

NICE CSII Review for the treatment of people with diabetes – Initial Comments on the Assessment Report of the Aberdeen HTA



September 2007

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.

Facts about diabetes

- Prevalence of diabetes is 2.2 million in the UK.¹
- Diabetes affects the young and old, and has particularly poor outcomes in those of lower socio-economic status and in those from black and minority ethnic groups.^{2,3}
- Evidence is available supporting the need for improved education of people with diabetes and their carers if better control and improved outcomes are to be achieved.^{4,5,6}
- Diabetes, if undetected or not well managed, can lead to many complications and have a devastating impact on quality of life.

Diabetes UK Comments on the Assessment Report

Pg 18 – Pregnancy – it would be useful to clarify what the “dearth of good evidence” relates to here.

Pg 22 – 1.1.3 - First sentence – should the second T2DM be T1DM.

- In relation to the age at which Type 2 diabetes “used to be seen almost exclusively”, Diabetes UK uses “over 40” not “over 45” for the White population and over 25 for the Black, Asian and ethnic minority population.⁷

Pg 24 – There are several references to short acting insulin throughout the report. Please use the terminology rapid acting insulin in relation to insulin for CSII.

Pg 26 – Modern Pumps – Some modern pumps also contain a carbohydrate counting facility which helps avoid incorrect settings for basal and bolus insulin.

Pg 27 – paragraph 1.2 b) – there is reference to death as a result of severe hypoglycaemia. It may be more appropriate to state “ very occasionally death”.

Pg 27, 31 – Fear of Hypoglycaemia – We welcome acknowledgement of the emotional and psychological impact of hypoglycaemia and the fear of hypoglycaemia on the individual, their quality of life and diabetes management. It is important this remains evident when considering the quality of life implications of treatment/technology choice.

Pg 43, 54 and throughout the document – HbA1c and glycaemic excursions – Whereas good diabetes control, as demonstrated by HbA1c results, is important for people with diabetes, so too is the impact of glycaemic excursions. More emphasis could be made in the report in relation to the

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impact of CSII on glycaemic excursions as discussed in the 5 Nations Trial (Report reference no: 219) which demonstrates the positive impact CSII can have on glycaemic excursions. HbA1c results alone do not demonstrate the glycaemic excursions encountered by the individual.

Pg 63 –In the conclusions drawn about the benefits of CSII for pregnant women, the judgement appears to be based mainly on biomedical measures and outcomes. If this is the case, the conclusions omit the potential quality of life benefits to pregnant /pre pregnant women.

Pg 78 - discontinuation rates may also be affected by how well a person's suitability to use CSII has been assessed.

- There is also a reference to a needle instead of a cannula on this page.

Pg 100 – section 2.9.2 – last sentence – awaiting these results should not prevent recommendations in the interim.

– 2.9.3 – paragraph 2 - The paragraph discusses the study in terms of hypoglycaemia, but does not appear to go on and demonstrate the results in relation to hypoglycaemia.

Pg 174 – paragraph 1 - There is a distinction that needs to be made between CSII specific education and structured education that all people with diabetes should receive. People going onto a pump will need to have CSII specific education and this will be delivered by those initiating the person on the pump, which may be in a different PCT area to the one that the individual lives in depending on arrangements for the delivery of pump services.

Perhaps rather than focussing on specific courses, the features of the education courses could be highlighted.

Section 6.1 paragraph 2 - Further clarification is needed regarding the aim of the paragraph, the figures quoted and what they include, and the time allowance for training.

Pg 175 - section 6.2 - first bullet point - could the evidence be provided supporting the statement regarding barriers and staff time. Further clarification is requested regarding the timings of “more at first” and “less later.”

Pg176 – second bullet point – please clarify how the 5 per cent figure was calculated. There is also no mention of people with Type 2 diabetes here.

In this same paragraph we suggest pump services are considered in geographical/spatial terms. Please also see the Diabetes UK Position Statement on Insulin Pump Therapy⁸ as it provides information regarding levels of provision. Of paramount importance is that all relevant people with diabetes have access to services.

