Cost-effectiveness of flexible intensive insulin management to enable dietary freedom in people with Type 1 diabetes in the UK

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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
A structured treatment and teaching programme (STTP), combining dietary freedom with insulin adjustment for Type 1 diabetes, was evaluated.

Type of intervention
Secondary prevention.

Economic study type
Cost-utility analysis.

Study population
The study modelled a mixed cohort of Type I diabetes patients, 54% of whom were female.

Setting
The educational intervention took place in an outpatient setting, with subsequent self medication in the community. The economic study was carried out in the UK.

Dates to which data relate
The model drew on sources published between 1991 and 2002. The prices were either adjusted or referred to sources dated either 2001 or 2002.

Source of effectiveness data
The effectiveness data were modelled from a synthesis of studies.

Modelling
Markov models with time- and state-dependent transition probabilities were used to project the progression of disease for nephropathy, retinopathy, neuropathy and erectile dysfunction over 10 years. The progression of these diseases was dependent on glycated haemoglobin A1c (HbA1c). Diagrams showing the health states for each Markov model and the possible transitions between them were presented. Hypoglycaemia and ketoacidosis were also considered for the model but these did not require Markov models.

In addition to the economic outcomes (below), the model predicted increases over a 10-year period in the amount of time spent free of diabetic retinopathy, end-stage renal disease (ESRD), and foot ulceration or amputation. It also predicted a reduction in the incidence of ketoacidosis.
Outcomes assessed in the review
The clinical parameters in the model included:

the reduction in HbA1c due to the STTP; and

the effect of HbA1c on hypoglycaemia, ketoacidosis and the different health states in the Markov models for nephropathy, retinopathy, neuropathy and erectile dysfunction.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
The parameters in the model were derived from 12 primary studies.

Methods of combining primary studies
Where more than one study was used to estimate the value of a single parameter, the results of those studies were combined using a narrative method.

Investigation of differences between primary studies
Not reported.

Results of the review
There is a steady fall in HbA1c to achieve a reduction of 0.9% 12 months after the intervention. This fall is sustained for 4 years.

After this period there is a steady rise in levels of HbA1c, resulting in a reduction of 0.26% after 10 years.

The transition probabilities were not reported.

Measure of benefits used in the economic analysis
The outcomes were measured in life-years and quality-adjusted life-years (QALYs), and were derived from EQ-5D valuations of health states using both public and patient tariffs. They were discounted at a rate of 1.5%. Quality of life data relating to symptoms experienced by patients with Type 2 diabetes were used in the absence of data for those with Type 1 diabetes.

Direct costs
The direct costs to the health service were evaluated. These included both diabetic treatment and complications. The costs were discounted at 6% per annum. The unit costs of STTP, diabetic control and the treatment of complications were all reported. The costs were reflated using the Health Service Cost Index. Discounted cumulated total costs per patient, as generated by the model, were reported by cost category. The costs of monitoring glycaemia were excluded as they were common to both groups. Neither the costing methods section, nor the tables, specified a timeline for the costs. However, most of the referenced sources referred to 2001. The costs were derived from NHS 2001 Reference Costs, the British National Formulary (version 41), the NHS Drug Tariff 2001, PSSRU Unit Costs 2001 and CIPFA 2001. No distinction was drawn between marginal and average costs.

**Statistical analysis of costs**
There was no statistical analysis of the costs.

**Indirect Costs**
The indirect costs were not included in the study.

**Currency**
UK pounds sterling ({}).

**Sensitivity analysis**
A one-way sensitivity analysis was performed. The parameters investigated (with altered assumptions shown in brackets) were the discount rate (0%), the extent of HbA1c reduction in the first year (1%), the duration of the initial impact of STTP (3 years), mortality rates (+/- 10%), progression rates to each of the major complications (+/- 10%), utility weights (+/- 10%), the cost of STTP (from 432 to 995) and benefit from ketoacidosis (no benefit). A further 3-way sensitivity analysis was performed using the most influential parameters simultaneously. The selection of ranges used in the sensitivity analysis was described as “plausible”.

