

**TABLE 2**
**Comparison of major direct and indirect health costs for the usual and enhanced groups of care**

| | Cost per unit | Usual care units and cost/patient | Enhanced care units and cost/patient |
|---|---|---|---|
| Medical visits* | $26.00 | 1.73 U/month = $44.98 | 0.39 U/month = $10.14 |
| Emergency visits† | $120.00 | 0.21 U/month = $25.20 | 0.04 U/month = $4.80 |
| Hospitalizations‡ | $558.00/day | 0.16 U/month = $89.28 | 0.08 U/month = $44.64 |
| Prescription drugs§ | Per year cost | $207.63/year or $17.31/month | $225.65 or $18.80/month |
| Pharmacist fees | Per year cost | $74.00/year or $6.25/month | $300.00 or $25.00/month |
| Days off of school or work¶ | $117.00/day | 1.44 days/month × $117.00 = $168.00 | 0.40 days/month × $117.00 = $47.00 |
| **Total of major costs (per month)** | | **$351.00** | **$150.00** |

**Unpublished data, British Columbia Ministry of Health, Victoria, 1998; †Data taken from reference 33; ‡Unpublished data, British Columbia Ministry of Health, Coordinating Committee on Reciprocal Billing, Victoria, 1998-99; §Unpublished data, BC Pharmacare for year of study, 1998; ¶Data taken from reference 34*

**TABLE 3**
**Overall study predictions and results in the British Columbia Community Pharmacy Asthma Study**

| | Predictions before study | Results |
|---|---|---|
| **Clinical outcomes** | | |
| Asthma symptoms | 25% reduction | 50% reduction |
| Peak flow rates | 15% increase | 11% increase |
| Beta-agonist use | 50% reduction | 50% reduction |
| Inhaled steroid use | 50% increase | Not significant |
| **Quality of life outcomes** | | |
| Quality of life scores | 30% improvement | 19% improvement |
| Knowledge levels | Not defined | More than doubled |
| **Economic outcomes** | | |
| Physician visits | 50% reduction | 75% reduction |
| Emergency room visits | 75% reduction | 75% reduction |
| Hospitalizations | Not defined | Not significant |
| Days off of work or school | 70% reduction | 61% reduction |
| Overall health costs | At least even | 57% reduction |

patients scored an overall evaluation of 1.2 – a very high score (1 = excellent, 2 = good). This unprecedented response suggests pre-existing excellent rapport between these patients and pharmacists.

## DISCUSSION

The complex design of the study recruitment was primarily due to modifications made by the BC Ministry of Health that sought to obtain data on 'control' patients for their studies. Although we recruited these 'control' patients who were part of our original 631 patients, they were not included in any of our data analysis.

Effectively, this study started with 405 patients. Of these, 201 (49%) dropped out, mainly because of breach of protocol requirements; more patients in UC (n=114) dropped out than in EC (n=87). This dropout rate is high but quite usual for studies conducted in community pharmacies, where dropout rates as high as high 60% are not uncommon (32). We eliminated another 42 patients (10%) because of insufficient data in their records. We have no data that would allow us to analyze whether this creates a biased population of asthmatic patients, other than to conclude that we probably studied a more compliant group.

The use of two different randomization methods was also an attempt to see if there were differences in randomization by pharmacy versus by patient alone. Although not a primary objective of the study, our analysis showed no difference in outcomes.

In addition, we were not able to detect evidence of bias in the allocation of patients, even though some pharmacists were more experienced than others and some pharmacies recruited more patients than others. The study design probably favours patients who would do well generally, since noncompliance would exclude many poor responders.

Overall expectations versus results are charted in Table 3. Despite aggressive goals at the beginning of the study, most were achieved and some were surpassed. The notable exception was corticosteroid use. Despite no apparent increased use, all other parameters improved. Discussion with participating pharmacists indicated that, at the beginning of the study, some patients were using their corticosteroid inhalers irregularly and others had poor technique – factors that improved in the study.

The two daily measures of PEFR and QoL (Figures 1 and 2) are unique in providing information between the start and stop dates. The QoL graph suggests that the maximum difference between the two groups occurs at about 130 days and persists after that. The subsequent twinned improvements and changes are probably due to external factors; seasonal variation in allergens may explain the phenomenon.

