Dear Mr Feinmann

My comments on the Appraisal Consultation Document are below.

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

No. No. In section 2.5 the report states that "Good control is indicated by a value of less than 7.5%..." yet in section 1.3, MDI is deemed to have failed to provide adequate control only is HbA1c is 8.5% or higher. That means that patients whose HbA1c is between 7.5% and 8.5% are considered to have sub-optimal control but will fall outside the criteria for getting a pump. The document does not make reference to any evidence to support a threshold HbA1c of 8.5%.

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

No. Section 4.1.3 states that observational studies were larger, of longer duration and more representative of people likely to be considered for CSII therapy, yet other sections repeatedly refer to the lack of statistically significant results in RCTs. This appears to weaken the document and gives the impression that NICE is rather reluctant in its approval of CSII.

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?

No. The Technology Appraisal issued in 2003 is already widely misinterpreted by PCTs and clinicians, and this review will simply add more confusion. The provisional recommendations seem to be a backward step from the earlier TA and it seems that patients will have an even harder battle to try to get this treatment. Please see further comments below.

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

No.

If you wish to comment on the evaluation report, please do so under a separate heading to your comments on the ACD.

<u>Further comments</u>

Section 1.1 - Needs clarification. Would a child of 11 years and a few months fall within this category?

Section 1.5 - Cannot be applied in the long term, or this would appear to allow a pump to be taken away after control has been optimised. It needs to be noted that HbA1c will not always fall with improved control, as repeated hypoglycaemic episodes can keep the HbA1c artificially low. Although the paragraph allows for an alternative ("or a decrease in the rate of ...") I suggest that this second half will be disregarded and people who are established on pump therapy will find their PCTs are trying to take their pumps back. Further, the setting of any targets needs to include what the clinicians will do to achieve those targets, in terms of support and education. Patients are already being threatened with the removal of their pump if their control deteriorates, which suggests that some clinicians see pump therapy as a reward rather than a treatment. I cannot understand how removal of a treatment tool can help to improve a bad situation. This section will make the current situation worse.

Section 1.6 - This is completely exclusive. This document should make allowance for individual cases whose clinician believes they would benefit from CSII to access it.

Section 2.2 - It should be noted that Type 2 diabetes mellitus occurs MAINLY in adults, but there is an increasing number of younger people, including teenagers, being diagnosed with Type 2 diabetes. The long term implications of this in the individual may show greater cost effectiveness if CSII is adopted sooner rather than later.

It would be helpful if the document also made reference to how long it is reasonable to try to optimise control with methods other than CSII, after an initial approach about CSII. It should also be noted that whilst structured education is useful and helpful to many diabetics, education does not have to be delivered in a structured environment. In this way, a patient's existing knowledge and experience of carbohydrate counting and dosage adjustment can be taken into account. If the appraisal insists on structured education prior to commencement of CSII, then patients will continue to wait sometimes

more than 18 months for a place on such a course.

Yours sincerely

Lesley Jordan
for IPUK