Open access follow up for inflammatory bowel disease: pragmatic randomised trial and cost effectiveness study

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 open access versus routine booked appointments for the follow-up of patients with inflammatory bowel disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients aged over 18 years with inactive or mildly active, but stable, inflammatory bowel disease. Patients with active disease requiring treatment, a stoma, or another disease that required regular follow-up, were excluded. Patients who were thought to be unable to comply with data collection were also excluded.

Setting
The setting was outpatient care. The economic analysis was carried out in Wales, UK.

Dates to which data relate
The effectiveness and resource use evidence related to October 1995 to November 1998. The unit cost data were derived from studies published in 1997 to 1998.

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

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

Study sample
Power calculations to determine sample size were conducted. These showed that, at a clinically important difference of 10 points on the SF-36 questionnaire (equivalent to a standardised difference of 0.5), a sample size of 170 patients (85 per group) would have 90% power to detect a significant difference at a significance level of 0.05. The authors acknowledged that this sample size was unlikely to reflect probable differences in the costs.

A total of 260 eligible patients (registered with 53 practices) were selected by three consultant gastroenterologists, one
staff doctor, two senior registrars, and four registrars. Eighty patients were excluded due to active disease requiring treatment (43), a general practitioner (GP) unwilling to participate (11), inability to comply with the study (10), stoma (8), other significant co-morbidity (7), and discharged from follow-up (1). Overall, 180 patients were randomised to follow-up through open access (88) or by routine appointment (92).

Study design
A randomised controlled trial conducted in two centres (Morriston and Neath Hospitals, Swansea) was used to analyse the interventions. The methods of randomisation and blinding for the assessment of outcomes were not reported. The duration of the follow-up was 2 years.

Seven patients from the open access group were lost to follow-up. Of these, 4 failed to attend the final appointment or complete the questionnaire, 2 withdrew, and 1 died. Nine patients from the routine appointments group failed to complete the study. Of these, 5 failed to attend the final appointment or complete the questionnaire, 3 withdrew, and 1 died. Thus, 81 patients from the open access group, and 83 from the routine appointments group, completed the final questionnaire and had data extracted from hospital records. The data were extracted from primary care records for 77 patients in the open access group and for 78 patients in the routine appointments group.

Analysis of effectiveness
Analysis was performed on the basis of intention to follow-up. The primary outcomes were measured using the generic SF-36 questionnaire and the disease-specific UK inflammatory bowel disease questionnaire. The questionnaires were completed in the clinic at recruitment and at the end of the study, and by post at 6-monthly intervals between. Two reminders were sent to non-respondents. Those who failed to attend the final appointment after two reminders were sent the final questionnaire by post. The patients' and GPs' preferences, satisfaction and views were assessed by postal questionnaires at the end of the study, supplemented by semi-structured interviews with a sample of GPs.

The changes from baseline were analysed using t-tests, in order to counteract the differences in baseline health-related quality of life scores. The authors stated that there was no significant difference between the groups at baseline in terms of their age, gender, diagnostic group, or quality of life. However, the number of patients who failed to complete the study differed significantly between the two hospitals. Twelve patients in the Morriston Hospital and 4 in the Neath Hospital failed to complete the study, (p<0.05)).

Effectiveness results
There were no significant changes in the mean health-related quality of life scores in either group over the two years of the study. No significant differences in changes in health-related quality of life scores at 6, 12, 18 and 24 months, compared with baseline, were detected between the groups.

The patients showed a preference for open access follow-up (103 out of 164, p<0.01). There were 85% (69 out of 81) in the open access group who preferred it, and 41% (34 out of 83) in the routine group who would have preferred open access. The main reason given for this preference was the appropriateness of attending only when ill.

Forty of the 53 practices that had patients participating in the study returned postal questionnaires for 155 patients, including 12 patients who did not complete the final patient questionnaire.

The GPs preferred open access for 108 patients (55 in the open access group, 53 in the routine care group) and routine follow-up for 35 patients (15 in the open access group, 20 in the routine care group). The difference was highly significant, even after making allowances for potential correlation for multiple responses from individual practitioners, (p<0.001). The preference for open access was associated with sensible patients, stable disease, and the effective booking of urgent review.

