NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Final Appraisal Determination

Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding

1 Guidance

1.1 Fluid-filled thermal balloon endometrial ablation and microwave endometrial ablation are recommended as treatment options for women with heavy menstrual bleeding in cases where it has been decided (by the woman and the clinician responsible for her treatment) that surgical intervention is the appropriate next step in management of the condition.

1.2 For heavy menstrual bleeding, the choice of surgical treatment should be made jointly by the woman and the clinician responsible for treatment. The decision should be made after an informed discussion taking into account the desired outcome of the treatment (such as normal menstrual bleeding [eumenorrhoea] or complete cessation of menstrual bleeding [amenorrhoea]), the relative benefits of all other treatment options and the adverse events associated with them, as well as the clinical condition, anatomical suitability and preferences of the woman.

2 Clinical need and practice

2.1 Heavy menstrual bleeding (HMB, also known as menorrhagia) is a significant cause of morbidity in premenopausal women in England and Wales. HMB is objectively defined as menstrual blood loss of more than 80 ml/cycle, or menstrual bleeding lasting longer than 7 days, over several consecutive cycles. However, in practice, the diagnosis is based on the woman's subjective assessment of blood loss.

2.2 HMB is a common disorder. It is estimated that 1 in 20 women in the UK aged 30–49 years consults her GP each year with HMB – approximately 1.5 million women in England and Wales. Referrals for menstrual disorders account for about 20% of all referrals to specialist gynaecology services, placing a significant burden on secondary healthcare services.

2.3 Many women who are referred to secondary care for HMB will eventually undergo hysterectomy. More than 47,000 hysterectomies were carried out in the NHS in England in 2000–01. It is estimated that HMB was the presenting complaint in about half of these cases. Furthermore, about half of all women who have a hysterectomy for HMB are believed to have a normal uterus removed.

2.4 HMB has adverse implications for quality of life. Women with HMB may have difficulties with daily activities such as work, social activities, hobbies and holidays. Many women report anxiety, depression, embarrassment and problems in their sex lives because of HMB. Anaemia is also common amongst women with HMB, and this may further impair quality of life.

2.5 Diagnosis of HMB is complex and is usually based on subjective evaluation of blood loss by the affected individuals. The blood loss can be estimated using pictorial blood-loss assessment charts (PBACs); this method takes into account the number of items of sanitary wear used and the degree of staining of each item. A PBAC score greater than 100 would normally indicate HMB. Although the 'gold standard' method of measuring blood loss is the alkaline haematin technique, which requires women to collect their used sanitary wear, this technique is rarely used outside research settings.

2.6 The cause of HMB is not known in the majority of cases, in which no pelvic or organic pathology is identified. However, HMB may have structural organic causes such as fibroids, adenomyosis, polyps, infections, pre-cancerous conditions or haematological disorders.

2.7 Treatment of HMB aims to reduce menstrual loss and hence to improve the quality of life of the individuals. First-line treatment is drug therapy. The most commonly used drugs are tranexamic acid (an antifibrinolytic drug), mefenamic acid (a non-steroidal anti-inflammatory drug) and combined oral contraceptives. The Royal College of Obstetricians and Gynaecologists' (RCOG) guidelines recommend that drug treatment should be given for at least three cycles before considering another treatment option. Another alternative sometimes used before surgical intervention is a levonorgestrel-releasing intrauterine system.

2.8 Surgical treatment is usually offered to patients who do not respond to drug treatment. Hysterectomy (removing the uterus as a whole or in part) is the only treatment for HMB that guarantees amenorrhoea (complete cessation of menstrual periods), but it is associated with peri- and postoperative complications, including incontinence and other urinary problems, fatigue, infection, pelvic pain and sexual problems. Overall, 1 in 30 women suffers a major adverse event during or soon after the operation. Additionally, the procedure has a mortality rate of 0.4–1.1 per 1000 operations. Hysterectomy is costly and has significant resource implications because it requires general anaesthesia, long operating theatre times and a hospital stay of up to 7 days after the operation. Full recovery may take 1–3 months.

