Cost-effectiveness of post-transplantation quality of life intervention among kidney recipients

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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
An experimental post-transplant care programme designed to improve quality of life (QoL) of kidney transplant recipients was assessed. The programme incorporated proactive, patient-initiated care to prevent transplant-related morbidities, as well as vocational rehabilitation counselling to maintain or become employed, and enhancement of social support.

Type of intervention
Rehabilitation (a post-transplant care programme).

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised renal patients who had undergone kidney transplantation. The inclusion criteria were aged older than 18 years, renal transplant, no pre-transplant diabetes, and the ability to read and understand English.

Setting
The setting was secondary care and the community. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data and resource use evidence were collected between July 1998 and August 2001. The costs were reported in 2001 prices.

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 sample of patients as that used in the effectiveness study.

Study sample
The authors did not report that power calculations were carried out to estimate the impact of chance on the results. Patients were enrolled into the study at the first post-discharge clinic visit, and were enrolled sequentially at the study setting. The control group (n=30) comprised individuals transplanted between July 5, 1998 and December 24, 1998. They had a mean age of 42.7 (+/- 12.4) years and 8 were females. A pilot group (n=22) comprised individuals transplanted between January 9, 1999 and May 24, 1999. The mean age was 41.2 (+/- 12.8) years and 7 were females.
The intervention group (n=128) comprised individuals transplanted between June 1, 1999 and February 22, 2001. The mean age was 42.5 (+/- 12.5) years and 45 were females. These samples were appropriate for the initial clinical study as they included patients who had received a renal transplant who might have benefited from some form of post-transplant care. There were no reports of patients excluded for any reason.

**Study design**
The basis of the analysis was a non-randomised trial with historical controls that was conducted at a single centre. The patients were followed throughout the first year after transplantation, with outcomes measured at baseline and 6 and 12 months. A detailed description of the intervention design and implementation procedure is available from the authors on request, although the details provided were fairly thorough. Twenty-six of the control group (n=30) reached the 6- and 12-month follow-up points. Twenty-one of the pilot group (n=22), reached the 12-month follow-up point. Of the intervention group (n=128), 107 reached the 6-month follow-up point and 70 reached the 12-month follow-up point. The authors argued that the lower number of patients reaching the follow-up points in the intervention group was due to data truncation rather than a high attrition rate. Blinding to the treatment groups was not possible in this instance.

**Analysis of effectiveness**
The analysis was conducted on an intention to treat basis. The primary health outcomes were a variety of QoL assessment tools, such as the Sickness Impact Profile, the Ferrans and Powers Quality of Life Index, and the Adult Self-Image Scale. A composite QoL measure, which comprised the three measures used in the effectiveness analysis, was developed. This composite measure could take a value between 0 and 100. In addition, the number of adverse events was recorded, as were data on social support and job-market training. The authors reported that the groups were comparable in terms of demographic characteristics. There were no statistically significant differences in race, gender, age, education, weight, cardiovascular risk assessment, and the number of months awaiting transplant.

**Effectiveness results**
The authors did not report the outcomes from the three individual QoL indices, the number of adverse events, or data for social support. Only the composite QoL index was reported.

The difference in the composite QoL index was statistically significant between the control and the intervention group at the first 6 months (74 versus 81; p=0.0169) and at 12 months (77 versus 82; p=0.0082).

The authors reported that 85.8% of patients who were working before the transplant had to return to work after 6 months. This increased to 87.8% after 12 months. Among patients who were unemployed before the transplant, 42% returned to work after 6 months and 86% after 12 months.

**Clinical conclusions**
The authors concluded that the intervention significantly improved the QoL of transplant patients.

**Measure of benefits used in the economic analysis**
The summary measure of health benefit was the number of quality-adjusted treatment-free days. The number of treatment-free days was quality-adjusted by combining this estimate with the composite QoL measure.

**Direct costs**
The study horizon was one year, therefore discounting was not necessary in this instance. The costing analysis included the direct QoL intervention costs (zero for the control group), and the direct inpatient and outpatient postoperative health care costs incurred by all patients, as well as other direct costs borne by patients and their families, and the direct costs to society caused by waiting and travel time. The costs to patients and their families were collated using cost diaries. Such costs covered out-of-pocket expenses for medications, health-related supplies and equipment, travel and from the study setting, payment to others to perform household chores, and any other expenses related to seeing a
health care provider not otherwise reimbursed by insurance. The travel costs were estimated from the mileage and a rate per mile travelled.

All the costs were adjusted into constant 2001 prices using the appropriate consumer price indices. The post-transplant medical treatment costs were collected from the billing records for hospitalisation, inpatient professional services and outpatient professional services. A cost-to-charge ratio was used to convert charges into cost estimates. Resource use was measured over the time horizon of the trial, July 1998 and August 2001.

