10 Parkway
London NW1 7AA
Tel 020 7424 1000
Fax 020 7424 1001
Email info@diabetes.org.uk
Website www.diabetes.org.uk

Christopher Feinmann
Technology Appraisal Project Manager

10th December 2007

Dear Christopher,

Appraisal Consultation Document – Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (review of technology appraisal guidance 57) – Diabetes UK's comments

Diabetes UK is one of Europe's largest patient organisations. Our mission is to improve the lives of people with diabetes and to work towards a future without diabetes through care, research and campaigning. With a membership of 175,000, including 6,000 health care professionals, Diabetes UK is an active and representative voice of people living with diabetes in the UK.

Overview
Diabetes UK believes that the recommendations as they stand will still restrict access to this technology for people with Type 1 diabetes over the age of 11 and people with Type 2 diabetes who would find it beneficial in terms of clinical and quality of life outcomes.

i) Do you consider that all the relevant evidence has been taken into account?

Evidence relating to the quality of life benefits of pump therapy and glycaemic excursions has not been given adequate consideration.

Quality of Life
The quality of life benefits, as reported in Diabetes UK's submission, go beyond reducing hypoglycaemia and fear of recurrent hypoglycaemia and have not been given due consideration within this appraisal process. The use of this technology elicits strong responses from users with many not wishing to revert back to MDI [1,2,3]. Whereas we acknowledge that the Committee considered observational studies and evidence submitted, the evidence given by patient organisations and available in less "rigorous" studies must be given more weight (see reference

below). The weakness of research in this area should not be used as a means to undervalue the important impact on quality of life of this technology[4], that has been identified by people with diabetes. Diabetes UK is calling for further research to be undertaken in assessing the quality of life benefits of CSII.
Quality of life improvements have been noted in various studies which include increased flexibility in food timing and diet, convenience, an increased sense of autonomy [1,2,5,6,7,8,], particularly in children[2,7], improved social relations[8] and improved sleep[1,5,7]. Some of these improvements have also been identified by the carers of those using CSII[7].
Diabetes UK recommends that CSII should be made available to people with diabetes requiring insulin based on individual clinical need, patient choice and suitability. Suitability should consider the motivation and ability of an individual to use the insulin pump, and clinical need should take into consideration all quality of life benefits.

Hba1c level
The use of Hba1c as the measure of control excludes consideration of glycaemic excursions. A person with diabetes can have good control as defined by their Hba1c level, but can be experiencing glycaemic excursions that impact negatively on their health. CSII has been shown to improve fluctuations in glycaemic excursions[1] but this has not been taken into account in the recommendations.

Diabetes UK disagrees with the whole premise that a person over the age of 11 years must have failed on MDI therapy before CSII is considered as a treatment option. Diabetes UK questions the selection of 8.5 per cent as the decisional level. Good glycaemic control is recognised as being in the range between less than or equal to 6.5 and 7.5 per cent. The JBS2 guidelines identify that optimal control is less than or equal to 6.5 per cent, with an audit target of less than 7.5[9] It is important to consider that the optimal target may not be suitable for all people, impacting on quality of life in relation to hypoglycaemia , therefore a range is given.

General comment
Section 2.5: When discussing good control it is important to acknowledge the benefits of the Hba1c range between 6.5 and 7.5, however targets should be individualised to take into account the importance of quality of life.

ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and the preliminary views on the resource impact and implications for the NHS are appropriate?

Diabetes UK is concerned that not enough weight has been given to quality of life benefits such as flexibility in food timing and diet, convenience, an increased sense of autonomy [1,2,5,6,7,8,], particularly in children[2,7], improved social relations[8] and improved sleep[1,5,7] . In addition whilst the Committee discuss the benefits CSII can bring in relation to glycaemic excursions this is then ignored in the recommendations. Diabetes UK questions the use of QALYs in adequately assessing all quality of life benefits.

Cost effectiveness and Quality of life

Section 3.4: Some of the costs attributed to CSII would also be costs associated with MDI. All people with diabetes on insulin will require lancets, test strips, glucometers, education at initiation of insulin and ongoing education. This should be acknowledged.

Section 4.2: Much of the cost effectiveness analysis is based on Hba1c levels and reductions in hypoglycaemia and fear of hypoglycaemia. Whereas these parameters are important they are not the only parameters to be considered. The QALY method of quantifying quality of life into a cost effectiveness calculation is not a sophisticated enough tool to be used to measure the quality of life benefits that can be achieved through CSII use. People with diabetes should not be penalised by restricted access to CSII because of the lack of available tools to adequately translate quality of life appropriately in terms of cost effectiveness.

Section 4.3.6: It appears inappropriate that all quality of life measures have been grouped together and considered within the three percent increment that is attributed to the avoidance of severe hypoglycaemia. The other quality of life benefits will not have the same "cost" as avoidance of hypoglycaemia.
The quality of life measures that appear not to have been considered are:

- Flexibility in food timing and diet
- Convenience
- An increased sense of autonomy, particularly in children
- Improved social relations
- Improved sleep

General comments regarding accuracy

Section 2.2: The statement about Type 2 diabetes fails to acknowledge the increasing numbers of children developing Type 2 diabetes.

