Is shared care with annual hospital review better value for money than predominantly hospital-based care in patients with established stable rheumatoid arthritis?

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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 study examined two approaches for the management of patients with established stable rheumatoid arthritis (RA), defined as disease persisting at 5 years after onset. The approaches were symptom control delivered predominantly by shared care (SCSC) and aggressive treatment delivered predominantly in the hospital (ATH). Patients offered SCSC were managed in primary care by general practitioners (GPs), with annual hospital review to control joint pain, stiffness and related symptoms through the use of analgesics, non-steroidal anti-inflammatory drugs, intra-articular steroid injections, disease-modifying antirheumatic drugs and low-dose steroids. The patient was encouraged to visit the GP with any new or deteriorating symptoms. Patients in the ATH arm were managed in the hospital clinic for symptom control and to suppress clinical and laboratory evidence of inflammation. This included minimising the number of inflamed joints and keeping the C reactive protein level below twice the upper limit of normal. The patient attended the hospital clinic every 4 months, or more often if clinically indicated.

Type of intervention
Treatment and monitoring.

Economic study type
Cost-utility analysis.

Study population
The study population included patients with established stable RA. Specific inclusion criteria were age over 18 years old, patients diagnosed with RA using the 1987 American College of Rheumatology criteria, and current outpatient attendees for at least 12 months. The patients were also required to have had the disease for longer than 5 years, have had no change in drug or dosage for at least 6 months, and be taking 7.5 mg or less prednisolone (or equivalent) daily.

Setting
The setting of the study was both primary and secondary care, and a hospital. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered between 1997 and 2002. The price year was 2001.

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

Study sample
Power calculations were performed in the planning phase of the trial. These suggested that, to detect a difference of
0.25 in Health Assessment Questionnaire (HAQ) scores at 90% power and 5% significance, and allowing for 20% loss to follow-up, 480 patients would be required. A total of 466 patients were finally recruited. Baseline data were available for 228 patients in the SCSC group and 232 patients in the ATH group. No information on patient demographics was given since readers were referred to the original clinical study.

Study design
This was a prospective, five-centre, randomised controlled observer-blinded study, which was carried out in England. No details of the randomisation process were reported. The length of follow-up was 3 years and the clinical outcomes were assessed every 4 months. Clinical data at 12 months were available for 217 patients in the SCSC group and 232 patients in the ATH groups. Data at 2 years were available for 207 patients (SCSC group) and 211 patients (ATH group), respectively. Final data (3 years) were available for 195 and 199 patients.

Analysis of effectiveness
The primary clinical outcome was the utility value, which was estimated using the EuroQol (EQ-5D) instrument. Utility values could not be estimated if patients had missing observations on one or more domains of the EQ-5D within an assessment. The missing utility value was imputed by linear interpolation if, and only if, observations to the left and right of the missing item were available and the patient completed the scheduled follow-up. Patients without a final utility assessment were treated as censored cases. No statistically significant differences in baseline utility scores were found between the two groups. Other details of the effectiveness analysis were not reported.

Effectiveness results
No statistically significant difference between groups was observed in terms of utility values at different time points of follow-up (12, 24 and 36 months).

For example, at 36 months, the mean utility value was 0.57 (+/- 0.24) (95% confidence interval, CI: 0.51 to 0.58) in the SCSC group and 0.54 (+/- 0.27) (95% CI: 0.50 to 0.58) in the ATH group.

Clinical conclusions
The effectiveness analysis showed that the utility values were comparable between groups.

Measure of benefits used in the economic analysis
The summary benefit measure used was the quality-adjusted life-years (QALYs). These were estimated using the utility values derived directly from the effectiveness analysis. Utility weights were estimated using the time trade-off approach. The benefits were discounted at an annual rate of 3.5%.

Direct costs
The analysis of the direct costs included resources borne by the NHS, social support services and patients. The health services considered in the analysis were hospital inpatient, outpatient and domiciliary visits, primary care visits, visits to other health care professionals, prescribed medications, aids and appliances. Dispensing costs were not included. The unit costs and the quantities of resources used were presented separately. No attempt was made to identify RA-related costs. Resource use was derived from the sample of patients included in the clinical trial. All patients were given a diary. The costs came from published national databases such as Personal Social Services Research Unit and reference costs. Discounting was relevant, as 3-year costs were evaluated, and an annual discount rate of 3.5% was used. All costs were inflated to 2001 prices using the hospital and community health price index.

Statistical analysis of costs
Missing data on resource use were derived using multiple imputation. Patients had to have one completed assessment at the start and one at the end of follow-up to be included in the multiple imputation. Patients without a final cost
assessment were treated as censored cases.

