

NICE Technology Assessment Report: Continuous subcutaneous insulin infusion for the treatment of diabetes – Comments by the Department of Health

1. It would be helpful if the report considered whether someone should only be offered CSII where impeccable care of their diabetes (as outlined in NICE Type 1 guidelines and HTA 60), including patient education, has failed.
2. We feel that the current protocol does not recognise structured patient education programmes as outlined in HTA 60 (for example the recommended intervention DAFNE), as an intervention that should be undertaken before MDI and be considered to have failed. This means that people who could potentially benefit from MDI if they were to be properly educated in self-management, may not have the chance to do so.
3. DAFNE is mentioned in paragraph 5.6 of the protocol, but this suggests that patient education could be an alternative to CSII. We would propose that patient education should be a part of routine care before CSII is considered.
4. Pages 36-39 of the report highlight areas of particular difficulty and make recommendations for areas where further guidance would be helpful.
 - a. We feel the use of the term “failure of multiple dose injection therapy” is unclear and has been interpreted differently. Would you please consider whether additional guidance can be provided that would help to reduce this variability.
 - b. The indication in the current guidance that only 1-2% of Type 1 patients are likely to benefit from CSII we feel is misleading.
 - c. In our view, the indications within the current guidance are very limited. A range of other indications have been suggested. A number of these are of the type that will never be subject to large randomised clinical trials, and you will need to give consideration to how these will be dealt with during review of the guidance.
 - d. Quality of life issues for adults, including the number of injections daily being required to achieve control, frequent sick days, marked glycaemic swings or dawn phenomenon, impaired exercise capacity, and difficulties with shift work or travel across time zones.
 - i. Additional issues for children and their parents, including school performance, inability to fully integrate into school life, behavioural issues eg meal times, and impact on family dynamics.
 - ii. Pregnancy including women contemplating pregnancy
 - iii. Acute painful neuropathy or symptomatic autonomic neuropathy

- iv. Hypoglycaemic unawareness
 - v. Extreme insulin sensitivity
 - vi. Needle phobia with adverse metabolic sequelae
 - vii. Insulin allergy
 - viii. Use in Type 2 diabetes, particularly for severe insulin resistance
 - ix. Availability of pumps on the basis of patient preference.
- e. In our view CSII for children has particular challenges given the diversity of their presentation, spectrum of age, and the complexity of management of diabetes in children. CSII can potentially be very beneficial for this group, and some paediatricians recommend that all children and adolescents should be offered the choice of CSII or MDI as an initial method of intensifying insulin therapy. This is an area on which further NICE guidance would be particularly helpful.
- f. Understanding of Type 1 diabetes has increased greatly following publication of the NSF and the Type 1 NICE Guideline. Principles from these publications need to be incorporated into future pump guidance.
- g. Would you please consider including a clear implementation plan for the revised guidance, with links made to this document to ensure consistent delivery of and access to pump services.
5. You might be aware that In March 2007 Department of health published *Insulin Pump Services*¹, which sets out the findings of the Insulin Pumps Working Group. This group included consultant diabetologists, paediatricians, diabetes specialist nurses and people with diabetes. This report states that:
6. ‘...CSII should be considered for those patients who have been unable to achieve their agreed care plan goals following impeccable Type 1 care. Impeccable Type 1 care is outlined in NICE Clinical Guideline 15 *Type 1 diabetes: diagnosis and management of Type 1 diabetes in adults*. The key components are:
- a. Patient centred care, including the development of an individualised care plan
 - b. A multi-disciplinary team approach
 - c. Patient education
 - d. Blood glucose control
 - e. Arterial risk-factor control
 - f. Surveillance and management of late complications’

¹ *Insulin Pump Services: Report of the Insulin Pumps Working Group* (Department of Health, 2007), http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_072777

7. The report also recommends areas for further research, and this includes a comparative trial between MDI, supported by structured education, and CSII.