Long-term economic evaluation of intensive patient education during the first treatment year in newly diagnosed adult asthma

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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
The use of intensive patient education for self-management, given during the first year of asthma treatment. The intervention consisted of a peak expiratory flow (PEF) meter and a diary. These were given to the patients so they could monitor and record their PEF values for at least two weeks every third month during the first year, and later to check their PEF at least once a month in the morning. The patients were also asked to monitor the PEF for two weeks before the control visits and whenever symptoms appeared. Patient education was given every third month during the first treatment year. This consisted of the repetition of self-management instructions, principles of asthma treatment, and use of drugs.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised newly-diagnosed adult asthma patients who were over 16 years of age. The patients were diagnosed according to the criteria of the American Thoracic Society.

Setting
The setting was a hospital (outpatients). The economic study was conducted at the South Karelia Central Hospital, Lappeenranta, Finland.

Dates to which data relate
No dates were given. The price year was 1993.

Source of effectiveness data
The effectiveness data were derived from a single study, whose main results had been published elsewhere (see Other Publications of Related Interest).

Study sample
Power calculations were made in order to detect a 5% change in the forced expiratory volume in 1 second (FEV1) with a power of 80% and a significance level of 5%. The minimum sample size was estimated to be 64 pairs. The initial study sample consisted of 162 newly-diagnosed adult asthma patients. There were 60 men and 102 women. The IG comprised 80 patients with a mean age of 43.1 years (range: 18 - 76). The CG comprised 82 patients with a mean age of 44.2 years (range: 19 - 76). There were 19 smokers in the IG and 16 in the CG. No patient was excluded from the
Study design
This was a randomised controlled trial with a 5-year follow-up. It was carried out in a single centre (the South Karelia Central Hospital in Finland). During the follow-up, 16 of the original 80 patients were lost from the IG, while 12 of the original 82 were lost from the CG. After 5 years, the overall study sample was reduced to 134 patients, 52 men and 82 women. There were 64 patients in the IG and 70 patients in the CG. The mean age was 43.9 years (range: 18 - 76) in the IG and 44.7 years (range: 19 - 76) in the CG. There were 9 smokers in the IG and 11 in the CG.

Analysis of effectiveness
The analysis used treatment completers only. However, the authors checked to see whether the baseline composition of the final groups was significantly different from those who had been initially enrolled in the study. They found that there was no significant difference between the patient groups at baseline when they considered all patients who had joined the original study, and only those who had stayed in the study for 5 years. The groups were tested to check for comparability and no significant differences were found.

The health outcomes referred to lung functions, airway hyper-responsiveness and quality of life. The outcomes measured were the forced vital capacity (FVC), FEV1, FEV% (FEV1/FVC), PEF, the provocative dose of histamine needed to cause a 15% drop in FEV1 (PD15), and the health-related quality of life (HRQOL). HRQOL was measured by the generic 15D, and the disease-specific St.George's Respiratory Questionnaire (SGRQ). The relative risk for sickness days during the whole follow-up period was also assessed.

Effectiveness results
Apart from FVC, all outcomes improved significantly in both of the study groups. The changes in the values of the variables were as follows.

FVC: 1.0 (95% confidence interval, CI: -4.1 - 1.9) in the IG and -0.3 (95% CI: -3.3 - 2.7) in the CG.
FEV1: 3.3 (95% CI: 0.2 - 6.4, p<0.05) in the IG and 1.8 (95% CI: -1.3 - 5.0) in the CG.
FEV%: 3.1 (95% CI: 1.1, 5.1, p<0.01) in the IG and 3.0 (95% CI: 1.2 - 4.7, p<0.001) in the CG.
PEF: 7.2 (95% CI: 4.6 - 9.6, p<0.001) in the IG and 4.6 (95% CI: 1.9 - 7.4, p<0.01) in the CG.
PD15 dose step: 1.4 (95% CI: 1.0 - 1.5, p<0.001) in the IG and 1.0 (95% CI: 0.8 - 1.4, p<0.001) in the CG.
15D: 0.04 (95% CI: 0.02 - 0.05, p<0.001) in the IG and 0.04 (95% CI: 0.02 - 0.05, p<0.001) in the CG.
SGRQ (total score): 12.0 (95% CI: 8.3 - 14.8, p<0.001) in the IG and 14.1 (95% CI: 10.8 - 17.0, p<0.001) in the CG.

There was no significant difference between the two groups in terms of the above changes.

There had been a significant difference at one year in FEV1, (p=0.02), and at 3 years in terms of the PD15 (p=0.04).

The authors stated that, compared with the CG, there had been a significantly lower relative risk for sickness days during the whole follow-up period in the IG. The odds ratio was 0.33 (95% CI: 0.28 - 0.40). The authors reported two supplementary pieces of information relating to the whole 5-year period, and suggested that these argued in favour of the IG. First, 152 sickness days were lost by the IG patients and 398 days were lost by the CG patients, (p=0.07). Second, 35 patients in the IG group and 23 in the CG group, (p=0.005), made recordings of their PEF, which could be seen as an indication of patient compliance.

Clinical conclusions
The patients’ health improved in both treatment groups. Five years after the start of the intervention, it could not be shown that there was any significant difference between the improvements in the groups.

**Modelling**
The costing was carried out prospectively on the same patient sample as that used in the effectiveness analysis.