2.9 First-generation endometrial ablation (EA) techniques were introduced almost 20 years ago as alternatives to hysterectomy. These techniques aim to reduce the menstrual bleeding by destroying (ablating) the entire thickness of the innermost layer of the uterus (the endometrium) and some of the underlying muscular layer (the myometrium) using electrical, thermal or laser energy. EA techniques do not guarantee amenorrhoea, but are less invasive and require fewer resources than hysterectomy. Preoperative medical therapy is given to suppress endometrial growth, because ablation is more likely to be successful if the endometrium is thin. All organic and structural causes of HMB should be excluded before considering EA, by any means, as a

treatment option. EA techniques are generally not suitable for women who wish to maintain fertility.

2.10 The most widely used first-generation EA techniques are transcervical resection of endometrium (TCRE), using a loop diathermy electrode, and roller-ball ablation (RB), using an electrode with a movable ball or cylinder. All first-generation EA techniques require direct visualisation of the endometrium using a hysteroscope. The success rates of these techniques depend heavily on the skills and experience of the operator.

2.11 Possible perioperative adverse effects with the first-generation EA techniques include electrosurgical burns, uterine perforation, haemorrhage, infection, and fluid overload (which may cause congestive cardiac failure, hypertension, haemolysis, coma and death). The incidences of complications following first-generation EA ablation techniques were reported by the MISTLETOE study (of more than 10,000 women) in England and Wales, and the Scottish Audit of Hysteroscopic Surgery (of around 1000 women). The rate of emergency hysterectomy was 6.6 per 1000 procedures in the MISTLETOE study and 2.0 per 1000 procedures in the Scottish Audit, and blunt uterine perforation was reported in 14.7 per 1000 procedures and 11.2 per 1000 procedures respectively. Combining the two audits, mortality from the first-generation EA methods was shown to be 0.26 per 1000 procedures.

3 The technologies

3.1 Second-generation EA techniques have been introduced with the aim of providing simpler, quicker and more effective treatment options for HMB compared with first-generation EA techniques and hysterectomy. These techniques are less operator-dependent than the first-generation techniques, but they rely heavily on the devices themselves to ensure safety and efficacy. Second-generation EA techniques include fluid-filled thermal balloon EA (TBEA), radiofrequency (thermoregulated) balloon EA, hydrothermal EA, 3D bipolar radiofrequency EA, microwave EA (MEA), diode laser

hyperthermy, cryoablation and photodynamic therapy. The most frequently used second-generation EA techniques in UK clinical practice, and the focus of this appraisal, are fluid-filled TBEA and MEA. These techniques do not require direct visualisation of the uterine cavity, and can be carried out under either local or general anaesthesia.

3.2 TBEA destroys the inner layers of the uterus by transferring heat from heated liquid within a balloon inserted into the uterine cavity. The two devices available in the UK, Cavaterm and Thermachoice, both involve an electronic controller, a single-use latex or silicone balloon catheter housing a heating element and two thermocouples, and an umbilical cable. TBEA cannot be used on women with large or irregular uterine cavities because the balloon must be in direct contact with the uterine wall to cause ablation. Cavaterm is contraindicated for women whose uterine cavity is more than 10 cm long (from the internal os to the fundus), and Thermachoice for women whose uterine cavity is more than 12 cm long, and for those who have a latex allergy. The use of endometrial thinning agents before TBEA is not recommended.

3.3 The MEA technique uses microwaves (at a fixed frequency of 9.2 GHz) to destroy the uterine glandular lining, using a hand-held applicator (microwave probe) that is inserted into the uterine cavity. The Microsulis MEA system consists of a system console that houses a control module with an embedded computer, a microwave generator, and a power supply. Additional components are a hand-held applicator, a pneumatic footswitch, coaxial and data cables, a printer (optional), a power cord and a portable trolley.