Statistical analysis of costs
Some p-values were calculated for sub-sets of cost, but not for the grand total cost estimates.

Indirect Costs
The indirect costs (i.e. productivity losses and intangibles) were not included in the study.

Currency
US dollars ($).

Sensitivity analysis
One-way sensitivity analyses were performed to measure the impact of changing assumptions on the results. For instance, the authors explored the impact of inflation, looked for the influence of higher costs arising from a lack of experience in the pilot period, and considered differences in wage rates.

Estimated benefits used in the economic analysis
The number of treatment-free days per patient was 355 for the control group, 356 for the pilot group and 353 for the intervention group.

The number of quality-adjusted treatment-free days per patient was 272 for the control group, 271 for the pilot group and 289 for the intervention group.

Cost results
For the control group, the costs per patient were $36,764 in the first 6 months, $8,734 in the second 6 months and $45,498 in total.

For the pilot group, the costs per patient were $21,900 in the first 6 months, $14,832 in the second 6 months and $36,733 in total.

For the intervention group, the costs per patient were $24,067 in the first 6 months, $13,692 in the second 6 months and $37,759 in total.

Synthesis of costs and benefits
The incremental (difference between intervention over control) cost per patient per treatment-free day was $24 in the first 6 months, $38 in the second 6 months and $29 over the first and second series of 6 months. However, this statistic does not relate directly to the costs and benefits reported above, which indicate the intervention group has greater quality-adjusted treatment-free days per patient and fewer costs, therefore indicating that the intervention is a dominant alternative.

Overall, the results were reported to be stable in response to the sensitivity analysis, except when the high costs of the pilot group were included in the calculation.
Authors' conclusions
The intervention programme was reasonably cost-effective, especially in comparison with the costs of the original transplant operation.

CRD COMMENTARY - Selection of comparators
The authors designed an experimental post-transplant care programme comparing the intervention group with a pilot group of patients and a historical control group. The control group represented current practice in the authors' setting. The comparator groups were well explained and the inclusion of a pilot group enabled the authors to separate out set-up and learning costs, which would not be incurred once a programme was established.

Validity of estimate of measure of effectiveness
The basis of the analysis was a non-randomised trial with historical controls. The sample used was representative of the kidney transplant population described. The patients were compared at baseline in terms of gender, skin colour and mean age at transplant, although further comparisons in terms of renal history might have been made. Although the authors described well-defined outcomes, they did not report in detail the effectiveness results relating to these outcomes. This severely limits the usefulness of the study.

Validity of estimate of measure of benefit
The number of quality adjusted treatment-free days was used as the summary measure of health benefits. The quality adjustment was carried out using a composite measure derived from existing well-being measures. The extent to which this quality adjustment has been validated was unclear. Therefore, readers should be careful when interpreting or attempting to generalise the results to their own setting, and even more careful when drawing comparisons with more widely accepted QoL measures (e.g. quality-adjusted life-years).

Validity of estimate of costs
The authors did not report a perspective for the costing analysis. Therefore, it is not possible to assess whether all the relevant costs were included. The authors reported that they assessed indirect costs but, in fact, these were other direct costs such as travel expenses. The relatively small differences between the costs in the patient groups suggest that the results might be highly sensitive to cost variation, as was demonstrated in the limited sensitivity analysis. Further sensitivity analyses might have been carried out to assess the impact of other cost variations. The unit costs and a detailed breakdown of cost by category were not reported. This would have been useful for readers trying to interpret the main cost drivers.

Other issues
The authors acknowledged that the results were not compared with completed studies and that this prevents them from making global statements concerning cost-effectiveness. The issue of generalisability was raised and, again, the authors realised the problems in generalising when the similarities between their own sample and the national population of kidney transplant patients are not known. The localised cost estimates further inhibit the ability to generalise the results. The presentation of results was hindered by the lack of effectiveness outcomes reported independently from a composite measure and summary measures of benefit. The conclusions related to the cost-effectiveness of the intervention programme relative to the historical control of no intervention, and so reflected the scope of the study. Several limitations were presented. These included the non-randomised nature of the study, the small sample size and the difficulties in generalisability.

Implications of the study
The authors did not make any recommendations for policy or practice following their study, although they made suggestions for further work. Such suggestions included an analysis using a multi-site randomised controlled trial, using medically fragile patients, and exploring longer run effects.
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Other publications of related interest

Ferrans CE, Powers MJ. Quality of life index; development and psychometric properties. Advances in Nursing Science 1985;8;15.


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