

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Continuous subcutaneous insulin infusion (insulin pump therapy) for the treatment of diabetes mellitus (review of technology appraisal guidance 57)

Appeal Hearing: Decision of the Panel

Introduction

1. An Appeal Panel was convened on 16 May 2008 to consider an appeal against the Institute's Final Appraisal Determination (FAD), to the NHS, on the use of continuous subcutaneous insulin infusion (CSII), or insulin pump therapy, for the treatment of diabetes mellitus.
2. The Appeal Panel consisted of Ms Jenny Griffiths (non-executive director of the Institute and chair of the Panel), Mr Mark Taylor (vice-chair of the Institute and Appeals Committee chair), Dr Maggie Helliwell (non-executive director of the Institute), Dr Peter Brock (Industry representative) and Mr Bob Osborne (Lay Member). All members confirmed they had no interest to declare in respect of the appeal under consideration.
3. The Panel considered an appeal submitted by the British Dietetic Association.
4. There are three grounds on which an appeal can be lodged:
 1. The Institute has failed to act fairly and in accordance with the published procedures as set out in the Institute's *Guide to the Technology Appraisal Process*;
 2. The Institute has prepared guidance that is perverse in light of the evidence submitted;
 3. The Institute has exceeded its legal powers.
5. The chair of the Appeals Committee (Mr Mark Taylor), in preliminary correspondence, had confirmed that the appellant had potentially valid grounds of appeal in relation to Ground 1 (failure to act fairly).
6. In view of the relatively discrete and limited nature of the appeal, the chair of the Appeals Committee had proposed that, rather than an oral hearing, the appeal should be determined through consideration of the written evidence. The British Dietetic Association had stated that they had no comment to make on this proposed process. The letter of appeal had been passed to the Appraisal Committee, who had prepared a written explanation of the points being challenged. The British Dietetic Association had been invited to comment on the Appraisal Committee's response: no further comment had been received.

7. Members of the Appeal Panel met by teleconference. As the appeal was being heard on written evidence, the following were not present: the appellant, the Appraisal Committee, members of the public or a legal adviser.

Ground of Appeal

8. The basis for the British Dietetic Association's (BDA's) appeal was that the recommendation in section 1.2 of the FAD was not included in any of the earlier drafts sent out for consultation. The BDA felt that consultees had not been given a fair opportunity to comment on this aspect of the guidance. The relevant part of Section 1.2 of the FAD states that: "children on insulin pumps would be expected to undergo a trial of MDI therapy [i.e. multiple daily injections] between the ages of 12 and 18 years."

Explanation by Appraisal Committee

9. The Chair of the Appraisal Committee, in his response dated 14 April 2008, stated that the Committee is required to consider responses to consultation, make any appropriate changes and clarify any areas of ambiguity, and that this is normally undertaken without a further round of consultation.
10. The part of the recommendation in the FAD that is subject to appeal was added to the guidance as a result of a consultation comment from the Juvenile Diabetes Research Foundation who noted that "there is no guidance about continuation of use of CSII (insulin pumps) for children once they reach the cut off age". The Appraisal Committee had acknowledged this point and agreed to insert the statement that, because children above the age of 12 are expected to be able to self-inject, children over 12 should undergo a trial of MDI. CSII would then be considered only if MDI does not provide acceptable glycaemic control, as with adults. The FAD stressed the need for flexibility in teenagers: the trial of MDI could be undertaken at any time between the ages of 12 and 18.

Consideration by the Appeal Panel

11. The Appeal Panel noted that it is inherent in a consultation exercise that documents may change as a result of consultation. The fact that the FAD differs from the earlier documentation does not of itself establish unfairness. The *Guide to the Technology Appraisal Process* states that the Appraisal Consultation Document (ACD) does not constitute the Institute's final guidance. The recommendations are provisional and may change in response to consultation.
12. The Appeal Panel discussed whether some new factor had been introduced by the consultation comment from the Juvenile Diabetes Research Foundation, which

should in fairness have been consulted on, by re-issuing an ACD for a further round of consultation. Examples given in the *Guide to the Technology Appraisal Process* include new data or additional analysis of the existing evidence, e.g. new trial evidence or new analysis of an economic model. The consultation comment from the Juvenile Diabetes Research Foundation did not raise any new factor of this type.

13. The Appeal Panel noted that in sections 1.1 and 1.2 of the Appraisal Consultation Document (November 2007), the proposed recommendations made a distinction between therapy for children younger and older than 11 years. The age of patients, and the needs of children and adults, had therefore been recognised and consulted on in the ACD and had not been introduced as a new consideration in the FAD.
14. In conclusion, the Panel did not uphold the appeal that the Institute had failed to act fairly and in accordance with the published procedures as set out in the Institute's *Guide to the Technology Appraisal Process*, by including the statement in section 1.2 of the FAD that children on insulin pumps would be expected to undergo a trial of MDIs, between the ages of 12 and 18 years. The Panel noted that:
 - It was important that the Appraisal Committee responded to valid concerns raised during the consultation process.
 - The revised statement at section 1.2 of the FAD clarified an area of ambiguity in the ACD for clinicians, patients and carers.
 - The revised statement at section 1.2 did not introduce any new consideration or factor into the appraisal process, as the recommendations in the ACD referred to the needs of children under and over the age of 11 years.

Conclusion

15. The Appeal Panel rejects this Appeal on the point put forward by the Appellant. In doing so, it notes that it is important that consultees feel able to raise issues concerning the way the consultation process works; and that the type of factor or consideration which might lead to the need for further consultation is tested from time to time.
16. There is no possibility of further appeal within the Institute against this decision of the Appeal Panel. However, the decision of the Appeal Panel may be challenged by an interested party through an application to the High Court for permission to apply for judicial review. Any such application must be made promptly and in any event within three months of the Decision or the issuing of the Guidance.