3.4 The MEA applicator must be cleaned and sterilised before each use. MEA can be used in women whose uterine cavity is irregular in shape as a result of mild to moderate fibroids, polyps or congenital abnormalities. MEA is contraindicated if classical Caesarean section has been performed, or if other uterine surgery has left a scar where the uterine wall is less than 8 mm thick.

The use of endometrial thinning agents before MEA is recommended, particularly if the uterus is large.

3.5 Although equipment failures for MEA and TBEA were reported in early usage, the devices have been improved and these failures are now much less common. Adverse events with second-generation EA techniques include uterine infection, perforation, visceral burn, bleeding, haematometra, laceration, intra-abdominal injury and cyclical pain. Women who do not respond to initial EA may require further ablations or, eventually, hysterectomy.

3.6 The outcome of EA is dependent on selecting the most appropriate technique for the individual patients' needs. TBEA may be considered more appropriate for women who wish to achieve eumenorrhoea rather than amenorrhoea.

3.7 The Cavaterm and Thermachoice control unit/generators cost £3990 and £6000 respectively, and the disposable balloon catheters cost £280 and £350. The Microsulis MEA system costs around £40,000 (with an additional £5000 per annum for the maintenance contract). However, most centres in the UK have a 'placement arrangement' with manufacturers, under which centres pay a fixed fee per treatment.

4 Evidence and interpretation

The Appraisal Committee considered evidence from a number of sources (see Appendix B).

4.1 Clinical effectiveness

4.1.1 A total of 13 publications relating to seven trials were identified by literature searches. One of the trials compared MEA with TCRE/RB, and six compared TBEA with TCRE, with RB, or with both. Two of these trials had a non-randomised, controlled design, and the rest were randomised controlled trials (RCTs). In addition, one manufacturer provided the translation of a small trial,

published in German, that compared TBEA with RB, and another unpublished RCT comparing TBEA with TCRE – this was submitted in confidence. Another manufacturer provided details of a study comparing MEA with RB that it conducted as part of its submission to the US Food and Drug Administration (FDA). In summary, 10 trials (two MEA and eight TBEA trials) were included in this review.

Microwave endometrial ablation (MEA)

4.1.2 One trial reported that at 12 months, 87% of women who had undergone MEA and 83% of women who had undergone RB had normal bleeding levels, defined as a PBAC score of less than 76. The difference could have arisen by chance ($p = 0.359$). Another trial that compared MEA with TCRE/RB reported a median bleeding score of 3 in both groups at 12 months, which fell at 24 months to 1 for the MEA group and 0 for the TCRE group. This bleeding score is the sum of the daily scores reported by the women, who were asked to grade the heaviness of their period on a five-point scale for each day of their period. The differences could have arisen by chance.

4.1.3 Only one trial, which compared MEA with TCRE/RB, reported bleeding patterns in terms of the length and severity of bleeding. Based on intention-to--treat (ITT) populations, at 12 months 6% of the MEA group and 5% of the TCRE/RB group had more than 3 days of heavy bleeding (2% MEA, 5% TCRE/RB at 24 months), and 11% of women in the MEA group required at least double their usual sanitary protection compared with 12% in the TCRE/RB group (7% MEA, 13% TCRE/RB at 24 months). The differences between the groups could have arisen by chance.

4.1.4 Amenorrhoea was reported as a clinical outcome in two MEA trials. In one trial, amenorrhoea at 12 months was reported for a median of 40% of women undergoing MEA, compared with 40% undergoing RB. At 36 months follow-up, the median amenorrhoea rates were 47% and 41% respectively

(p = 0.19). The other trial reported similar median values for amenorrhoea in ITT populations at 12 months (55% in MEA versus 46% in RB, p = 0.106).

4.1.5 Two MEA trials reported patient satisfaction. In one trial, 69% of both MEA and TCRE/RB groups were totally or generally satisfied at 12 months, and 74% of those undergoing MEA and 64% of those undergoing TCRE/RB were totally or generally satisfied at 24 months. The study was underpowered to detect whether this observed clinically important difference of 10% could have arisen by chance. Another trial, which compared MEA with RB, reported that 98% of women undergoing MEA were very satisfied or satisfied at 12 months compared with 99% of those undergoing RB.

