Improved outcomes in indigent patients with ketosis-prone diabetes: effect of a dedicated diabetes treatment unit

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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 use of a specialised medical programme in a diabetes treatment unit (DTU). The programme consisted of an endocrinologist, who was available 24 hours a day through a voice-mail system, a nurse and a part-time diabetes educator and nutritionist. The patients in this programme made scheduled visits to the DTU clinic at least four times per year and had free access to insulin if they could not afford it. This intervention was compared with no scheduled programme, although the patients in this group could still access the endocrinologist and have free access to insulin if they could not afford it.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised indigent patients with Type 1 diabetes who were prone to DKA. Those with conditions known to cause "anion gap" acidosis or ketosis, such as alcoholic ketoacidosis, pregnancy or renal insufficiency (other than a mild, reversible state) were excluded from the study.

Setting
The setting was primary care. The economic study was carried out at the Ben Taub General Hospital, Houston, Texas. The Ben Taub hospital belonged to the Harris County Hospital District (HCHD), a large multiethnic, indigent health care system in Houston.

Dates to which data relate
The effectiveness and resource use data were collected from 1 July 1999 to 30 November 2001. The price year was 2000/2001.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

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

Study sample
The study sample size does not seem to have been determined in the planning phase of the study, and no power calculations were performed retrospectively. All patients with Type 1 diabetes mellitus admitted to the Ben Taub General Hospital during 1 July 1999 and 30 June 2001, due to DKA, were admitted into the study. During the study period, 115 patients were assessed. Of these, 57 (49.6%) had follow-up in the DTU outpatient clinic (+DTU group). The remaining 58 (50.4%) refused to join the programme or did not visit the DTU clinic even once, and hence had no follow up (-DTU group). The +DTU group comprised 32 (56%) males and 25 (44%) females, and the mean age was 38 (+/- 15) years. The -DTU group comprised 29 (52%) males and 28 (48%) females, and the mean age was 36 (+/- 14) years. No significant differences were found between the two study groups, even for employment status, education levels, or health insurance coverage.

Study design
This was a cohort study that was carried out at several centres of the HCHD. The median duration of follow-up of the patients was 675 days (range: 144 - 862). No loss to follow-up was quoted for the +DTU group. However, in the -DTU group, 18 (31%) patients did not attend any clinic even once for follow up-care, and 8 (14%) could not be contacted.

Analysis of effectiveness
All of the patients in the study seem to have been accounted for in the analysis. The primary health outcomes used in the analysis were:

the number of readmissions due to DKA per patient and per patient per year;

the number of patients readmitted to hospital; and

the rates of haemoglobin A1c (Hb1Ac).

To determine whether a -DTU patient had been readmitted to hospital, there was a biweekly survey of the admission lists at the two HCHD hospitals. In addition, monthly telephone surveys were made to all -DTU patients to enquire if they had been readmitted to any hospital. At analysis, the groups were shown to be comparable in terms of their age, gender, socioeconomic status and prognostic features.

Effectiveness results
Nine patients (16%) in the +DTU group were readmitted because of a DKA episode, compared with 25 (43%) in the -DTU group, (p=0.0001). Thus, participation in the DTU programme conferred a relative risk reduction in readmission for DKA of 63%, and an absolute risk reduction of 27%. The number-needed-to-treat to prevent one readmission was 3.7.

There were fewer readmissions for DKA per patient in the +DTU group (0.22 +/- 0.6) than in the -DTU group (1.17 +/- 2.2), (p=0.003). Similarly, there were fewer DKA readmissions per patient per year in the +DTU group (0.13 +/- 0.3) than in the -DTU group (0.74 +/- 1.2), (p=0.0003).

Patients in the +DTU group had lower HbA1c levels (10.4 +/- 2.3%) than those in the -DTU group (13.5 +/- 2.3%), (p<0.0001).

