NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA151 Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus

This guidance was issued July 2008 with a review date of February 2011.

Background

At the GE meeting of 1 March 2011 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	The guidance should be transferred to the 'static guidance list'.	
Rationale for selecting this proposal	New evidence found while preparing the review proposal on CSII is unlikely to have a substantive effect on the recommendations of TA151. It is recommended that this appraisal is transferred to the static list, where it can be monitored on an ongoing basis.	

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation	The guidance should be transferred to the 'static guidance list'.
post consultation:	

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Association of Children's Diabetes Clinicians	Agree	The ACDC committee have considered and reviewed the current guidance Appraisal 151; Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus.	Comment noted.
		We do agree that there is currently no new evidence to warrant review of the guidelines. We therefore agree with your proposal for the original guidance to be added to the static list.	
British Society for Paediatric Endocrinology and Diabetes	Agree	The feeling is that TA151 is a useful document and that there is really no new evidence to warrant a review. We feel that the current guidance is accurate and appropriate.	Comment noted.
Diabetes UK	No objection	Having consulted, Diabetes UK does not object to the proposal to move the guidance to the static list, provided as mentioned, that ongoing monitoring of the evidence will occur to identify when it highlights the need for a further appraisal. Furthermore we believe that this decision should not affect the opportunity for a separate appraisal of continuous glucose monitoring, at an appropriate point in the future.	Comment noted. Technology appraisals on the static guidance list remain in their current form unless NICE becomes aware of substantive new information which necessitates a review.
Eli Lilly	Agree	We agree with the proposal to move TA151 to the static list	Comment noted.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
NHS Quality Improvement Scotland	No comment	NHS Quality Improvement Scotland (which will become Healthcare Improvement Scotland on 1 April 2011) has no comment to make on the proposal to move TA151 to the static list	Comment noted.
INPUT-Insulin Pump Therapy	Agree	We do not know of any new evidence that would have a material effect on the guidance, and we are therefore happy for NICE technology appraisal guidance number 151 to be moved to the static list	Comment noted.
Medicines and Healthcare products Regulatory Agency	No objection	We are not aware of any new evidence that impinges on the July 2008 guidance on continuous subcutaneous insulin infusion.	Comment noted.
Novo Nordisk	No objection	Novo Nordisk is not aware of any evidence that would have a material effect on the guidance. Novo Nordisk is listed as a possible comparator as it manufacturers insulin detemir (Levemir)®, insulin aspart (NovoRapid®) should also be considered as this is the most commonly prescribed bolus insulin in the UK.	Comment noted. The matrix of consultees and commentators has been updated to acknowledge that Novo Nordisk also manufacture insulin aspart.
The Public Health Wales NHS Trust	Agree	The Public Health Wales NHS Trust agrees with the proposal that the original guidance should be transferred to the static list.	Comment noted.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Nursing	No objection	Nurses caring of people with diabetes were informed of the proposals to move the TA151 Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus to the static list. Their views were sought as to whether or not there were aware of any evidence which would suggest that a review would be beneficial.	Comment noted.
		The feedback I have received suggest that there are no objections to move this guidance to the static list. There are no further comments to make on behalf of the Royal College of Nursing.	
National Diabetes Nurse Consultant Group	Agree	From a paediatric perspective, we are very concerned about the proposal that children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years. Whilst I appreciate that this would be very appropriate if a young person is not achieving improved outcomes on the pump, it does not seem to be ethical to enforce less optimal treatment in those young people who are using insulin pump therapy successfully. With the exception of this concern, I am more than happy for the guidance to be moved to the static list.	Comment noted. The Committee considered that the continuation of CSII could not equitably be supported in children over 12 years of age, without a trial of MDI before the child reached adulthood at the age of 18 years.

No response received from:

Manufacturers/sponsors	General
 Advanced Therapeutics UK (DANA R Insulin Pump) Animas (Johnson & Johnson) (Animas 2020) Medtronic (Paradigm Veo) Roche Products (Accu-Chek Combo, Accu-Chek Spirit; Accu-Chek D-Tron Plus) 	 Association of British Healthcare Industries Board of Community Health Councils in Wales Care Quality Commission Commissioning Support Appraisals Service Department of Health, Social Services and Public Safety for
Patient/carer groups Action for Children Action for Sick Children Afiya Trust Black and Ethnic Minority Diabetes Association (BEMDA) Black Health Agency Children's Society Chinese National Healthy Living Centre Diabetes Research & Wellness Foundation Equalities National Council Healthier Weight Centres Insulin Dependent Diabetes Trust Insulin Pumpers UK	 Northern Ireland Diabetes UK Cymru EUCOMED National Association of Primary Care NHS Alliance NHS Commercial Medicines Unit NHS Confederation Scottish Medicines Consortium Possible comparator manufacturer(s) Sanofi Aventis (insulin glulisine, insulin glargine) Relevant research groups Diabetes Foundation
 Juvenile Diabetes Research Foundation Muslim Council of Britain Muslim Health Network National Childbirth Trust National Children's Bureau National Obesity Forum 	 Heart Disease and Diabetes Research Trust MRC Clinical Trials Unit National Institute for Health Research Policy Research Institute on Ageing and Ethnicity Research Institute for the Care of Older People

 National Parent Partnership Network Network of Sikh Organisations South Asian Health Foundation Specialised Healthcare Alliance Surya Foundation Weight Concern WellChild Professional groups Association for the Study of Obesity Association of British Clinical Diabetologists Association of British Diabetes Specialist Nurses British Association for Services to the Elderly British Diabetic Association British Geriatrics Society Diabetes Monitoring Forum Primary Care Diabetes UK Royal College of Pathologists Royal College of Physicians Royal College of Physicians Royal Society of Medicine United Kingdom Clinical Pharmacy Association 	Assessment Group • Assessment Group tbc • National Institute for Health Research Health Technology Assessment Programme <u>Associated Guideline Groups</u> • None <u>Associated Public Health Groups</u> • None
 Others Department of Health NHS Barnet 	

- NHS Western Cheshire
- Welsh Assembly Government

GE paper sign-off: Elisabeth George, Associate Director – Technology Appraisals Programme

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