4.1.6 One trial used the SF-36 questionnaire to examine the impact of MEA and TCRE on quality of life. Following treatment, six of the eight items improved significantly compared with baseline in the MEA group, and seven items improved significantly in the TCRE group.

4.1.7 Although the duration of procedures was defined inconsistently in the trials, MEA procedures took less time than TCRE and/or RB. In one trial, the mean operating time was 11.4 minutes for MEA and 15.0 minutes for TCRE/RB (p < 0.001). The other trial reported 'anaesthesia times' of 39.3 minutes for MEA and 47.1 minutes for RB, and 'treatment times' of 3.5 minutes for MEA and 20.3 minutes for RB. These differences were all statistically significant at the p < 0.01 level.

4.1.8 One trial reported that 8% of women in the MEA group had undergone further ablation or hysterectomy at 12 months (6% hysterectomy, 1% TCRE and 1% other ablation), and 8% of women in the TCRE plus RB group had undergone hysterectomy, but none of this group had undergone further ablation. The difference could have arisen by chance. Another trial reported that 1 out of 209 women in the MEA group and 1 out of 106 women in the RB group had undergone hysterectomy after 12 months, and none required further ablation.

Thermal balloon endometrial ablation (TBEA)

4.1.9 Four TBEA trials reported changes in PBAC score. One trial, which compared TBEA with RB, reported that at 12 months, 73% of the TBEA and 70% of the RB group had normal bleeding levels, defined as a PBAC score of less than 100. Another trial reported that 71% of the TBEA and 79% of the RB group had normal bleeding levels at 12 months, defined by a more stringent criterion (that is, a PBAC score of less than 76). This second study reported mean PBAC scores of 41.1 in the TBEA group and 40.2 in the RB group (mean score reductions of 343.2 and 345.5, respectively). Another trial did not report actual PBAC scores, but stated that these were significantly better for the TBEA group than for the RB group at 24 months ($p = 0.01$), although not at 6 or 12 months. This trial measured treatment success as a post-operative PBAC score of less than 185, and 78% of women in the TBEA group and 76% of women in the TCRE group achieved this at 24 months. Results from the fourth trial were submitted to the Institute in confidence.

4.1.10 At 24 months, between 5% and 8% of patients who had undergone TBEA, and between 9% and 15% of those who had undergone TCRE or RB, were still experiencing HMB. At 60 months, these figures were 2% for the TBEA group and 1% for the TCRE or RB group. No trial reported statistically significant differences between the groups for recurrent HMB.

4.1.11 Amenorrhoea was reported as a clinical outcome in five TBEA trials. Amenorrhoea at 12 months was reported in between 10% and 40% of women for TBEA, and between 17% and 30% for TCRE/RB. The differences were statistically significant in only one trial (14% for TBEA versus 22% for RB, $p < 0.05$). At 36 months, 13% of women undergoing TBEA and 21% of women undergoing RB had amenorrhoea, and at 60 months 10% of women undergoing TBEA and 14% of those undergoing RB had amenorrhoea. These results are for ITT populations.

4.1.12 Six TBEA trials reported patient satisfaction. Of these, five reported non-significant differences in patient satisfaction between TBEA and TCRE and/or RB groups. The proportion of women who were satisfied or very satisfied with the treatment ranged between 79% and 100% in TBEA groups, and between 54% and 100% in TCRE and/or RB groups at 12 months. The trial with the longest follow-up reported that 42% of women in the TBEA group and 44% of women in the RB group were satisfied at 60 months (ITT populations). Only one trial reported statistically significant differences between the TBEA and the TCRE and/or RB groups. In this trial, 43% of women undergoing TBEA evaluated the treatment outcome as 'excellent' at 12 months compared with 24% of women undergoing TCRE and RB. These figures were 35% and 4% respectively at 24 months.