There were apparent differences between EC and UC patients in the initial number of ER visits that biased any change with time between the two groups. However, ER use still decreased significantly in the EC group. For days off from work or school, there was a similar imbalance in the initial values that mitigated against finding a difference with EC; if the initial values had been more equal, the difference might have had more statistical significance. A weakness of the trial was the patient and pharmacist recording of outcome measures. Ideally, particularly for the health service utilization measures, we would have preferred to use the data from BC Health; however, logistical and computer issues made the data unreliable.

The use of pharmacists who had generally improved their level of care through their commitment to the HOP cooperative and through specific education was probably negatively biased as sites of UC. We were concerned that the level of UC would produce such high results that any effect of EC would not be measurable; we were wrong. The ongoing criticism is that the UC in this study was probably at an already elevated level and therefore generalizability of the study must be cautious.

It is, to some extent, unfair to compare the patient response in this study with other studies; however, when compared with other studies with different interventions, these results are generally among the best and probably more sustained than in most others. Compared with the recent pharmacist study in the United States (20), our results are considerably better – again, probably because of the commitment of the BC pharmacists and their understanding of how pharmaceutical care leads to better asthma self-management.

Although ancillary to the study, we completed a poststudy meeting and survey of pharmacist participants in October 2000. In summary, pharmacists increased their score for:

- recognition of drug-related morbidity in community
- reduction of morbidity by resolving drug-related problems in asthma patients
- routine consideration of therapy outcomes to improve QoL
- knowledge and skill to contribute to patients' drug therapy decisions
- making therapy decisions with patient independent of team
- priority given to counselling

- priority given to working with other health professionals to optimize therapy
- patient feedback that they make a difference

Regarding interaction with physicians, pharmacists found that after physicians heard a few success stories from their patients, they looked on the collaboration more positively. They began to refer patients to the study, as well as respond to and act on recommendations, often without having to see the patient. A strong clinical trust slowly began to build. They felt positively exposed to a different way to practice. Indeed, they felt that they were able to show the profession as a whole their clinical potential if they get more involved. Some quotes:

> "After two years, this work at our pharmacies became the 'way we did business' – doctors send us patients for extra training and education now, regularly."

> "Patients expect to pay – they see the value – they talk to their friends with asthma – they phone for appointments."

> "In short – attitudes have changed."

## CONCLUSIONS

An asthma education and care protocol, based on guidelines, 'readiness to change' and the principles of pharmaceutical care (responsibility for outcomes, patient involvement in therapy), administered by specially trained community pharmacists, significantly improved clinical, humanistic and economic outcomes in patients.

This is the largest study of pharmaceutical care in community pharmacies in Canada and the most in-depth study of specialized training with pharmaceutical care in asthma yet published.