Section 2.3: The sentence relating to the symptoms of severe hypoglycaemia needs to be amended to state "very occasionally *death*"

Section 2.5: Not all people with Type 2 diabetes will need to lose weight therefore it is better to refer to weight management than weight loss.

Section 3.2: For clarity please alter these statements as follows:
The pump can be programmed to deliver a *different* basal rate of insulin *each hour* throughout the day, with higher infusion rates at meal times *which maybe a bolus or extended over a chosen period of time…*

Section 4.3.6: What is appropriate in relation to long acting insulin analogues?

iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

CSII must be available as a choice of insulin administration for all people with diabetes who have the commitment and competence to use the technology. It should not be perceived as being reserved as a specialised treatment for those who are not achieving a particular level of control, and it should not be restricted on the basis of cost. This could be seen as creating a perverse incentive for poor control and limits the treatment choices available. This directly contravenes the government's agenda to increase choice for people with long term conditions to support self management. Choice of treatment is one of the key "choices" that people with diabetes wish to make on the basis of individual clinical need.

Diabetes UK is concerned with the following with regards to the recommendations:

- The use of an Hba1c level to determine whether or not an individual should be considered for pump therapy will unfairly restrict access to CSII. The Hba1c level will exclude access to CSII for people with diabetes achieving an Hba1c of less than 8.5 per cent. The Hba1c level chosen does not reflect current evidence regarding good blood glucose control. It does not take account of individuals who will have an Hba1c within the range of 6.5 to 7.5 per cent, but who are experiencing significant fluctuation in their glycaemic excursions.
- The recommendations as they stand do not consider the quality of life benefits of CSII beyond reducing hypoglycaemia as stated in Diabetes UK's submission.
- The recommendations exclude people with Type 2 diabetes from accessing CSII
- The age cut off that requires those over the age 11 to have been failed by MDI therapy does not consider the clinical and quality of life benefits that pump therapy can bring. In addition the recommendation to make the age cut off 11 years of age is in appropriate and will particularly disadvantage adolescents (See Question iv).
- The recommendation regarding removing CSII where it is not deemed successful is problematic. It does not identify the need to review progress and provide support to address any issues before the removal of CSII is even considered.

Diabetes UK is also concerned that the details regarding the implementation tools have not been published with the appraisal document. This has restricted the ability of consultees to comment on how the recommendations will be implemented in practice and how implementation will be monitored.
Further recommendations regarding education and the competence of the specialist team are also made to ensure this is highlighted appropriately within the guidance and recommendations (see below).

Implementation
Section 5.3: Diabetes UK is disappointed that the details of the implementation tools cited in section 5.3 have not been published with the appraisal consultation document. This is not a transparent way of working, and has restricted the ability of stakeholders to comment effectively on the impact the guidance will have in practice. Organisations need to know how NICE intends

to ensure that its guidance is implemented fairly and what audit criteria will be used otherwise there is the risk of another postcode lottery developing. The National Diabetes Support Team/Department of Health Insulin Pump working group document, supported by Diabetes UK, should be used as the basis to guide implementation. It is based on consensus of opinion from experts in the field .

Education as part of implementation

Section 1.4:

It is important that the specialist team initiating people onto pump therapy are delivering education, and are competent to deliver this education. The pump therapy specialist team need to be working together with the individual's diabetes care team where they are not the same, and this should be explicitly referenced.

Section 1.4: The recommendation regarding the importance of the team members needed within the trained specialist team, should state "must comprise" rather than "should normally comprise".

Reviewing the effectiveness of CSII

Section 1.5/ 4.3.11: This recommendation does not identify the need to review progress and provide support to address any issues before removal of CSII is even considered. It is vital that a review that involves the individual with diabetes takes place. Diabetes UK also queries why adults and children over 11 years old have been singled out with regards to this recommendation as the safety implications would apply to all on CSII.

As a result, Diabetes UK recommends the recommendation is changed as follows:

Following initiation, CSII use should be reviewed with an individual (and where appropriate, their carers) where improvements in glycaemic control or quality of life are not apparent. Appropriate target improvements should be set by the responsible healthcare team in partnership with the individual (and where appropriate, their carers). The decision about whether to continue CSII therapy or not should be made in partnership based on individual clinical need and choice.

The decision about whether or not a person continues on CSII is a case by case consideration and should not be decided on the basis of national recommendations. Similarly the definition of a reasonable time period is for case by case consideration as a decision made by an individual in partnership with their healthcare professional team.

iv) Are there any equality related issues that may need special consideration?

Diabetes UK believes that some members of the diabetes community will be unfairly excluded from accessing CSII as a result of the recommendations as they stand. These concerns are outlined below.

People with Type 2 Diabetes

Section 1.6 and 4.3.9: The decision not to recommend CSII for people with Type 2 diabetes appears to have been made on cost effectiveness grounds owing to a lack of available evidence.