4.1.13 Five trials consistently reported shorter procedure times for TBEA compared with TCRE and/or RB. Of these, two studies reported the percentages of operations that took less than 30 minutes. For TBEA these percentages were 65% and 100%, and for TCRE and RB they were 24% and 53% respectively. These differences were significant in both studies ($p < 0.05$). The mean operating times were between 11.5 and 24 minutes in the TBEA groups compared with between 37 and 45 minutes in the TCRE and/or RB groups. The differences were statistically significant in all trials.

4.1.14 Six trials reported the proportion of women who required further intervention. At 12 months, between 1% and 10% of women in the TBEA group required further interventions compared with between 2% and 16% in the TCRE and/or RB groups. In one trial, 5% of women undergoing TBEA and 10% of women undergoing TCRE plus RB had had an additional procedure, and these percentages rose to 6% and 15% respectively at 24 months. This difference in the repeat surgery rate was statistically significant ($p < 0.01$). In the trial with the longest follow-up period, repeat procedures had been done for 15 of the 76 women (19.7%) in the TBEA group (13 hysterectomies and two repeat ablations), compared with 9 of 71 women (12.7%) in the RB group (seven

hysterectomies, two repeat ablations, and one dilatation and curettage) at 60 months.

4.2 Cost effectiveness

4.2.1 Only one published study was identified. Three economic analyses were made available to the Institute as part of manufacturers' submissions, and the Assessment Group developed its own model.

4.2.2 The published study compared the costs of vaginal hysterectomy, TBEA and RB in 147 women in France. The total costs for each treatment group were calculated 24–36 months after the surgery, taking into account the subsequent resource use only (for example, re-interventions). The total costs were estimated to be around £3670 for vaginal hysterectomy, £870 for TBEA and £910 for RB (€5321, €1263 and €1320 respectively, converted to pounds sterling at 2003 rates).

4.2.3 The Microsulis model suggested that MEA is less costly and more effective than other EA techniques, and therefore is a dominant strategy. However, hysterectomy was more effective but more costly than MEA, at an incremental cost-effectiveness ratio (ICER) of around £4600 per quality-adjusted life-year (QALY).

4.2.4 The Cavaterm model estimated that TBEA is cost saving when compared with hysterectomy or other EA techniques. Cost per treatment success was £767 for Cavaterm, £828 for Thermachoice, £865 for TCRE or RB, and £2050 for hysterectomy, based on RCT data only.

4.2.5 The Thermachoice model, which used the cost estimates from the published French study (see Section 4.2.2), estimated that the ICERs for hysterectomy and TCRE compared with TBEA were £1197 (€1736) and £950 (€1378) respectively per additional woman with amenorrhoea, £13,648 (€19,789) and £11,552 (€16,751) per additional woman with eumenorrhoea or less, and £9748 (€14,135) and £18,379 (€26,650) per additional satisfied patient.

4.2.6 The Assessment Group's model was a Markov model, which examined the progress of six hypothetical cohorts of women with HMB treated separately by TBEA, MEA, TCRE, TCRE and RB, RB, or hysterectomy. The model took the perspective of the NHS and calculated incremental cost utility between different treatment options over 10 years. This model concluded that the second-generation techniques (MEA and TBEA) are more cost effective than the first-generation techniques (TCRE and/or RB). Although base-case analysis showed that TBEA dominated MEA (in other words TBEA was less costly and more effective than MEA), the overall differences in costs and utilities were negligible, and moreover the results were sensitive to small changes in utility values. Both TBEA and MEA were dominated by hysterectomy; however the model did not take into account either patient preference or suitability. The ICER of hysterectomy versus second-generation EA techniques was around £2000 per QALY in the base-case analysis.

4.3 Consideration of the evidence

4.3.1 The Committee reviewed the data available on the clinical and cost effectiveness of TBEA and MEA, having considered evidence on the nature of the condition and the value placed on the benefits of these treatments from women with HMB, those who represent them, and clinical experts. It was also mindful of the need to take account of the effective use of NHS resources.