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## REFERENCES

1. Ernst P, Fitzgerald JM, Spier S. Canadian asthma consensus conference summary of recommendations. Can Respir J 1996;3:89-100.
2. Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma. NIH Publication 91-3042. Bethesda: National Institutes of Health, 1991.
3. British Asthma Guidelines Coordination Committee. British guidelines on asthma management: 1995 review and position statement. Thorax 1997;52(Suppl 4):S1-S24.
4. Evans RE, Mullally DI, Wilson RW, et al. National trends in the mortality and morbidity of asthma in the US. Chest 1987;91(Suppl):L65S-74S.
5. Asthma – United States: 1980-90. MMWR Morb Mortal Wkly Rep 1992;41:733-5.
6. Boulet LP. Asthma education: What has been its impact? Can Respir J 1998;5(Suppl A):91A-6A.
7. Gibson PG, Coughlan J, Wilson AJ, et al. Self-management education and regular practitioner review for adults with asthma (Cochrane Review). In: The Cochrane Library, Issue 1. Oxford: Update Software, 2002.
8. Patterson R, Greenberger PA, Patterson DR. Potentially fatal asthma: the problem of noncompliance. Ann Allergy 1991;67:138-42.
9. Rizzo JA, Rizzo A. Evaluation of incorrect use metered dose inhalers in patients with chronic lung diseases. Chest 1993;1034(Suppl):289S. (Abst)
10. Kesten S, Zive K, Chapman KR. Pharmacists' knowledge and ability to use inhaled medication delivery systems. Chest 1993;103(Suppl):289S. (Abst)
11. Kocabus A, Tetiher T, Sagin B. Incorrect use of metered dose inhalers. Chest 1993;103(Suppl):289S. (Abst)
12. Asthma in Canada: A Landmark Survey. Mississauga: Glaxo Wellcome Inc, 2000.
13. Molfino NA, Nannini LJ, Rebuck AS, Slutsky AS. The fatality prone asthmatic patient: follow-up study after near-fatal attacks. Chest 1992;101:621-3.
14. Marder D, Targonski P, Orris P, Persky V, Addington W. Effect of racial and socioeconomic factors on asthma mortality in Chicago. Chest 1992;101(Suppl):426S-9S.
15. Carr W, Zeitel L, Weiss K. Variations in asthma hospitalizations and deaths in New York City. Am J Public Health 1992;82:54-65.
16. Self TH, Kelso TM, Abou-Shala N, Rumbak MJ. Clinical pharmacist initiated programs for improving outcomes in adult, African American asthmatics. First National Conference on Asthma Management. Arlington, October 11 to 13, 1992. (Abst)
17. Kelso TM, Self TH, Rumbak MJ, Stephens MA, Garrett W, Arheart K. Educational and long term therapeutic intervention in the ED: effect on outcomes in adult indigent minority asthmatics. Am J Emerg Med 1995;13:632-7.
18. Kelso TM, Abou-Shala N, Heilker GM, Arheart K, Portner TS, Self TH. Comprehensive long term management program for asthma: effect on outcomes in adult African Americans. Am J Med Sci 1996;311:272-80.
19. Im J. Evaluation of effectiveness of an asthma clinic managed by an ambulatory care pharmacist. Calif J Hosp Pharm 1993;5:5-6.
20. Oauley TR, Magee MJ, Cury JD. Pharmacist-managed, physician-directed asthma management program reduces emergency department visits. Ann Pharmacother 1995;29:5-9.
21. Herborg H, Soendergaard B, Froekjaer L, et al. Quality improvement of drug therapy for asthma patients – evaluation of a cooperative Danish programme. Fédération Internationale Pharmaceutique Annual Meeting. Vancouver, September 1997. (Abst)
22. Weinberger M, Murray MD, Marrero DG, et al. Pharmaceutical care program for patients with reactive airways disease. Am J Health Syst Pharm 2001;58:791-6.
23. Weinberger M, Murray MD, Marrero DG, et al. Effectiveness of pharmacist care for patients with reactive airways disease: a randomized controlled trial. JAMA 2002;288:1594-1602.
24. Narhi U, Airaksinen M, Tanskanen P, Erlund H. Therapeutic outcomes monitoring by community pharmacists for improving clinical outcomes in asthma. J Clin Pharm Ther 2000;25:177-83.
25. Cordina M, McElnay JC, Hughes CM. Assessment of a community pharmacy-based program for patients with asthma. Pharmacother 2001;21:1196-203.
26. Role of the pharmacist in improving asthma care. National Asthma Education and Prevention Program. Am J Health Syst Pharm 1995;52:1411-6.
27. Juniper EF, Guyatt GH, Epstein RS, Ferrie PJ, Jaeschke R, Hiller TK. Evaluation of impairment of health related quality of life in asthma: development of a questionnaire for use in clinical trials. Thorax 1992;47:76-83.
28. Health Outcome Pharmacies Asthma Disease State Module, 1998.

29. Prochaska JO, Velicer WF, Rossi JS, et al. Stages of change and decisional balance for 12 problem behaviors. Health Psychol 1994;13:39-46.
30. The Promise of Disease Management. Boston: Boston Consulting Group, 1995, iv.
31. Munroe WP, Kunz K, Dalmady-Israel C, Potter L, Schonfeld WH. Economic evaluation of pharmacist involvement in disease management in a community pharmacy setting. Clin Ther 1997;19:113-23.
32. Tsuyuki RT, Johnson JA, Simpson SH, et al. A randomized trial of the effect of community pharmacist intervention on cholesterol risk management. Arch Intern Med 2002;162:1149-55.
33. Krahn MD, Berka C, Langlois P, Detsky AS. Direct and indirect costs of asthma in Canada. CMAJ 1996;154:821-31.
34. Average Annual Earnings Adjusted for Sex Ratio of Asthma Patients. Ottawa: Statistics Canada, 1998.