**Indirect Costs**
Productivity costs were not considered.

**Currency**
UK pounds sterling (GBP).

**Sensitivity analysis**
Bootstrap was performed to derive CIs around the costs, benefits and cost-utility ratios. Cost-effectiveness acceptability curves were generated. A sensitivity analysis was also carried out to test alternative approaches to imputing missing data. The impact of the costs of drug treatment and trial protocol-driven visits was also investigated. Finally, a net benefit for SCSC with respect to ATH was calculated assuming a willingness-to-pay of 30,000 per QALY.

**Estimated benefits used in the economic analysis**
The mean total QALYs over the 3-year study period were 1.67 (± 0.56) with SCSC and 1.60 (± 0.60) with ATH. The mean difference was 0.07 (95% CI: -0.04 to 0.18).

**Cost results**
The mean total costs over the 3-year study period were 4,540 (± 4,700) with SCSC and 4,440 (± 4,900) with ATH. The mean difference in costs was 106 (95% CI: -768 to 979).

**Synthesis of costs and benefits**
Incremental cost-utility ratios were calculated in order to combine the costs and benefits of the alternative strategies.

Under base-case assumptions, the incremental cost per QALY gained with SCSC over ATH was 1,517.

The cost-effectiveness acceptability curve showed that, if decision-makers were prepared to pay at least 2,000 to gain one QALY, SCSC would be cost-effective in 50% of bootstrapped estimates.

If the willingness-to-pay were 13,000, SCSC was likely to be cost-effective in over 80% of cases.

At a threshold of 30,000 per QALY gained, the net benefit of SCSC was 2,059 (95% CI: -1,199 to 5,752).

The sensitivity analysis corroborated the robustness of the base-case results. Slightly unfavourable results were achieved if the costs and QALYs were adjusted for differences in baseline utility.

**Authors’ conclusions**
Symptom control delivered by shared care (SCSC) was likely to be more cost-effective than aggressive treatment delivered in the hospital (ATH) for the management of patients with stable rheumatoid arthritis (RA) in the UK.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear as an aggressive approach was compared with a more standardised one. Both approaches were described in full. You should decide whether they are valid comparators in your own setting.
Validity of estimate of measure of effectiveness
The clinical estimate used in the analysis of effectiveness was derived from a clinical trial, which was published elsewhere. Thus, only a few details of the methods and design of the study were reported in the current paper. In general, the use of a large, prospective, randomised study should ensure the validity of the effectiveness analysis. Further, the study had sufficient power to detect statistically significant differences between the groups. The multi-centre design enhances the representativeness of the study sample. Final clinical results were adjusted for differences in baseline utility scores, and bootstrapping was appropriately used to handle variability in the clinical estimates. Methods for dealing with missing data were accurately described.

Validity of estimate of measure of benefit
QALYs were an appropriate benefit measure given that the interventions have a strong impact on quality of life, the most relevant dimension of health for patients with RA. The approach used to derive the QALYs was reported. In addition, QALYs have the advantage of being comparable with the benefits of other health care interventions. Discounting was performed, as recommended by UK guidelines, and the impact of varying the discount rate was investigated in the sensitivity analysis.

Validity of estimate of costs
A broad perspective was adopted, which approximated to a societal viewpoint. The analysis focused on the overall costs rather than on costs related to RA, which would have been a difficult task. Extensive information on the unit costs, quantities of resources used and the price year was provided, which will help in replicating the analysis in other time periods and settings. The sources of the costs were given; the costs were derived from typical UK sources. Statistical analyses were carried out to deal with not only missing economic data but also the non-normal distribution of the costs.

Other issues
The authors made limited comparisons of their findings with those from other studies and stated that their estimates of the costs were somewhat lower than those observed in other studies. On terms of the generalisability of the study results to other settings, the authors stated that the centres participating in the study covered different types of medical institutions, thus the transferability to routine clinical practice should be high. In addition, to facilitate transferability of the results to settings outside the trial in England, protocol-defined visits were excluded from the analysis and national average unit cost data were used. However, the results may not be transferable to other countries.

The authors noted some limitations of their analysis. First, the patients completed a large number of record forms. Second, resource use was assumed to be zero if there was no information. Third, data on the use of medicines were incomplete. Fourth, the issue of missing and censored data might have affected the validity of the economic analysis. However, the sensitivity analysis confirmed that the method of imputation did not affect the conclusions of the analysis.

Implications of the study
The study results appear to support the use of SCSC for the treatment of established RA. The authors noted that more clinical studies should be performed in order to establish whether further suppression of disease activity, using aggressive combination disease-modifying antirheumatic drugs or biological agents, is feasible in RA patients.

Source of funding
Funded by the UK Department of Health.

Bibliographic details
Other publications of related interest

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Indexing Status

Subject indexing assigned by NLM

MeSH

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