4.3.2 Based on the available evidence on the effectiveness of TBEA and MEA, the Committee concluded that TBEA and MEA are likely to be as effective as first-generation EA techniques in terms of reducing abnormal menstrual bleeding patterns in women with HMB. However, the Committee considered that there was not sufficient evidence to differentiate between TBEA and MEA in terms of their overall effectiveness when all potential outcomes were considered jointly.

4.3.3 The Committee took into account the potentially less invasive nature of the second-generation techniques and the possibility that they could be

performed under local anaesthesia as outpatient procedures. The Committee was also mindful of the potential advantages of delivering these treatments (TBEA and MEA) under local anaesthesia and in an outpatient setting. However they heard from the experts that the application of EA techniques other than under general anaesthesia was not likely to be acceptable for present routine clinical practice in the UK.

4.3.4 Having reviewed the economic models submitted to the Institute, the Committee concluded that TBEA and MEA are cost-effective treatment alternatives for HMB. However, the Committee concluded that in the absence of reliable effectiveness data (particularly from head-to-head trials), it was not possible to draw conclusions on the relative clinical and cost effectiveness of TBEA and MEA. Additionally, the Committee was persuaded that the relative merits of these techniques varied greatly for individual patients, and was highly dependent on the specific outcome that was appropriate for any particular patient. The Committee therefore considered that the issue of choice for the individual rendered differences in overall effectiveness between the techniques less relevant. It concluded that these techniques may separately be appropriate for specific subgroups of women, and the choice between them should be made by the woman and the clinician responsible for her treatment, following informed discussion.

4.3.5 Having consulted with experts, the Committee concluded that the continued availability of first-generation EA techniques is important because for some women with HMB these techniques may remain the most appropriate options. The NHS should consider locally how it will ensure that both second-generation techniques are available, in order to facilitate appropriate choices for individual patients.

4.3.6 The Committee accepted that hysterectomy is the only option that can guarantee amenorrhoea, but considered that it should not be offered to patients by default, even when the desired outcome is the complete cessation

of menstruation. The potential risks and benefits of all available options should be clearly explained to the individual. The patient and the clinician responsible for treatment should make the decision jointly.

5 Recommendations for further research

5.1 Further good-quality studies are needed in the following areas.

- To investigate the comparative clinical and cost effectiveness of TBEA and MEA, preferably in head-to-head RCTs.
- To investigate the clinical and cost effectiveness of second-generation EA techniques compared with levonorgestrel-releasing intrauterine systems.

6 Implications for the NHS

6.1 The impact of second-generation EA techniques on the NHS budget will depend on the number of women eligible for each technique and the uptake rates, which will be greatly influenced by the preferences of patients and clinicians.

6.2 It is estimated that around 26,000 hysterectomies are performed in the UK each year for HMB and a further 16,000 EAs are carried out, of which about 2000 are performed using second-generation techniques. The Assessment Group estimated that if all hysterectomies were replaced by EA, the annual cost saving would be of the order of £29 million, assuming half of the procedures were replaced by first-generation techniques, and the remaining half were split between TBEA and MEA. Under a hypothetical scenario of all hysterectomies being replaced by second-generation EA techniques, the cost saving would be more than £32 million per annum. However, these figures represent ceilings of the potential cost savings, and it is highly unlikely that all hysterectomies for HMB will be replaced by EA, because hysterectomy will remain the most appropriate option for some women. Also, it is unlikely that such savings would be realised in financial terms for two reasons: the

estimates represent amounts of resources that would remain within the system (but might nevertheless be redeployed); and the estimates are based on average costs (for example, of days in hospital avoided), some of which are fixed and therefore would not be saved, but could be available for other purposes.

7 Implementation and audit

7.1 All clinicians who care for women with HMB should review their current practice and policies to take account of the guidance set out in Section 1.

