Is self-care a cost-effective use of resources: evidence from a randomized trial in inflammatory bowel disease


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 study examined a whole-system approach to self-management in inflammatory bowel disease (IBD). The intervention consisted of an evidence-based self-help guidebook, patient-centred consultations, and a direct access service allowing patients to self-refer when they felt it was necessary.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised a sample of patients with established IBD.

Setting
The setting was primary care. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were derived from a study published in 2004. The costs referred to 1999/2000 prices.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
Limited information on the primary study was provided in the current economic evaluation. Overall, 651 patients with complete records from an initial sample of 700 patients were enrolled in the clinical trial. There were 285 patients in the control group and 366 patients in the intervention group.

Study design
This was a prospective, randomised clinical trial that was carried out in 19 centres in the northwest of England. The unit
of randomisation was the participating hospital. The length of follow-up was one year. Since data were lost for some patients, the propensity score method of multiple imputation was used.

**Analysis of effectiveness**

The analysis of effectiveness appears to have been conducted on the basis of treatment completers only. The data were analysed in such a way as to account for the clustering effect associated with randomisation by centre. The primary outcome measure used in the current economic evaluation was the change in quality of life. This was assessed using the EuroQol 5D (EQ5D) instrument, a generic measure of health status in which health is characterised across five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). The authors did not state whether the study groups were comparable.

**Effectiveness results**

The mean EQ5D score changed from 0.7453 (+/- 0.0158) to 0.7071 (+/- 0.0181) in the intervention group and from 0.7288 (+/- 0.0151) to 0.6909 (+/- 0.0186) in the control group.

Thus, the mean change was -0.01892 (+/- 0.0100) in the intervention group and -0.01870 (+/- 0.0071) in the control group.

The authors stated that no statistically significant differences between the two groups were observed.

**Clinical conclusions**

The effectiveness analysis showed that health-related quality of life worsened slightly in both groups.

**Measure of benefits used in the economic analysis**

The summary benefit measure used was the expected number of quality-adjusted life-years (QALYs). This corresponded to the estimated mean change in EQ5D that was estimated directly in the clinical trial.

**Direct costs**

The analysis of the costs was performed from the perspective of the NHS. It included the costs of the study intervention, general practitioner (GP) visits, inpatient stay, outpatient appointments and medications. The unit costs were, for most items, presented separately from the quantities of resource used. The resource use data were derived from the sample of patients in the clinical trial, using case record forms, patient questionnaires, patient diaries and the patients’ hospital medical records. The costs were estimated from national unit costs such as Personal Social Services Research Units and the British National Formulary. Discounting was not relevant as the costs were incurred over a 1-year time horizon. The costs were estimated using 1999/2000 prices.

**Statistical analysis of costs**

The costs were presented as mean values +/- standard deviations. Missing data on resource use were imputed using the propensity score method of multiple imputation.

**Indirect Costs**

The indirect costs were not considered.

**Currency**

UK pounds sterling (£).
Sensitivity analysis
A sensitivity analysis was carried out to assess the implications of including patients with complete data in the analysis, rather than using the partially imputed data-set included in the base-case analysis.

Estimated benefits used in the economic analysis
The intervention was associated with a small mean reduction in QALYs of 0.00022 per patient compared with the control group. This difference was not statistically significant.

Cost results
The mean costs per patient over one year were 922 (+/-60.56) in the intervention group and 1,070 (+/- 51.61) in the control group.

The cost-difference between groups was 148 (+/- 100.13).

Synthesis of costs and benefits
An incremental cost-utility ratio was calculated in order to combine the costs and QALYs of the alternative strategies.

The incremental cost per QALY gained with usual care over the study intervention was 676,417.

The authors used a cost-effectiveness acceptability curve to show that the probability that the study intervention was both less costly and more effective than usual care was over 90%.

At a threshold of 30,000 per QALY, the probability of the study intervention being more cost-effective than usual care was 63%.

The sensitivity analysis showed that the results of the unadjusted analysis were conservative, while the use of complete case analysis favoured the intervention group.

Authors' conclusions
A whole-system approach to self-management in inflammatory bowel disease (IBD) led to a reduction in health care costs, owing to reduced hospital attendances, without adversely affecting patient outcomes in the UK.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. It reflected the standard pattern of care for patients with IBD in the authors' setting. However, a description of conventional care was not provided. You should decide whether these are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. As the main trial was published in another paper, limited information on the design and other aspects of the study were reported. Few details on the method of sample selection and randomisation were provided. The authors did not report whether the study groups were comparable at baseline. The use of power calculations was not reported. The length of follow-up was appropriate. The main analysis included only patients with complete data, although a sensitivity analysis was carried out by imputing missing values. A strength of the study was its multi-centre design. These issues should be considered when assessing the validity of the primary estimate.

Validity of estimate of measure of benefit
The benefit measure used in the analysis was appropriate since QALYs capture the impact of the intervention on the
most relevant dimension of health (i.e. quality of life), although the intervention had no impact on survival. Further, QALYs can be compared with the benefits of other health care interventions. Change in quality of life was estimated using a validated instrument to elicit the patients' preferences, although this tool might not be very sensitive for patients with IBD. The use of utility weights directly derived from the patients included in the clinical trial represents a strength of the study.

Validity of estimate of costs
The analysis of the costs was consistent with the chosen perspective. Indirect costs were not considered, which was appropriate given the viewpoint of the analysis, but the inclusion of patient expenses would have been interesting. Extensive information on the unit costs and quantities of resources used was provided, which will facilitate replication exercises in other settings. The source of the data was explicitly reported for all items. The cost estimates were specific to the study setting and the impact of using alternative economic estimates was not investigated. The price year was also given, thus enhancing the possibility of reflating the costs in different time periods. Statistical analyses of the costs were carried out, and cost estimates were adjusted to take the impact of missing values into consideration.

Other issues
The authors did not compare their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Limited sensitivity analyses were carried out, thus caution will be required when transferring the results of the analysis to other settings. The authors acknowledged that caution will also be required when generalising the current findings to populations that are not characterised by periods of activity and remission of the disease. Moreover, cost reductions might not be observed in health care systems with different treatment patterns.

Implications of the study
The study results suggest that a whole-system approach to self-management in IBD might be a cost-effective strategy, especially for patients with phases of remission and activity of the disease. However, the authors pointed out the uncertainty associated with cost and clinical estimates.

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