NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA78; Fluid filled thermal balloon and microwave endometrial ablation for menstrual bleeding

This guidance was issued April 2004 with a review date of 2011, when the first of two National Institute for Health Research technology assessments of treatments for heavy menstrual bleeding is due to be published.

Background

At the GE meeting of 13 March 2012 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	No significant new evidence has become available which is likely to lead to a change in the TA78 recommendations. Although there is an ongoing study evaluating the clinical and cost-effectiveness of LNG-IUS compared with standard treatment, the new evidence identified demonstrates that LNG-IUS would not be an appropriate comparator for thermal endometrial ablation because LNG-IUS should be offered as a treatment option before invasive procedures. Therefore, it is proposed that TA78 be moved to the 'static guidance' list.

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 post consultation:	The guidance should be transferred to the ‘static guidance list’.

Respondent	**Response to proposal**	**Details**	**Comment from Technology Appraisals**
Healthcare Improvement Scotland	No comment	We have no comment to make on the proposal to transfer this guidance to the static list and we have noted this accordingly in our records.	Comment noted.
Medicines and Healthcare Products Regulatory Agency	Agree	We would entirely agree that there has been no significant new evidence which has become available which would change the original recommendations. We therefore support your approach.	Comment noted.
Department of Health	Agree	The proposal seems entirely logical but I am concerned about the list of consultees. NICE asked for urgent comments if there were omissions from the list. I have attached a copy in which I have highlighted the Professional Groups that should not have an interest in this subject eg BASE and BGS since these deal with postmenopausal women. Of more concern is the fact that they have not included the RCOG which must be the most important Professional Body with clinicians who have appropriate knowledge and experience to make	Comment noted. The Royal College of Obstetricians and Gynaecologists (RCOG) were sent the review proposal and given additional time to provide comments.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
		informed comments on this area of treatment and management.	
Boston Scientific	Agree	We support this proposal.	Comment noted.
Royal College of Nursing	No comment	The feedback I have received from nurses working in this area of health suggest that there are no comments to submit on the review of the above guidelines.	Comment noted.
Royal College of Obstetricians and Gynaecologists	Disagree	The RCOG does recommend revising this paper. The reason that this needs a revision is that microwave ablation was bought out by Hologic (manufaturers of Novasure endometrial ablation) and is now unavailable in the UK, i.e. it has been removed by a competitor, which has reduced options for health care purchasers and Gynaecologists. The scientific evidence supports the use of both of the techniques for the treatment of eligible women with heavy periods.	Comment noted. TA78 recommends both fluid-filled thermal balloon endometrial ablation and microwave endometrial ablation techniques as treatment options. The availability of the products in the UK is beyond the control of NICE. There is no substantial new evidence that would indicate a review of the guidance that would be of value for the NHS.

No response received from:

Manufacturers/sponsors	General
• Hologic UK (Acculis, NovaSure Endometrial Ablation System) • Idoman Ltd (Thermablate EAS)	• Board of Community Health Councils in Wales • Care Quality Commission

- Johnson and Johnson (Gynecare Thermachoice)
- Lumenis (Gynelase)
- PNN Medical (Cavaterm)

Patient/carer groups
- Afiya Trust
- Black Health Agency
- Counsel and Care
- Equalities National Council
- Muslim Council of Britain
- Muslim Health Network
- South Asian Health Foundation
- Specialised Healthcare Alliance
- Wellbeing of Women
- Women's Health Concern

Professional groups
- British Association for Services to the Elderly
- British Geriatrics Society
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal College of Physicians
- Royal Society of Medicine
- United Kingdom Clinical Pharmacy Association
- Association of Surgeons of Great Britain and Ireland
- Royal College of Anaesthetists
- Royal College of Surgeons
- British Society for Colposcopy and Cervical Pathology

- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- National Association of Primary Care
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

Possible comparator manufacturers
- Bayer Healthcare (Mirena – levonorgestrel-releasing intrauterine system)

Relevant research groups
- MRC Clinical Trials Unit
- National Institute for Health Research
- Research Institute for the Care of Older People
- British Society for Paediatric and Adolescent Gynaecology (BritSPAG)

Assessment Group
- Assessment Group tbc
- Evidence Review Group tbc
- National Institute for Health Research Health Technology Assessment Programme

Associated Guideline Groups
- National Clinical Guideline Centre

Others	Associated Public Health Groups
• NHS Eastern and Coastal Kent • NHS Northamptonshire • Welsh Government	• None

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