Executive Summary

Context

In February 2003, the National Institute for Health and Clinical Excellence (NICE) recommended the use of continuous subcutaneous insulin infusion (CSII), also known as 'insulin pump' therapy, as an option for patients with type 1 diabetes, provided they had failed on multiple dose insulin (MDI) and were willing and able to use the therapy effectively. NICE considered that MDI therapy had failed if the patient was unable to maintain their blood glucose level within a recommended range without experiencing 'disabling hypoglycaemia'.

NICE assumed that 1-2% of those with type 1 diabetes would fulfil the criteria for insulin pump therapy. Current provision of insulin pumps in the UK is within the range of 1-2%, but in certain parts of the country usage levels are significantly less, demonstrating varying barriers to access to the technology. The UK also demonstrates dramatically lower usage than in most other countries of comparable economic standing and level of healthcare provision, where up to 20% of people with type 1 diabetes are treated with CSII. Recent statements by the Department of Health Working Group on Insulin Pumps and the Association of British Clinical Diabetologists (ABCD) advise that access to insulin pump therapy remains inconsistent throughout the UK.

Background

Type 1 diabetes remains a significant burden to patients, the NHS and society as a whole. The maintenance of near-normal blood glucose levels is the accepted treatment priority and when attained, patients experience fewer long-term complications and the progression of existing complications is significantly delayed. However, consistently maintaining reduced levels of blood glucose puts the patient at an increased risk of hypoglycaemia, a debilitating condition, which can lead to seizure, coma and death.

Effective control of type 1 diabetes is achieved through the sustained maintenance of blood glucose levels within defined levels via the administration of insulin. Therapy is mainly delivered through intensive insulin treatment as either optimised MDI or CSII. Insulin pumps facilitate the use of faster-acting insulin resulting in greater predictability of insulin levels, closely mimicking normal insulin secretion.

Clinical effectiveness

The most representative summary of clinical evidence available on the impact of insulin pumps has been summarised in a recent meta-analysis by Pickup & Sutton (academic in confidence). [redacted]

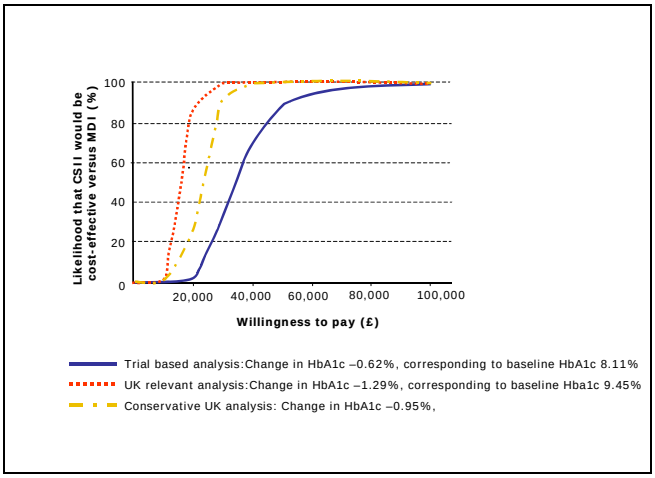
CSII may also have substantial benefits for patients' quality of life (QoL) and treatment satisfaction. There have been numerous studies examining the impact of insulin pumps on patient QoL published since the original NICE appraisal. However, many studies fail to capture the real-life benefits, such as convenience, reduced worry and greater freedom, reported by patients receiving insulin pump therapy.

Cost-effectiveness

A cost-effectiveness analysis utilising data from the meta-analysis by Pickup & Sutton considered three scenarios: a UK relevant analysis using the mean HbA_{1c} observed in all UK type 1 patients; a trial-based analysis using the mean HbA_{1c} reported from the meta-analysis (statistically more robust, but less representative of UK patients) and a conservative UK analysis using intermediate values between the UK relevant and the trial-based analysis.

In each of the scenarios investigated, CSII was associated with improved life expectancy and quality-adjusted life expectancy, as well delayed development of any diabetes-related complications.

- The UK-relevant analysis, which assumes a mean UK cohort baseline HbA_{1c} of 9.4%, estimated that using CSII in place of MDI produces an incremental cost-effectiveness ratio of £16,842/QALY.
- A trial-based analysis, which assumes a mean baseline HbA_{1c} of 8.11% as reported by the meta-analysis, estimated a cost per QALY of £34,330.
- A conservative UK analysis, assuming a mid-point baseline HbA_{1c} value, produced a cost per QALY of £22,897.



Deterministic and probabilistic sensitivity analyses demonstrate that the model is robust to substantial changes in key parameters. The main driver of the analysis is the choice of discount rates; based on the trial-based analysis, using discount rates of 6% (costs) and 1.5% (health benefits) reduced the cost per QALY estimate by approximately 45% to £18,997.

There are several limitations associated with economic evaluations of diabetes therapy. For instance, costs of insulin treatment regimens with MDI are invariably estimated using dose-based estimates of insulin requirement after accounting for variation in subject weight; therefore, the current analysis should be viewed as conservative.

Wider NHS Implications

Previously, NICE estimated that up to 2% of patients with type 1 diabetes would be suitable for CSII. The recent statement by the Department of Health Insulin Pumps Working Group indicates that there is under-provision of CSII services in the UK and that, based on countries where CSII is an established therapy, 20% of patients with type 1 diabetes should be receiving insulin pump therapy.

Based on a projected uptake of CSII of 5%, 10%, 15% and 20% in consecutive years, the additional incremental annual cost to the NHS of CSII compared with MDI would range from approximately £22 million up to £65 million over the first 4 years. This estimate does not include potential cost offsets from a reduction in diabetes-related complications as captured in the economic analysis.

As outlined by the Department of Health Insulin Pumps Working Group, the provision of CSII requires the continued development of a single cohesive service providing specialist nursing support, patient education and advice.

Conclusion

The clinical and economic evidence presented in this cross-industry submission builds on the original appraisal of insulin pumps (TA57, 2003). The evidence is considered to support the original recommendation; that insulin pumps be recommended as an option for people who have failed to maintain their diabetes with MDI, and who have the commitment and competence to use the therapy effectively, in line with the recent report from the Department of Health Insulin Pumps Working Group.

It is now widely recognised that the assumption of 1-2% of patients that are suitable for pump therapy, under the original guidance, was an under-estimate. [redacted]

Whilst it is recognised that not all patients with type 1 diabetes are suitable candidates for pump therapy, international experience demonstrates a proportion of these patients, potentially up to 20%, if appropriately selected and managed, can obtain significant benefits.