Regarding the training and qualifications required of the specialist team please refer to the Insulin Pumps Working Group Document (Report reference no:103). In addition consider a diabetes specialist dietitian and a nurse and consultant with a special interest.

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Pg 177 - Under the Pickup and Keen criteria – the criterion “able to perform CSII procedures” – this will need to be clarified further to ensure people are not unnecessarily excluded because the correct support to enable them to use CSII has not been provided.

Pg 178 – We concluded the reference was to Table 41

Pg 179 – first paragraph - quality of life benefits and choice in technology do not appear to have been considered, when debating whether or not a person remains on CSII.

Pg 181 – The concept of a contract is unacceptable. It can create unnecessary anxiety and pressure. As mentioned in the report, contracts are not used in other aspects of care.

Pg 182 – It is important to outline explicitly what the consensus between the different sets of criteria are.

Pg 183 – Consider also the research recommendations in the Insulin Pumps Working Group report.

Pg 184- paragraph B – Could this include similar structured education courses.

-paragraph C – this appears to have the distinct aim of dissuading use of CSII.

- section F - It is not clear how the different points in this section relate to one another.

Pg 186 – it is not clear what the last sentence has concluded. CSII should be available to people with diabetes who meet appropriate criteria and the quality of life benefits that the technology itself can provide must be considered. In short appropriateness should be determined by clinical need, personal choice and suitability. Those using CSII should have access to appropriate education that both enables them to self manage their condition and to use this technology.

Generic Comments

We recommend that the guidance itself looks at the needs of children and young people separately to adults.

The report itself demonstrates the importance and existence of quality of life benefits for people with diabetes when using CSII. Throughout the document there is emphasis on comparing the impact of “best MDI” versus CSII, particularly in reducing hypoglycaemic events, occasionally drawing the conclusion that CSII might not be needed if best MDI can reduce the amount and/or severity of hypos. Whereas the reduction in severity and occurrence in hypos is important, it is only one of the potential beneficial outcomes of using CSII. It is important the other quality of life benefits occurring from using the technology of CSII, and the choice in technology available for people with diabetes, are also considered in drawing conclusions about the use of CSII. Insulin activity should not be the only consideration.

There is a reference to the importance of focussing on treatment type as opposed to diabetes type within the report (pg 18). Considering that more people with Type 2 diabetes are going onto

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insulin and for a longer period of time, we recommend people with Type 2 diabetes are not excluded for consideration in relation to CSII use.

Cost effectiveness – The difficulty in translating quality of life benefits into cost effectiveness calculations should not be a reason to underestimate the importance of quality of life benefits.

Language - throughout the document it is preferable to refer to diabetes as a condition not a disease and to people with diabetes rather than diabetics.

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References

¹ Quality Outcome Framework Statistics 2005/6

http://www.diabetes.org.uk/Professionals/Information_resources/Reports/Diabetes_prevalence_2006/

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² Chaturverdi N, Jarret J, Shipley MJ, Fuller JH. Socio-economic gradient in morbidity and mortality in people with diabetes: Cohort study findings from the Whitehall Study and the WHO multinational study of vascular disease in diabetes. *BMJ* 1998; 316:100-106

³ Mather HM, Chaturverdi N, Fuller JH. Mortality and morbidity from diabetes in South Asians and Europeans: 11 year follow-up of the Southall Diabetes Survey, London, UK. *Diabetic Medicine* 15: 53-59

⁴ UK Prospective Study Group (UKPDS). Effect of intensive blood glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34) *The Lancet*. Vol 352, September 12, 1998

⁵ Diabetes Control and Complications Trial (DCCT) Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *The New England Journal of Medicine*. Vol 329: 14. September 30, 1993

⁶ UK Prospective Diabetes Study Group (UKPDS). Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes (UKPDS 38). *BMJ* Volume 317, 12 September 1998

7 Diabetes UK (2006) Early Identification of People with Type 2 Diabetes - Position Statement
http://www.diabetes.org.uk/About_us/Our_Views/Position_statements/Early_identification_of_people_with_Type_2_diabetes/

8. Diabetes UK (2006) Insulin Pump Therapy – Position Statement
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