Forty-four GPs favoured a gastrointestinal nurse practitioner as point of contact while 10 GPs were opposed to this.

Clinical conclusions
The authors concluded that open access follow-up delivered the same quality of care and was preferred by patients and GPs.

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

No summary measure of benefit was used in the economic analysis. The study was therefore categorised as a cost-consequences analysis.

**Direct costs**

The cost/resource boundary appears to have been that of society. The direct costs included the primary and secondary health care costs. These included the costs of outpatient visits, inpatient days, investigations (full blood count, erythrocyte sedimentation rate and C reactive protein, biochemical profile, colonoscopy, rigid and flexible sigmoidoscopy, biopsy, vitamin B-12, folate, and ferritin), surgery, home visits, and drugs. The valuation of hospital resources was based on estimates provided by the trusts during the trial. The costs of outpatient and GP home visits were derived from Netten et al. (see Other Publications of Related Interest no.1). The drug costs were obtained from the British National Formulary (see Other Publications of Related Interest no.2). The cost of GP surgery visits was obtained from another published study (see Other Publications of Related Interest no.3). The price year was not explicitly stated. The quantities and the costs were reported and analysed separately. No discounting was necessary, as the duration of follow-up was 2 years.

**Statistical analysis of costs**

The cost data were compared using the Mann-Whitney U-test. In addition, the mean and standard deviation (SD) were reported for each variable, as these were the statistics of interest.

**Indirect Costs**

The indirect costs analysed included the patients’ lost work time, valued using average wages, and the patients transport costs, estimated using figures from the Automobile Association.

**Currency**

UK pounds sterling (€).

**Sensitivity analysis**

No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**

See the 'Effectiveness Results' section.

**Cost results**

The resource use and cost results were derived from comprehensive data available for 155 patients.

Open access patients had fewer day visits, (p=0.019), fewer outpatient visits, (p=0.002) and cost less in total investigations, (p=0.032).

There were no significant differences in the numbers of inpatient days or specific investigations.

The mean National Health Service costs were 1,046 (SD=948) in the open access group and 951 (SD=680) in the routine visit group, (p=0.89).
The mean patient borne costs were 115 (SD=82) in the open access group and 122 (SD=64) in the routine visit group, (p=0.07).

The mean societal costs were 1,160 (SD=1,007) in the open access group and 1,074 (SD=724) in the routine visit group, (p=0.78).

Only the mean cost for secondary care was significantly lower for open access patients than for routine outpatients, 582 versus 611, (p=0.012).

**Synthesis of costs and benefits**
Not applicable due to the cost-consequences approach adopted.

**Authors' conclusions**
Open access follow-up delivered the same quality of care as routine outpatient care, and was preferred by the patients and GPs. It used fewer resources in secondary care but similar total resources.

**CRD COMMENTARY - Selection of comparators**
The authors justified their selection of routine outpatient follow-up as the comparator on the grounds it was the usual current practice in their settings. You should decide whether the comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis used a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. Power calculations were performed in the planning phase of the study. Appropriate statistical analyses were undertaken to account for potential baseline differences in the patients' health-related quality of life. Although the authors stated that the analysis was performed according to intention of follow-up, it is unclear how the outcomes for those patients who did not complete the study were treated.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study. However, since the quality of life was assessed during the study, a summary benefit measure reflecting the overall impact of the interventions on the patients' health would have been useful.

**Validity of estimate of costs**
All the categories of costs relevant to the societal perspective were included in the analysis. The major costs and categories were reported separately. Appropriate statistical analyses of the quantities and/or costs were conducted. No sensitivity analyses were performed for the quantities and the unit costs, and the uncertainty associated with the results was not investigated. The costs were analysed for those patients for whom all available cost data were extracted.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not explicitly addressed. The authors did not present their result selectively. They also reported that their study had limited power to detect true cost differences. The study enrolled patients with inactive or mildly active, but stable, inflammatory bowel disease and this was reflected in the authors' conclusions.

**Implications of the study**
The authors suggested that introducing a specialist gastrointestinal nurse, as a single telephone point of contact for
patients, was the best way to improve arranging urgent appointments for open access follow-up. They stated their intention to introduce and evaluate this approach. Further studies are needed to evaluate the shared care in other conditions, such as arthritis, epilepsy, heart failure and multiple sclerosis.

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