**Measure of benefits used in the economic analysis**
The effectiveness analysis showed that there was no significant difference between the two groups of patients, 5 years after the intervention began. Therefore, the economic analysis was based on the differences in costs between the two groups.

**Direct costs**
The costs were calculated for asthma medication (information only available after year 1), oral corticosteroids and antibiotics (average retail price used), patient education, visits to the outpatient clinic, inpatients days, emergency visits, and the nurse and physiotherapist time (13/hour). The cost of asthma medication was obtained from the Finnish Social Insurance Institution. The costs of patient education, outpatient and emergency visits, and inpatient days were obtained from the South Karelia Central hospital.

Discounting was not carried out in the main analysis. In a sensitivity analysis, 3% and 6% were used as possible values. The quantities and costs were not analysed separately. Some costs were excluded because they were common to both groups. These were the costs of diagnosis, visit for randomisation, and the follow-up visits at 12 months, 36 months and 5 years. The costs of drop-outs were not included in the analysis, but these were no different from the costs of those who remained in the study.

**Statistical analysis of costs**
Statistical analysis of the total costs was carried out to test for statistical significance of the results.

**Indirect Costs**
The patient’s time taken to attend clinic and the days off sick were included in the analysis, the details of which were published elsewhere (see Other Publications of Related Interest). The price year was not given. Discounting was carried out in the sensitivity analysis at 3% and 6%.

**Currency**
UK pounds sterling (£). These were converted from Finnish marks (FIM) at a rate of FIM 9 = 1.

**Sensitivity analysis**
A sensitivity analysis was carried out on the discount rate, which was varied between 0 and 6%.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
Indirect costs: in the IG, the mean cost was 323 (range: 141 - 2,406) and the median was 144 (range: 141 - 200). The corresponding values in the CG were 490 (range of mean: 46 - 7,166) and 56 (range of median: 46 - 612).

Anti-asthma drugs for 4 years: in the IG, the mean cost was 803 (range: 6 - 2,816) and the median was 739 (range: 341 -
1,213). The corresponding values in the CG were 1,064 (range of mean: 0 - 72,623) and 787 (range of median: 546 - 1,244).

Total costs: in the IG, the mean cost was 1,906 (range: 726 - 7,506) and the median was 1,727 (range: 1,319 - 2,241). The corresponding costs in the CG were 2,286 (range of mean: 636 - 9,842) and 1,640 (range of median: 1,283 - 2,668).

The differences in the costs between the two groups were not statistically significant.

The duration of the costs was 5 years.

Synthesis of costs and benefits
The costs and benefits were not combined, since there was no statistically significant difference in both costs and effectiveness measures.

Authors' conclusions
There was no long-term difference in terms of the effectiveness between the two groups of patients. The intensive intervention (IG) cost less than the control intervention (CG), but this result was not statistically significant.

CRD COMMENTARY - Selection of comparators
The comparator, a conventional patients education programme for one month, was valid. It had been justified in an earlier paper (see Other Publications of Related Interest) reporting earlier results. The comparator was standard practice in the authors' country, Finland. You should assess whether it represents a currently used intervention in your own setting.

Validity of estimate of measure of effectiveness
The source of the effectiveness data was the authors' study. The study design, a randomised controlled trial, was appropriate for the study question. All of the patients had agreed to participate in the study, thus the patients studied were likely to be representative of the study population. The patient groups were shown to be comparable at baseline. Generally, the analysis of effectiveness was handled credibly. However, the authors did not state whether the measurements of lung function were taken at the same time of day. Also, the authors noted that there had been a significant difference in the number of sick days taken between the two groups, fewer being taken by the IG than the CG. They did not, however, give the time profile of the days taken off, so that it could be seen whether this was likely to continue after the 5-year follow-up.

Validity of estimate of measure of benefit
The authors concluded that there was no statistically significant difference between the effectiveness of the two interventions, and therefore, did not derive a summary measure of health benefit.

Validity of estimate of costs
All the relevant categories of costs were included. However, the first year of the drug costs was not included. Some of the costs common to both interventions were excluded, such as the costs of diagnosis, randomisation visit, and the follow-up visits at 12 months, 36-months and 5 years. The quantities were not reported separately from the prices. Therefore, it could not be seen how sensitive the results were to changes in the drug prices or costs of medical personnel. Also, the authors did not explain clearly how prices had been converted from Finnish marks to UK pounds sterling, that is, whether they used a constant exchange rate or a different one each year. The authors also did not state whether the drug prices had been converted to a constant price year. These issues are important because if the costs were treated correctly, the study might have shown a statistically significant difference between the two kinds of intervention.
Other issues
The authors made appropriate comparisons of their results with the findings of other studies. However, the issue of generalisability to other settings was not addressed. The authors’ conclusions on effectiveness reflect the scope of the analysis, but the conclusions in terms of the costs do not. The authors present conflicting conclusions about the cost evidence. Sometimes they state that there was no statistically significant difference between the two groups, whilst at other times they present the difference in costs as being important. The authors are aware that, despite the advantages of a 5-year follow-up, they have not fully understood the time profile of the health outcomes in the two groups.

Implications of the study
The authors state that further work is required if the effects of the intensive patient education programme are to be understood. They hypothesise that frequent visits in the first year, rather than the educational component of the visits, may be responsible for some of the benefit of the programme. They also state that their study shows the importance of long-term follow-up in asthma programmes, and it would surely be interesting to carry on with this follow-up for more years.

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Other publications of related interest


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