Development, implementation, and evaluation of a community pharmacy-based asthma care model
Saini B, Krass I, Armour C

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
A pharmacist-led asthma care programme for asthma management in the community was evaluated.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with asthma. The inclusion criteria were patients with a prior diagnosis of asthma who used bronchodilator medication more than three times per week, those with frequent acute attacks, or those with general concerns about their asthma. Children younger than 12 years of age and patients with major co-morbidities, or who were terminally ill, were excluded.

Setting
The setting was community care (community pharmacies). The economic study was carried out in Australia.

Dates to which data relate
The implementation and evaluation of the asthma care model was carried out between June 2000 and May 2001. Data on the outcomes and medication usage were collected alongside the trial. Data on hospitalisation events were collected over a 6-month period. The price year was not stated, but it can be inferred to have been 2001.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing of medication and hospitalisation events was conducted prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were used to determine the sample size. Based on an improvement of 25%, 95% confidence intervals and a power of 90%, and allowing for a drop-out rate of 20%, 50 patients were required in each group. Fifty-two patients were recruited in the intervention group, with 39 completing the 6 months as stipulated in the project protocols (75% retention rate). Twenty-two patients were recruited in the control group. As the rate of recruitment and
retention was found to be very low, a second group of 28 patients (second control group) was recruited at a time point that coincided with the postservice data collection in the intervention group. The overall number of participants was 52 in the intervention group and 50 in the control group.

**Study design**

The study was a parallel controlled trial that was carried out in two distinct geographical areas. The area for conducting the intervention was selected on the basis that it had a cohesive pharmacists' association and general practitioners who were supportive of the notion of pharmacy-based asthma services. Another area, which matched the intervention in terms of both general and asthma-related demographics, was chosen as the control. Pharmacists in the control area were not offered any training whereas, in the intervention area, the asthma care-training programme was implemented.

The duration of follow-up was 6 months, with outcomes and medication usage reported at baseline and 1, 3 and 6 months after the initial visit. The drop-outs or total number of patients lost to follow-up in the control group were not reported. No reasons were given for the loss to follow-up. No blinding of the outcome assessment was reported.

**Analysis of effectiveness**

The analysis of the clinical study, whilst unspecified, appears to have been conducted on an intention to treat basis. The primary clinical outcomes were:

- asthma severity,
- medication profile,
- action plan ownership,
- asthma-related quality of life,
- perceived control of asthma,
- asthma-related knowledge and
- hospitalisation events.

The groups were shown to be comparable at baseline on a few variables tested. Independent sample t-tests showed no significant differences between the intervention and control groups in age, (p=0.16), age at diagnosis, (p=0.92), gender, (p=0.63) and occupational profiles, (p=0.46). Quality of life was the only parameter significantly different between the two groups. The authors concluded that the patient groups were generally comparable. The groups were also similar in terms of pharmacy characteristics, including the average number of daily prescriptions dispensed, (p=0.86) and the average number of staff employed, (p=0.57). No adjustment for confounding variables was reported.

**Effectiveness results**

The authors presented the clinical results as pairwise comparisons, comparing results obtained at 6 months (i.e. final visit) with those at baseline in both groups. Student’s t-test for independent samples was carried out.

There was a significant reduction in asthma severity in the intervention group versus the control group, (p<0.001). The mean score (+/- standard deviation) changed from 2.6 +/- 0.5 to 1.6 (+/- 0.7) in the intervention group, and from 2.3 (+/- 0.7) to 2.4 (+/- 0.5) in the control group.

In the intervention group, the proportion of patients who had action plans was 57% compared with 12% at baseline, (p<0.001).

There was a significant improvement in perceived control of asthma (index of 11 - 55 scores) at 6 months: 42.5 (+/- 5.2) in the intervention group versus 36.7 (+/- 9.5) in the first control group and 39.2 (+/- 5.8) in the second control
group, (p<0.001).

