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 a pharmacy-based therapeutic drug monitoring (TDM) programme for cyclosporine (CsA), in the treatment of stable renal transplant recipients. A clinical pharmacist provided the service. The philosophy of the programme was based on:

- the recognition of a social need;
- the patient-centred approach;
- caring as a modus operandi; and
- specific responsibilities to identify, resolve, and prevent drug therapy problems.

The TDM guidelines for CsA made the following suggestions:

- identify the factors affecting the pharmacokinetic profile of using CsA;
- avoid the use of nephrotoxic drugs and identify the factors causing CsA toxicity;
- counsel patients on the signs of CsA toxicity and the importance of dental hygiene;
- confirm blood-sampling time;
- maintain the same assay method for CsA concentration; and
- maintain adequate CsA concentrations for a double or triple immunosuppressant regimen.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised stable renal transplant recipients with a renal transplant age greater than one year, who were being treated with CsA.

Setting
The setting was a hospital. The economic study was carried out in Taiwan.
Dates to which data relate
The effectiveness, resource use, and cost data were collected between January and June 1999. The price year was 1999.

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
Thirty-one patients were randomised to the control group and 22 to the test group. There were 10 males in the control group and 11 in the test group. Six patients in the control group had had their transplant within the last 3 years, compared with 7 in the test group. The patients were selected from those attending the CsA TDM programme at the authors' institution. No power calculations were used to determine the sample size.

Study design
This was a prospective randomised controlled trial carried out at a single centre. It was unclear for how long the patients were followed-up. Four patients in the control group, and one patient in the test group, did not complete the study.

Analysis of effectiveness
The clinical study was analysed on an intention to treat basis. The primary health outcomes used in the analysis were the health-related quality of life, and the numbers of drug-related problems, adverse drug reactions, and rejection episodes. The health-related quality of life was measured by the International Quality of Life SF-36 Taiwanese Standard Version. The two groups were comparable in terms of gender, transplant age and patient age.

Effectiveness results
The SF-36 scores tended to decrease from baseline to final follow-up in the control group, and to increase in the test group. When comparing the SF-36 scores between the groups at baseline and at follow-up, the scores for the pharmacist intervention (test) exceeded those of the non-pharmacist group (control). The number of drug-related problems was 182 in the test group and 144 in the control group. The number of adverse drug reactions was 373 in the test group and 376 in the control group. The number of rejection episodes was small and was similar across the groups. Less than 25% of the drug-related problems showed no improvement or were worse at follow-up.

Clinical conclusions
The authors argued that although the SF-36 scores did not improve significantly with the intervention, the final scores on the eight dimensions were generally higher than the scores of the control group.

Measure of benefits used in the economic analysis
The measure of health benefits used in the economic analysis was the health-related quality of life, as measured by the International Quality of Life SF-36 Taiwanese Standard Version.

Direct costs
The direct costs were not discounted due to the short time horizon of the study (less than one year). The quantities were reported, but no unit costs were provided. The direct costs were for the time spent on training, chart reviewing, and working with patients in the clinic. The quantity/cost boundary adopted was that of the hospital. The price year was 1999. The total time spent on each intervention in the test group was 39.99 minutes. The total number of full-time
equivalences required per year was 0.2 in the test group.

**Statistical analysis of costs**
The total costs per intervention, per 6 months, and per year were reported for the test group.

**Indirect Costs**
The indirect costs were not included.

**Currency**
Taiwanese dollars (NT$).

**Sensitivity analysis**
No sensitivity analyses were carried out.

**Estimated benefits used in the economic analysis**
The SF-36 scores for the control group tended to decrease from baseline to final follow-up, whereas those for the test group tended to increase. When comparing the SF-36 scores between the groups at baseline and at follow-up, the scores for the pharmacist intervention exceeded those of the non-pharmacist group.

**Cost results**
The cost NT$133.9 per intervention in the test group. The total cost was NT$42,180 per 6 months and NT$84,360 per year.

**Synthesis of costs and benefits**
The costs and the outcomes were not combined.

**Authors' conclusions**
The authors argued that the economic value of therapeutic drug monitoring (TDM) and clinical pharmacokinetic services in the area of transplantation was thoroughly assured.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator was justified on the grounds that it represented the previous treatment. You should decide if this health technology is relevant to your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a prospective randomised controlled trial, which was appropriate for the study question. The authors did not show whether or not the study sample was representative of the study population. However, they did report the demographic characteristics and show that the groups were comparable in terms of these characteristics. The data were collected from chart reviews and from face-to-face interviews with the patients.

**Validity of estimate of measure of benefit**
The benefits were estimated directly from the effectiveness analysis. They were derived from what is likely to have been a reliable instrument, which is population specific (to Taiwan).
Validity of estimate of costs
The positive features of the cost analysis were that all the relevant categories of the direct costs were included, and the price year was reported. However, the unit costs were not reported, and the authors did not conduct sensitivity analyses on the quantities or the costs. Further, the costs were estimated from local rates, thus limiting the generalisability of the results.

Other issues
The authors did not make appropriate comparisons of their findings with those from other studies. In addition, they did not address the issue of generalisability to other settings. The authors did not seem to present their results selectively. The study considered stable renal transplant recipients with a renal transplant age of greater than one year, who were being treated with CsA, and this was reflected in the authors’ conclusions.

The study may have suffered from a small sample size, thus limiting the extent to which statistically significant results could be found. The authors did not calculate the cost-effectiveness ratios or conduct an incremental cost-effectiveness analysis. The patients in the two treatment groups were allowed to discuss problems relating to their medical condition, possibly introducing bias in the measurement of the treatment outcomes. The treatment delivered depended on the competence and experience of the pharmacists, thus introducing performance bias into the study (i.e., systematic differences in the care provided apart from the intervention being evaluated). The authors’ conclusion, that the economic value of TDM services has been assured, cannot be upheld given these limitations.

Implications of the study
The authors argued that the implementation of a TDM service could have a positive result on the quality of life of the stable renal transplant recipient. This would be achieved by meeting the expectation of the patient's drug-related needs, and by resolving the problems associated with drug therapy.

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