However, by restricting access to CSII, this will potentially continue to limit the number of people with Type 2 diabetes using CSII therefore continuing to limit the evidence available. One small study has demonstrated that CSII improves the bioavailability of insulin which suggests that CSII would be a suitable option for people with severe insulin resistance[10].
The distinction between type of diabetes is also unhelpful when considering forms of insulin administration. What needs to be considered is where a person is physiologically and psychologically with their use of insulin. Some people with Type 2 diabetes have the same insulin requirements as people with Type 1 diabetes and therefore should be considered as eligible for CSII on the grounds of individual need, suitability and personal choice considering both quality of life and biological factors.
The demographics of people with Type 2 diabetes are also changing, with an increasing number of children being diagnosed with Type 2 diabetes. The impact of a younger population with Type 2 diabetes includes people having Type 2 diabetes for a longer duration, the possibility of more people progressing to insulin use at a younger age and more pregnant women with Type 2 diabetes. As a result to exclude people with Type 2 diabetes from the recommendations for CSII is to exclude many people who have a right to access a choice of treatment that may provide the best benefits for them.

Hba1c level
The inclusion of a particular Hba1c level (8.5 per cent) as an indicator that MDI has failed is both unfair and restrictive. Having to *fail* to achieve an Hba1c level of 8.5 per cent instantly restricts access to CSII for those individuals who are achieving good control and ignores the quality of life benefits that can be gained from CSII. Diabetes UK also questions the selection of 8.5 per cent as the decisional level. Good glycaemic control is recognised as being in the range between less than or equal to 6.5 and 7.5 per cent. The JBS2 guidelines identify that optimal control is less than or equal to 6.5 per cent, with an audit target of less than 7.5. [9] It is important to consider that the optimal target may not be suitable for all people, impacting on quality of life in relation to hypoglycaemia , therefore a range is given.

Age cut off
Section 4.3.6:
The decision to include an age cut off that requires those over the age of 11 to have been failed by MDI therapy will unfairly restrict access to CSII. It does not consider the clinical and quality of life benefits that can be achieved on CSII. Furthermore the choice of age 11 as a cut off is peculiar and based on a broad generalisation regarding the ability of child to use MDI at school. Not all children older than 11 will be able/ allowed to self inject an afternoon dose of insulin in school. The upheaval to the child and other family members caused by parents having to go into to school during the day to give an injection will not be adequately addressed by this generalisation. Many local paediatric services organise their clinics in age bands. The usual age bracket for juniors ends at age 12 not age 11.
This age cut off will particularly disadvantage adolescents who will be going through their transitional phase of life. The transitional phase is well recognised as a stage when many young people experience difficulties with their diabetes control and engagement with services. The quality of life benefits that CSII can bring, particularly in enabling more flexibility in the young person's routine make CSII a very valid treatment option for this age group.

Diabetes UK urges the committee to consider the comments made above and ensure that they do not inappropriately restrict access to this treatment option for people with diabetes with the competence and commitment to use this technology. We look forward to feedback from NICE in due course.

Yours sincerely

[redacted]
Diabetes UK

References:

1.Hoogma, R.P.L.M., Hammond,P.J, Gomist,G et al (2006) " Comparison of the effects of continuous subcutaneous insulin infusion (CSII) and NPH-based multiple daily insulin injections (MDI) on glycaemic control and quality of life: results of the 5- nations trial" Diabetic Medicine 23 (2) pp 141 -147

2.Barnard, KD. Skinner, TC (2007) "Qualitative study into quality of life issues surrounding insulin pump use in type 1 diabetes" Practical Diabetes International 24(3)

3. Bruttomesso, D. Pianta, A. et al (2002) "Continuous subcutaneous insulin infusion (CSII) in the Veneto region: efficacy, acceptability and quality of life" Diabetic Medicine 19 pp 628-634

4. Barnard KD, Lloyd CE, and Skinner TC. Systematic literature review into QOL and CSII and matched cohort study exploring QOL issues associated with CSII use - Poster www.roche-diagnostics.co.uk/news/NicePoster.pdf

5. Low, KG. Massa, L. et al (2005) "Insulin pump use in young adolescents with type 1 diabetes: a descriptive study" Pediatric Diabetes 6:22-31

6. Garmo, A. Pettersson-Frank,B. et al (2004) "Treatment effects and satisfaction in diabetic patients changing from multiple daily insulin injections to CSII" Practical Diabetes International 21 (1)pp 7-12

7. Sullivan-Bolyai,S. Knafl, K. et al (2004) "Parent's reflections on managing their children's diabetes with insulin pumps" Journal of Nursing Scholarship 36 (4) pp 316-323

8. Linkeschova R, Raoul M, Bott U, Berger M and Spraul M. Less severe hypoglycaemia, better metabolic control and improved quality of life in Type 1 diabetes mellitus with continuous subcutaneous insulin infusion (CSII) therapy; an observational study of 100 consecutive patients followed for a mean of 2 years. Diabetic Medicine. 2002. 19;746-751.

9. Joint British Societies 2 (2005) Joint British Societies' Guidelines on prevention of cardiovascular disease in clinical practice *Heart Vol 91Supplement v*

10. Nielsen, S. Kain,D. et al (2005) " Use of continuous subcutaneous insulin infusion pump in patients with type 2 diabetes mellitus" The Diabetes Educator 31(60) pp 843-848