7.2 Local guidelines, protocols or care pathways that refer to the care of women with HMB should incorporate the guidance.

7.3 To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C.

7.3.1 A woman with HMB who has decided with the clinician responsible for treatment that surgical intervention is the appropriate next step in management is offered TBEA and MEA as treatment options, if they are not contraindicated.

7.3.2 The woman and the clinician responsible for treatment decide jointly on the choice of surgical treatment for HMB after an informed discussion.

7.4 Local clinical audits on the care of women with HMB could also include measurement of compliance with accepted clinical guidelines or protocols.

8 Related guidance

8.1 The following technologies are part of the Institute's ongoing Interventional Procedures Programme.

- Microwave endometrial ablation: due to be issued autumn 2003.
- Balloon thermal endometrial ablation: due to be issued autumn 2003.
- Free fluid endometrial ablation: due to be issued Autumn 2003

9 Proposed date for review of guidance

9.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider any new evidence on the technology, in the form of an updated Assessment Report, and decide whether the technology should be referred to the Appraisal Committee for review.

9.2 The guidance on this technology will be reviewed in June 2006.

Professor David Barnett
Chair, Appraisal Committee
June 2003

Appendix A. Appraisal Committee members

NOTE The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets twice a month other than in December, when there are no meetings. The Committee membership is split into two branches, with the chair, vice-chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and ongoing topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declaration of interests, are posted on the NICE website.

Dr Jane Adam
Radiologist, St George's Hospital, London

Dr Sunil Angris
General Practitioner, Waterhouses Medical Practice, Staffordshire

Dr Darren Ashcroft
Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences, University of Manchester

Professor David Barnett (Chair)
Professor of Clinical Pharmacology, University of Leicester

Professor John Brazier
Health Economist, University of Sheffield

Professor John Cairns

Professor of Health Economics, Health Economics Research Unit, Institute of Applied Health Sciences, University of Aberdeen

Professor Mike Campbell

Statistician, Institute of General Practice & Primary Care, Sheffield

Dr Peter I Clark

Consultant Medical Oncologist, Clatterbridge Centre for Oncology, Wirral, Merseyside

Dr Mike Davies

Consultant Physician, University Department of Medicine & Metabolism, Manchester Royal Infirmary

Professor Cam Donaldson

PPP Foundation Professor of Health Economics, School of Population and Health Sciences & Business School, Business School – Economics, University of Newcastle upon Tyne

Professor Jack Dowie

Health Economist, London School of Hygiene and Tropical Medicine

Dr Paul Ewings

Statistician, Taunton & Somerset NHS Trust, Taunton

Ms Sally Gooch

Director of Nursing, Mid-Essex Hospital Services NHS Trust, Chelmsford

Professor Trisha Greenhalgh

Professor of Primary Health Care, University College London

Dr George Levvy

Lay Representative; Chief Executive, Motor Neurone Disease Association, Northampton

Dr Gill Morgan

Chief Executive, NHS Confederation, London

Professor Philip Routledge

Professor of Clinical Pharmacology, College of Medicine, University of Wales, Cardiff

Dr Stephen Saltissi

Consultant Cardiologist, Royal Liverpool University Hospital

Mr Miles Scott

Chief Executive, Harrogate Health Care NHS Trust

Professor Andrew Stevens (Vice-Chair)

Professor of Public Health, University of Birmingham

Professor Mary Watkins

Professor of Nursing, University of Plymouth

Dr Norman Waugh

Department of Public Health, University of Aberdeen

Appendix B. Sources of evidence considered by the Committee

A The assessment report for this appraisal was prepared by Peninsula Technology Assessment Group, Peninsula Medical School, Universities of Exeter and Plymouth, Wessex Institute for Health Research and Development, University of Southampton.

Garside R, Stein K, Wyatt K, et al. *Fluid-filled Thermal Balloon and Microwave Endometrial Ablation Techniques for Heavy Menstrual Bleeding*, January 2003.

