Impact of a critical pathway on inpatient management of diabetic ketoacidosis
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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 critical pathway for the management of patients with diabetic ketoacidosis (DKA). A multidisciplinary team involving representatives from several departments (Emergency Medicine, General Internal Medicine, Critical Care Medicine, Endocrinology, Nursing and Pharmacy) created the pathway. The pathway focused on 7 key areas:

- the administration of intravenous (IV) fluids to correct the calculated fluid deficit;
- the administration of IV insulin;
- the non-administration of bicarbonate if the pH was equal to or greater than pH 7.1;
- the administration of potassium;
- the correction of anion gap acidosis before stopping the IV insulin infusion;
- the allotment of adequate time for subcutaneous insulin to act before stopping the IV insulin infusion; and
- education on sick-day management before discharge.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised non-pregnant adult patients admitted to the hospital with a primary or secondary diagnosis of DKA.

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

Dates to which data relate
The effectiveness and resource use data were gathered from January to December 1997 in the control group, and from January to December 1998 in the intervention group. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was 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 analysis of effectiveness.

Study sample
The use of power calculations was not reported. The sample of patients was identified through the emergency department and hospital costing information system of the hospital. All eligible patients admitted to the General Medicine and Critical Care Medicine Services during the study periods were considered. Of the 89 patients identified in 1997, 72 were included in the control group. Their mean age was 37 (+/- 14) years and the duration of diabetes was 14 (+ 9) years. Of the 97 patients identified in 1998, 77 were included in the intervention group. Their mean age was 36 (+/- 12) years and the duration of diabetes was 14 (+/- 8) years. In both groups the reasons for exclusion were patients being transferred from other institutions, or being admitted to other services.

Study design
This was a prospective comparative study with historical controls, which was carried out in a single centre. The patients were followed until hospital discharge and no loss to follow-up was observed. The assessment of the outcomes was not blind. General medicine house officers rotating through the Emergency Department, General Medicine and Critical Care Services managed all the patients.

Analysis of effectiveness
All the patients included in the initial study sample were considered in the analysis of effectiveness. The primary health outcome was LOS. The secondary outcomes were the degree of adherence to DKA critical pathway recommendations (evaluated using 10 variables) and outcomes to be avoided. A sub-group analysis was performed on the basis of the attending physician, whether a general internist alone or with endocrinology consultation. Regression analyses were carried out to determine whether there was any correlation between process of care and the outcomes. The study groups were comparable at baseline in terms of the clinical and demographic characteristics.

Effectiveness results
The mean (+/-standard deviation) LOS was 4.9 (+/- 9.4) days (median 2.4) in the control group and 3.0 (+/- 2.9) days (median 2.1) in the intervention group, (p>0.05). For the intervention group, the LOS was significantly shorter in the sub-group of patients who were attended by a general internist alone. The LOS was 5.2 (+/- 10.6) days in the pre-implementation phase versus 2.4 (+/- 2.1) days in the post-implementation phase.

In terms of the degree of adherence to the pathway, significantly more intervention patients received the recommended fluid volume (88% versus 71%), education in sick-day management (77% versus 54%) and endocrinology consultation (38% versus 21%).

Other indicators of programme adherence were not significantly different between the groups.

Rates of hypoglycaemia, hypokalaemia and inappropriate bicarbonate administration were low and were comparable between the groups.

The regression analysis showed that the recommended fluid replacement at 24 hours (after adjusting for baseline anion gap) was significantly associated with time to correction of the anion gap. Also, the amount of insulin received in the first 8 hours was significantly associated with time to correction of the anion gap. Finally, longer time to correction of the anion gap was significantly associated with the insulin infusion rate.

Clinical conclusions
The effectiveness analysis showed that the critical pathway did not result in significant reductions in LOS or outcomes.
to be avoided.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.

**Direct costs**
Discounting was irrelevant since the costs per patient were incurred during a short time. The unit costs and the quantities of resources used were not reported separately. The economic analysis focused only on the cost of hospitalisation. This covered nursing, supplies and all services associated with hospitalisation. The cost/resource boundary of the hospital was adopted. Resource use was derived using actual data, which were estimated from the sample of patients involved in the effectiveness study. The costs came from the Financial Services Division of the hospital and were derived using the Transition Systems Inc. costing information system. As in the effectiveness study, sub-group analyses were carried out in which the patients receiving or not receiving endocrinology consultation were considered separately. The price year was not reported, but the prices are likely to refer to 1997 and 1998 when the resource use data were gathered.

**Statistical analysis of costs**
The costs were presented as mean values +/- standard deviations, as well as median values. Statistical tests were carried out to test the statistical significance of differences in the estimated costs.

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

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were conducted.

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

**Cost results**
The mean costs were $6,441 (+/- 15,204; median $3,074) in the control group and $3,625 (+/- 3,478; median $2,613) in the intervention group, (p>0.05). The difference in costs did not reach statistical significance in the sub-group analysis.

**Synthesis of costs and benefits**
The costs and benefits were not combined because a cost-consequences analysis was conducted.

**Authors’ conclusions**
The implementation of a critical pathway for the inpatient management of diabetic ketoacidosis (DKA) led to a trend towards shorter hospital stay and costs, mainly due to recommended fluid management. Statistically significant reductions in length of stay (LOS) were observed in the sub-group of patients treated without endocrinology consultation. The authors speculated that there is room for improvement, even after the implementation of the critical
pathway, especially in the area of insulin administration.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator (standard practice before the implementation of the new pathway) was appropriate to reflect the routine approach used for the inpatient management of patients with DKA. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The basis of the effectiveness evidence was a prospective observational study. The authors acknowledged that this entails a number of limitations. To reduce the impact of confounding factors, data on potential confounders were collected in both study periods and regression analyses were carried out. As the study evaluated intervention and control patients in two different timeframes, trends in these two periods were compared for factors such as LOS, in order to capture the true effect of the critical pathway. The authors discussed the reasons for the choice of a single site in which to carry out the study and for their preference for a non-randomised design. A further threat to the internal validity of the analysis was the lack of power calculations and the fact that there was no evidence that the sample size was appropriate. These issues tend to limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The authors reported few details of the economic analysis. The perspective of the study was not explicitly stated, but it appears to have been that of the hospital. Information on the unit costs and quantities of resources was not provided. The price year was not reported, which makes reflation exercises in other settings difficult. The source of the cost data was given. The resources were gathered prospectively. The costs were treated stochastically and wide differences were observed. However, these differences did not reach statistical significance, thus suggesting that the economic study could be underpowered. Sensitivity analyses were not carried out and the cost estimates were specific to the study setting.

**Other issues**
The authors made some comparisons of their findings with those from other studies that evaluated aspects considered in the current study. However, the comparisons were concerned only with the effectiveness side of the analysis. The authors also addressed the issue of the generalisability of the study results to other setting. They stated that the study was conducted in a single teaching hospital, which might not be representative of other medical centres.

**Implications of the study**
The study results showed that the introduction of a critical pathway for DKA led to less variability in cost and LOS. The authors suggested that larger randomised studies are needed to confirm the results of the present study.

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**Bibliographic details**