There was also a statistically significant improvement in asthma-related knowledge (index of 0 - 31 scores): 23.1 (+/- 5.0) in the intervention group versus 20.3 (+/- 5.7) in the first control group and 20.3 (+/- 5.6) in the second control group, (p=0.04)

**Clinical conclusions**
The study revealed that there was a significant reduction in asthma severity in the intervention group, compared with the control group, as well as a significant improvement in perceived control of asthma and asthma-related knowledge.

**Measure of benefits used in the economic analysis**
The clinical outcomes were left disaggregated. In effect, a cost-consequences analysis was performed.

**Direct costs**
The resource use quantities were not reported separately from the unit costs. Hospitalisation events were collected at baseline and at 1, 3 and 6 months (i.e. four visits in total). Diaries designed for medication usage records were provided to patients who completed them for 15 days before each visit. Discounting was not required as the costs were incurred during a 6-month period. The authors did not state whether the economic analysis adopted a societal or health care provider perspective. The price year was not stated, but it can be inferred to have been 2001.

**Statistical analysis of costs**
The costs were treated deterministically. The statistical significance of mean cost-differences between the control and intensive groups was not tested.

**Indirect Costs**
The indirect costs were not considered. However, their relevance cannot be assessed as no perspective was reported and a rationale for their exclusion was not provided.

**Currency**
Australian dollars (Aus$). No conversion rates were reported.

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
The clinical outcomes were left disaggregated and not linked to the cost analysis. See the 'Effectiveness Results' section.

**Cost results**
The mean monthly medication costs per patient were Aus$264.80 at baseline. These were reduced to Aus$253.70 by the end of the intervention, which represents savings of Aus$11.00 per patient per month.

Hospitalisation data collected in the intervention group showed savings of Aus$1.50 per patient per month.

The cost-savings related to an overall decrease in asthma severity were Aus$8,400.10 monthly for the group of intervention patients who completed the study (n=39).
The mean costs at baseline and at 6 months were not reported for the control group.

The costs of adverse effects do not seem to have been relevant to the analysis.

**Synthesis of costs and benefits**
The costs and benefits were not combined because of the cost-consequences approach adopted.

**Authors’ conclusions**
The study demonstrated the successful implementation of an asthma care model in a community pharmacy. A specialised asthma care model can offer community pharmacists an opportunity to contribute towards improving asthma management in the Australian community.

**CRD COMMENTARY - Selection of comparators**
The authors did not provide any justification for the choice of the comparator. It was unclear whether the standard treatment provided in the control group represented current practice. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The comparability of the intervention and control groups was not demonstrated satisfactorily. The inclusion of a second control group added further confusion to the comparability of the three groups and their posterior analysis. The authors recognised that the study did not meet the standards of a randomised controlled design, but the implications of their research design should have been discussed further. The reasons for loss to follow-up and the difficulties encountered in patient recruitment should also have been discussed. Given these limitations, it is possible that the internal validity of the effectiveness results is low.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The study was, in effect, a cost-consequences analysis.

**Validity of estimate of costs**
The perspective adopted in the analysis was not reported and should have been clearly stated by the authors. The cost results and their implications were hard to understand as they were only reported for the intervention group. It was unclear whether all relevant resource use had been included. No measure of uncertainty around the mean was provided, and the costs for the control group were not reported. The lack of reporting reduces the overall validity of the results obtained.

**Other issues**
The authors stated that the asthma care model developed and implemented in this study was the first of its kind in Australia. However, the generalisability of their results to other settings was not addressed. The research design could have been improved in a number of ways. The authors listed the limitations of their study in their discussion.

**Implications of the study**
The authors suggested that the results of the asthma care model should be used to develop systems and resources on a larger scale, to help reduce levels of morbidity from asthma in the community. The authors implicitly suggested that a large randomised controlled trial should also be carried out, collecting medication data alongside the trial in order to conduct a cost-effectiveness analysis.
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