Record Status
This is an economic evaluation that meets the criteria for inclusion on NHS EED.

CRD summary
The study objective was to assess the cost-effectiveness of skills training in flexible intensive insulin therapy for adults with type 1 diabetes mellitus. The authors concluded that Dose Adjustment for Normal Eating (DAFNE) was a cost-effective programme despite limited long-term improvements in HbA1c although there was some uncertainty surrounding the cost per additional QALY estimate. There were a few reporting issues but overall the study methodology was good. The authors' conclusion appears to be appropriate.

Type of economic evaluation
Cost-utility analysis

Study objective
The study objective was to assess the cost-effectiveness of skills training in flexible intensive insulin therapy for adults with type 1 diabetes mellitus.

Interventions
The intervention was the Dose Adjustment for Normal Eating (DAFNE) structured five-day education programme for type 1 diabetes mellitus patients. The programme was based on teaching skills in flexible intensive insulin therapy. Training was delivered in groups of six to eight participants by trained DAFNE educators. The comparator was no training.

Location/setting
UK/secondary care

Methods
Analytical approach:
A patient-level simulation model (Sheffield Type 1 Diabetes Policy Model) was simulated events over a lifetime horizon. The authors stated that the analysis adopted a National Health Service perspective.

Effectiveness data:
Two patient-level data sets and published literature were used to populate the model. The 5,000 simulated individuals in the model were representative of the participants in the DAFNE trial.

The main clinical effectiveness estimate effectiveness was measured as a reduction in HbA1c, which reduced the risk of developing long-term diabetes-related complications in the model. Baseline HbA1c was based on data from a randomised controlled trial (RCT) conducted in England in 2002. The effectiveness of DAFNE was based on an analysis of longer-term follow-up data from a more recent DAFNE RCT. It was assumed that HbA1c returned to baseline levels at five years for the DAFNE arm and remained at baseline levels in the control arm.

Monetary benefit and utility valuations:
Each health state in the model was associated with a utility value with utility decrements applied for each complication. Utility values were derived from three published papers and the authors' assumptions.

Measure of benefit:
Health benefit was measured in terms of quality-adjusted life-years (QALYs) discounted at an annual rate of 3.5%.

Cost data:
The cost categories included were the intervention cost, insulin costs, long-term complications and adverse events. Most costs were derived from NHS Reference Costs, British National Formulary or UKPDS 65 (prospective diabetes study). DAFNE was assumed to cost £359 per patient. The annual cost of insulin was assumed to be slightly higher in the DAFNE arm based on data from the DAFNE RCT. Future costs were discounted at an annual rate of 3.5% and presented in UK pounds sterling (£).

Analysis of uncertainty:
Probabilistic sensitivity analysis was conducted to explore the impact of parameter uncertainty on the results. The model was run using eight plausible alternative treatment effectiveness assumptions. A cost-effectiveness acceptability curve (CEAC) was constructed and presented.

Results
Over a lifetime horizon, DAFNE resulted in an additional 0.0294 QALYs at an additional cost of £462 compared with no DAFNE with a mean incremental cost-effectiveness ratio (ICER) of £14,400 per QALY (95% CI £10,110 to 18,690). There was a 54% probability that DAFNE was cost-effective at a willingness-to-pay threshold of £20,000 per QALY.

The base-case result was robust to most of the sensitivity analysis assumptions tested. The exception was that the 12-month HbA(1c) improvement associated with DAFNE would not be maintained past the first year, for which the ICER rose to £78,227 per QALY.

Authors' conclusions
The authors concluded that DAFNE was a cost-effective programme despite limited long-term improvements in HbA(1c) although there was some uncertainty surrounding the cost per additional QALY estimate.

CRD commentary
Interventions:
The intervention was clearly described. No other alternative interventions were discussed. The comparator of no DAFNE seemed reasonable.

Effectiveness/benefits:
The sources used to derive effectiveness estimates were clearly reported and were of a good methodological standard. It was not clear whether a systematic review for all available relevant evidence was conducted so it was unclear whether the effectiveness estimates were derived from the best available evidence. The effectiveness estimates themselves were not reported clearly. The model transition probabilities were clearly reported in an online supplement. The authors highlighted that the analysis only took into account the HbA1c benefit; published data showed significant additional benefits for psychosocial outcomes, severe hypoglycaemia and diabetic ketoacidosis. No information was reported on how the utilities were measured or valued so the quality of these estimates was unclear.

The authors highlighted that use of published data from non-UK settings to define risk of long-term complications was a limitation of their analysis; some of these were very old and may not have been representative of current UK risks.

Costs:
The cost categories included in the analysis appeared appropriate. A clear breakdown of the costs for each cost category and sources used to derive them was reported in an online supplement. No information on resource use was reported and no justification was supplied for the assumed price of the intervention. The price year was not reported. Future costs were discounted appropriately.

Analysis and results:
The model was clearly described and a diagram was provided. An incremental analysis was conducted and was the most appropriate form of analysis to assess cost effectiveness. The results were reported clearly. In the probabilistic sensitivity analysis the model simulations were only run 500 times. This was unlikely to have been sufficient to adequately capture the expected variance in outcomes due to parameter uncertainty. The authors argued that although the sensitivity analysis suggested that DAFNE would not be cost-effective if HbA1c improvements were not maintained past 12 months, this was not likely to be true given that published evidence suggested HbA1c benefit was
maintained for four to seven years.

The authors stated that the results of the analysis only applied to populations that matched the DAFNE RCT entry criteria and should not be generalised to the broader population now covered by the DAFNE programme since its expansion.

Concluding remarks:
There were a few reporting issues but overall the study methodology was good. The authors’ conclusion appears to be appropriate.

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