Clinical conclusions
The intervention combining the services of a specialist endocrine team, intensive education, and a targeted removal of administrative barriers to regular outpatient care, resulted in substantial reductions in the rate of DKA readmission and Hb1Ac levels.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. A cost-consequences approach was therefore adopted.
Direct costs
The resource quantities and the costs were not reported separately. The direct costs included in the analysis were those from the HCHD health care system. These were the outpatient costs in the DTU and non DTU clinics, the inpatient costs of treating DKA, and the costs of pharmacy visits and medical personnel. The costs were estimated from the billing records in outpatient clinics and from the central computerised database for inpatient clinics. Discounting was irrelevant, as the median follow-up was less than 2 years, and was not undertaken. The price data refer to the years 2000 and 2001.

Statistical analysis of costs
Descriptive statistics (mean plus standard deviation) were used to compare the total costs between the two groups. The data were transferred to the JMP 3.2.2 programme (SAS Institute) for statistical analysis.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total cost of medical care per patient per year was $3,427.20 (+/- 6,275.60) in the +DTU group and $10,119.90 (+/- 19,688.10) in the -DTU group, (p=0.01).

Synthesis of costs and benefits
The costs and benefits were not combined as a cost-consequences approach was undertaken.

Authors' conclusions
The dedicated outpatient diabetes treatment unit (DTU) resulted in significant decreases in diabetic ketoacidosis (DKA)-related readmissions, haemoglobin A1c (HbA1c) values and the cost of diabetes care in a multiethnic, indigent, ketosis-prone population.

CRD COMMENTARY - Selection of comparators
There was no explicit justification for the comparator used. However, the lack of a dedicated diabetes programme for indigent patients, most of them uninsured, would appear to represent current practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a prospective cohort study. Ideally, as the authors pointed out, the patients would have been randomised at onset to either the DTU programme or no intervention (-DTU). This could have avoided the potential of
systematic differences between the two groups. For example, those who chose to participate in the DTU programme could have had more health care problems than those who did not participate, and joined the programme for that reason, thus biasing the results of the programme downwards. However, even though a randomised controlled trial was not conducted, no statistically significant differences were noted between the two groups for socioeconomic characteristics, prognostic features, age, gender, and reasons for non compliance. One aspect of the study that could have biased the results of the intervention programme downwards was that the patients in the non intervention group still received some of the benefits of the DTU programme (access to the endocrinologist and free access to insulin if they could not afford it). It is also worth noting that the -DTU group had a significantly higher loss to follow-up than the +DTU programme, although the authors did not explain why.

**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 analysis.

**Validity of estimate of costs**
All the categories of cost relevant to the perspective adopted (HCHD health care system) were included in the analysis. However, as the authors only provided the total costs of each category (e.g. total costs of inpatient and outpatient clinics), it was unclear whether all the relevant costs were included in the analysis. Thus, it is not possible to say whether any omissions could have affected the authors' conclusions. The costs and the quantities were not reported separately, which will weaken the generalisability of the results. The cost data were taken from the authors' setting. A statistical analysis of the prices was performed and the total costs were presented with their mean and standard deviations, to account for variability in the data. No further analysis of the prices was conducted and, since all the costs were incurred in less than 2 years, discounting was unnecessary. To determine the total outpatient costs, the prices were proxied from the billing records. The years to which the cost data referred (2000/01) were given, thus helping relflation exercises to other settings.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. Many of these studies involved paediatric populations, who have been shown to be more compliant with insulin injections than the indigent population, and who are all covered through Medicaid and thus have a safety net not available to most of the indigent population. However, such studies found generally positive results similar to those from this study. The issue of generalisability to other settings was partly addressed when comparing the findings to those from other studies. The authors do not appear to have presented their results selectively. The authors' conclusions reflected the scope of the analysis, as the study focused on indigent patients with ketosis-prone diabetes and that was reflected in the authors' conclusions. The authors did not report any further limitations of their study.

**Implications of the study**
Even though the DTU resulted in significant health benefits, the authors pointed out that substance abuse was a major problem in both study groups, with the DTU having little influence on this factor. Thus, improved therapy for substance dependence is a goal for the future management of DKA-prone patients with diabetes.

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None stated.

**Bibliographic details**

**PubMedID**
Other publications of related interest
Javor KA, Kotsanos JG, McDonald RC, et al. Diabetic ketoacidosis charges relative to medical charges of adult patients

Diabetes 2001;50 Suppl 2:A144.


Musey VC, Lee JK, Crawford R, et al. Diabetes in urban African Americans. I. Cessation of insulin therapy is the

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