National Institute for Health and Clinical Excellence

Appraisal Consultation Document
Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (review of technology appraisal guidance 57)

DMEG response on behalf of the BDA

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

We have no further evidence to add and generally agree with the interpretation of the evidence base given

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?

We note in the conclusion of the assessment report (section 7.5) that "If (pump) use is expanded, there will be considerable educational need for both patient and healthcare professional. The education for patients should include structured education such as DAFNE"

We are disappointed that this part of the assessment report conclusion does not appear to have been incorporated into the main ACD guidance

The assessment report states that the cost per patient of a DAFNE course is about £240. Indeed NICE HTA 60 (section 3.5) states that the cost per patient of a DAFNE course is around £545 (though we understand this figure is out of date and £ 260 – 300 may be the most current figure.) This is not an insubstantial figure. Unfortunately, in many areas, PCTs have refused to commission these courses on the basis of their cost or on the basis that this education should be provided as part of the current service

We are disappointed that structured education for pump patients (and the cost implications of this) have not been given adequate coverage in the ACD.

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?

We welcome the change in guidance on hypoglycaemia to now include the persistent anxiety about recurrence of hypoglycaemia that is associated with adverse effects on quality of life.

We are concerned (section 1.4) that whilst the trained specialist team is defined as a physician with a specialist interest in insulin pump therapy and a diabetes specialist nurse; the specialism of the dietitian in not mentioned. We strongly feel that the ACD should change the term "dietitian" to the term "advanced diabetes specialist dietitian." This is important as general dietitians do not have the skills or experience necessary to manage patients on insulin pumps.

We feel (section 1.2) that in addition to pump users and carers having the commitment and competence to use pump therapy effectively, there should be a statement added to the effect that pump users should also be free of major psychological and psychiatric problems (Pickup and Keen 2001)

We are disappointed that the ACD does not make an attempt to more clearly define the term" high level of care" (section 1.3) in relation to the failure of MDI. The assessment report, in its conclusion states that "*The education for (pump) patients should include structured education such as DAFNE"* We are confused as to why this pivotal recommendation does not appear to feature in the main body of the ACD

We feel that the ACD should recognize structured education(as outlined in NICE HTA 60) or 1:1 interventions with detailed input around matching insulin to carbohydrate intake as being necessary before MDI can be said to have failed.

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

We are unsure why a distinction has been made between adolescents and children < 11 years in terms of their eligibility for the pump. Indeed most of the research quoted seems to relate to both children and adolescents. One of the major reasons appears to be that adolescents are technically able to self inject at lunch time, thus giving them a reasonable shot at "good control on an MDI regimen." We feel that many adolescents despite being *able* to inject at lunch time are prohibited from doing so by the stigma associated with injecting in front of peers or being singled out by being made to inject in a school medical room. We also feel that the erratic nature of blood sugar control during puberty should be a factor to consider when deciding whether this group should be included for pump eligibility

General comments

Section 2.4 appears to refer only to type 1 diabetes but this is not clear. In addition the section states that "daily life activities need to be arranged around an inflexible structure of meal times and insulin injections." It is not clear whether this statement refers to traditional insulin regimens (including twice daily) or encompasses newer MDI regimens. This needs clarification. We feel the statement can only be said to apply to more traditional insulin regimens

Section 2.5 suggests that type 2 diabetes is always initially "managed by weight loss." Some patients with type 2 diabetes are slim at diagnosis and do not need to lose weight. We would prefer the use of the term "lifestyle change to include weight loss if necessary."

References

Pickup J, Keen H. Continuous subcutaneous insulin infusion in type 1 diabetes: Is beneficial in selected patients and should be more widely available. *British Medical Journal*

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