**Estimated benefits used in the economic analysis**
The incremental life-years gained after 10 years amounted to 5.31 per 100 patients. This figure was reduced to 5.16 after discounting, which was equivalent to an increase in longevity of 19 days per patient.

QALY gains valued using the EQ-5D tariff and a patient-rated visual analogue scale amounted to 12.2 and 9.9, respectively, per 100 patients.

**Cost results**
The 10-year discounted costs were negative, with treatment savings outweighing the cost of the intervention by 2,237 per patient (2,535 undiscounted).

The total costs were 33,778 per patient in the intervention group versus 36,015 in the control group.

Major incremental costs per patient (discounted at 6% and quoted in pounds sterling) were:

- STTP, 545;
- insulin therapy, 456;
- outpatient review, -362;
- the treatment of foot ulcers, -938;
- renal drugs and clinics, -171;
renal dialysis, -1,565; and
the treatment of erectile dysfunction, -2,237.

**Synthesis of costs and benefits**
The extent of negative incremental costs and positive incremental gains in both life expectancy and QALYs was illustrated using quadrants I and II (North-East and South-East quadrants) of the conventional cost-effectiveness plane. The dominance of STTP over conventional treatment rendered cost-effectiveness ratios irrelevant. Years to breakeven were used to indicate how rapidly the intervention became cost-effective. This occurred after 4.5 years in the baseline case.

The most influential parameters in the one-way sensitivity analysis were (with the revised years to breakeven reported in brackets) were the extent of the reduction in HbA1c (5.25 years) and the cost of STTP (5.75 years).

Taking all three most detrimental values from the univariate sensitivity analysis into a multivariate sensitivity analysis did not alter the principal conclusion of an increase in longevity and a reduction in costs discounted over 10 years.

**Authors’ conclusions**
The authors concluded that the model they used robustly demonstrates that the structured treatment and teaching programme (STTP) has the potential to be both cost-saving and to reduce both mortality and morbidity, provided that the results demonstrated in Europe can be successfully transferred to the UK.

**CRD COMMENTARY - Selection of comparators**
Current practice is always an appropriate comparator. However, there may be other plausible alternatives that were not evaluated in this study.

**Validity of estimate of measure of effectiveness**
The authors did not report a systematic review of the literature to determine the effectiveness of treatment. Instead, they used data from the available studies selectively. Of any two studies considered, the one with the more "conservative" implications was used in the modelling. Few clinical data were reported.

**Validity of estimate of measure of benefit**
The benefits were measured both in terms of life-years and QALYs. Valuations derived from members of the public and from patients (the latter using a visual analogue scale) were applied to health states described by the EQ-5D.

**Validity of estimate of costs**
All the categories of cost relevant to the chosen (NHS) perspective were apparently reported. The unit costs and the total costs per patient were reported, from which it should be possible to infer the quantities predicted by the model. However, quantities per patient were not explicitly stated. Resource use was modelled from other sources, with a sensitivity analysis used to test assumptions. Price information was derived from published sources. The sensitivity analysis on the costs was apparently conducted on the combined price and quantity information. Discounting followed standard procedures, as recommended by the National Institute for Clinical Excellence. Although not evident from the text itself, the date to which the prices related was implicit from the references.

**Other issues**
The authors compared their results with those derived from an Austrian study. However, this study was itself used in the modelling that the authors conducted. The question of generalising the results beyond the NHS was not considered. The authors discussed the application of complication rates from Type II diabetes to a cohort with Type I diabetes. They
concluded that biases could operate in either direction, but the sensitivity analyses should have adequately examined these possible biases.

**Implications of the study**
The authors advocate the use of the STTP as a way of enabling individuals to manage their own lifestyle and condition.

**Source of funding**
None stated.

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