B The following organisations accepted the invitation to participate in this appraisal. They were invited to make submissions and comment on the draft scope, assessment report and the Appraisal Consultation Document (ACD). Consultee organisations are provided with the opportunity to appeal against the Final Appraisal Determination.

I Manufacturer/sponsors:

- Ethicon Ltd
- Johnson & Johnson Medical
- Microsulis Medical Ltd
- Wallsten Medical SA

II Professional/specialist and patient/carer groups:

- Department of Health
- Medical Women's Federation
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Obstetrics and Gynaecology
- Welsh Assembly Government
- Women's Health

- Women's Health Concern

III Commentator organisations (without the right of appeal):

- Haringey Primary Care Trust
- Melton, Rutland and Harborough Primary Care Trust
- NHS Quality Improvement Scotland

C The following individuals were selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups. They participated in the Appraisal Committee discussions and provided evidence to inform the Appraisal Committee's deliberations. They gave their expert personal view on fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding by attending the initial Committee discussion and/or providing written evidence to the Committee. They are invited to comment on the ACD.

- Dr Mary Ann Lumsden, Reader/Honorary Consultant, Women's Health Concern
- Margaret CP Rees, Reader in Reproductive Medicine, John Radcliffe Hospital on behalf of Women's Health Concern
- Professor RW Shaw, Professor of Obstetrics and Gynaecology, Derby City General Hospital
- Ruth Teddern, Health Information Officer, Women's Health
- Pat Thompson, Health Information Officer, Women's Health

Appendix C. Detail on criteria for audit of the use of fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding

Possible objectives for an audit

An audit on the treatment of women with heavy menstrual bleeding (HMB) could be carried out to ensure the following.

- Thermal balloon endometrial ablation (TBEA) and microwave endometrial ablation (MEA) are being offered as treatment options.
- Women with HMB are involved in the choice of treatment.

Possible patients to be included in the audit

An audit on the treatment of women with HMB could be carried out on women referred for surgical intervention over a suitable period, for example 3 or 6 months.

Measures that could be used as a basis for an audit

The measures that could be used in an audit of TBEA and MEA are as follows.

Criterion	Standard	Exception	Definition of terms
1. The woman is offered TBEA and MEA as treatment options	100% of women in the audit	A. The woman has contraindications for TBEA and MEA as follows: For TBEA: (1) the woman's uterine cavity is large or irregularly shaped or (2) the woman has a latex allergy (for Thermachoice). For MEA: (1) the woman has had uterine surgery that has left a scar where the uterine wall is less than 8 mm thick or (2) the woman has had a classical Caesarean section	Clinicians will need to agree locally on how the offer of the option of TBEA and MEA is documented for audit purposes. A large uterine cavity is > 10 cm from the internal os to the fundus for Cavaterm and > 12 cm in length for Thermachoice.
2. The woman and the clinician responsible for treatment decide jointly on the choice of treatment for HMB after an informed discussion of: a. the woman's desired outcome of the treatment **and** b. the relative benefits of all the treatment options and the adverse events associated with them **and**	100% of women in the audit	None	Clinicians will need to agree locally on all other treatment options and the adverse events associated with them and on how an informed discussion is documented for audit purposes. The clinician responsible for treatment is ordinarily the specialist gynaecologist. For 2a, desired

c. the clinical condition, anatomical suitability and preferences of the woman			outcomes could be normal menstrual bleeding or complete cessation of menstrual bleeding.

A locally based audit on HMB also could include measures related to previous drug treatments for HMB and to appropriateness of the use of hysterectomy.

Calculation of compliance

Compliance (%) with each measure described in the table above is calculated as follows.

$$\frac{\text{Number of patients whose care is consistent with the } \textbf{criterion} \textit{ plus } \text{number of patients who meet any } \textbf{exception} \text{ listed}}{\text{Number of patients to whom the } \textbf{measure} \text{ applies}} \times 100$$

Clinicians should review the findings of measurement, identify whether practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.