National Institute for Health and Clinical Excellence

Continuous subcutaneous insulin infusion for the treatment of diabetes (review)

Royal College of Nursing

Introduction

With a membership of over 400,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

Response to the Appraisal Consultation Document on the health technology appraisal of Continuous subcutaneous insulin infusion for the treatment of diabetes (review)

The Royal College of Nursing welcomes the opportunity to review this document. We consider that the relevant evidence & summaries of clinical effectiveness have been taken into account.

- We agree with the provisional recommendations relating to children being offered CSII and agree that it is very difficult to manage the young child on alternative insulin regimens.
- We note that MDI can be 'by-passed' if considered to be inappropriate which takes the child's individual circumstances into consideration. This is a positive step. We agree with the statement that 'those receiving the treatment and their carers have the commitment and competence to use the therapy effectively'.

December 2007

- With regards to paragraph 1.4, section 4-'Evidence and interpretation' (4.3.6), supports and explains the reason for setting the HbA1c level at 8.5%. Judging from clinical experience, for a cohort of people receiving CSII, this level of HbA1c would have excluded many of them from being eligible for CSII. There is a fear that this may open the flood gates for people wishing to receive CSII. However anecdotally, people who are interested in CSII are usually a small proportion of people with type 1 diabetes. There are no recommendations for how many people in terms of percentages of people with type 1 diabetes services who will be able to start or how much funding will be available for specialist teams. Some indication and guidance in respect of this would be very helpful.
- It would also be helpful to label the two bullet points in paragraph 1.3 as either (a) or (b) and to highlight the '**or**' as it could be easily missed.
- 'Disabling hypoglycaemia-repeated and predictable occurrence and persistent anxiety about recurrence' etc- this criteria is probably the one that we can envisage being used more often with regards to eligibility for CSII and as the appraisal points out later, people who use CSII have highlighted and described the changes in hypoglycaemia that they have experienced on CSII. The question of measurability of the issues in this section is commented upon below in 1.5.
- Paragraph 4.3.7 talks about 'CSII being recommended for children younger than 11 years' - does this imply that pump therapy can be offered at diagnosis? We consider that this needs to be clarified in order for the document to be able to guide the NHS.
- Paragraph 1.4 highlights the importance of CSII therapy being initiated only by trained teams. We strongly agree with this recommendation. However, the recommendation stresses that the physician should have a special interest in pump therapy but no mention is made of any requirements for the Clinical Nurse Specialist (CNS). We consider that there needs to be clarity about what a 'trained team' looks like - suggestions include having documented attendance at training days, being a 'certified pump trainer', evidence of starting a minimum number of children on a pump per year, clinic being able to demonstrate audited outcomes of the patients started on pump therapy. Specialist pump training, both initial and on going training of the specialist team needs to be factored in to this with regards to resources (both time and finance).
- For paediatric health professionals, the main worry is always when the child is in the nursery or school setting. Based on experience of supporting pump therapy, this can work very well in this environment. However, if the child is not competent to do so themselves, an appropriate adult needs to be identified in this setting to support the

child in the daily management of their diabetes. Therefore, there needs to be some thought about training and documentation for these specific carers, who are often teachers or identified support workers rather than school nurses.

- Paragraph 1.5 - 'Improvement' is an important aspect to address. Not only should there be measurable biomedical improvements in glycaemic control but there should be quality of life improvements for the person using CSII for example a reduction in the frequency and severity of hypoglycaemia and a reduction in anxiety about recurrence. The quality of life improvements are difficult to measure. Will there be any guidance or recommendations as how to measure these- for example what tools/questionnaires etc?
- Further, as a trained specialist team is involved, it should be the specialist 'team' or a team member representing the specialist team (in discussion with the person receiving treatment and carer (as appropriate)) that is involved in setting the targets for improvement rather than just the responsible physician.
- Section 4.3.11 of the appraisal consultation document states that if there are no demonstrable benefits seen within a 'reasonable time period' CSII would be withdrawn. It would be helpful to have an indication of what is considered a 'reasonable time period' - e.g. 6-12 months?
- We note that Accu-Chek DTron plus pump made by Roche does not appear on the currently available list of pumps. It uses pre-filled cartridges.
- In describing the technology, point 3.2 states that 'a higher infusion rate at meal time' can be delivered. This suggests that the pump delivers this automatically. Given the point above that there needs to be thought about pumps (or indeed any insulin therapy) in school settings, there needs to be clarity that additional insulin is given only when an individual button pushes. We suggest that this point is re-worded to read 'which are programmed in by the user with additional boluses of insulin at meal times'. This might help to clarify the difference between basal rates and boluses and will clear any potential confusion.
- With regard to cannula changes, the maximum recommended time for them to be in use is 3 days. After 3 days (or more frequently if indicated) a new one should be used. Therefore saying the cannula is repositioned every 3 days is misleading. It suggests the same cannula is repositioned.
- This final comment relates to equity. Currently there is real disparity in different geographical areas as to whether pump therapy is offered to young people or not. This seems to relate more to the interest of the particular team than to issues relating to funding. As a consequence families have to travel lengthy distances to be offered this

mode of therapy. This should be born in mind in drawing up any implementation support tool.

The Appraisal Consultation Document appears to be a thorough and fair interpretation of the evidence available to date. The guidance as to how this is to be coasted and implemented would be imperative.