

Dear Christopher

I have the following comments to make about the ACD:

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

Yes, I think there has been a comprehensive review of the evidence

- 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?

I think the clinical effectiveness interpretation is reasonable. In terms of cost effectiveness it is difficult to know quite what cost to attribute to hypoglycaemia requiring hospitalisation, which should be at least be that of an A&E attendance, more than a simple out-patient cost but as stated in the ACD not the cost of an in-patient stay. Whether this makes a material difference to the cost-effectiveness analysis is questionable, since the major factor for hypoglycaemia related costs is the disutility of fear of hypoglycaemia.

- 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?

I think that the recommendations regarding use in children are excellent and will enable much more appropriate use of pump therapy for this patient group. The only issue with respect to this is the definition of the cut-off age - this would best be written as aged 12 and under, to encompass all primary school aged children, with children older than 12 then included with the adult guidance. As far as the latter is concerned the HbA1c cut-off appears arbitrary, although presumably reflects the view from the cost-effectiveness analysis that the ICER was only acceptable with a highish starting HbA1c and a significant drop on CSII. Whilst there is little doubt that this change to the guidance opens up access to CSII to a significantly larger adult population, the problem is that this HbA1c target does not reflect other NICE guidance. For example in the draft guidance for Diabetes in Pregnancy, there is a statement that CSII should be considered where MDI has failed to achieve the target HbA1c of 6.1% with no mention of hypoglycaemia. For consistency it would therefore read better if this guidance stated that CSII should be considered when the individual HbA1c target is not achieved

ie "it has been impossible for the individual to maintain their target haemoglobin A1c (HbA1c) level"

It would also be better if the following section read

"the person has experienced disabling hypoglycaemia"

as there are a number of patients who having once experienced disabling hypoglycaemia make every effort to avoid it in future to the detriment of their overall control as defined by HbA1c.

Finally as was alluded to at the committee meeting there are a cohort of patients with type 2 diabetes who effectively become like a patient with type 1 diabetes in terms of intensified insulin therapy, and might be considered for CSII if MDI fails to optimise glycaemic control. Whilst I would not want to encourage CSII use in type 2 diabetes it might be reasonable to state "CSII is not routinely recommended for people with type 2 diabetes".

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

I think these have been adequately addressed in differentiating between children and adults.

Best wishes

Peter (Hammond)