Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with
those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the safety and efficacy of photodynamic endometrial ablation does not appear adequate to support the use of this procedure outside formal research. It is suitable for use only within good quality research studies approved by a research ethics committee and with explicit patient consent. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute is not undertaking further investigation at present.

2 The procedure

2.1 Indications

2.1.1 Photodynamic endometrial ablation is used to treat heavy menstrual periods, also known as menorrhagia.

2.1.2 Menorrhagia is a very common problem. Hysterectomy has been the standard treatment for women with menorrhagia who have not responded to medical therapy. Minimally invasive procedures used to destroy the lining of the uterus (the endometrium) are alternatives to hysterectomy. They include using lasers, radiofrequency waves, electrocautery, microwaves, heated saline or a heated balloon. Photodynamic endometrial ablation is one of these minimally invasive procedures.

2.2 Outline of the procedure

2.2.1 Photodynamic endometrial ablation involves injecting a photosensitive
chemical into the uterine cavity through a hysterosalpingography catheter. A probe inserted through the cervix uses a laser to activate the photosensitive chemical, which destroys the endometrium. It can often be carried out under local anaesthetic on a day-case basis.

2.3 **Efficacy**

2.3.1 The evidence relating to this procedure was extremely limited and was based on one very small case series that included two women with menorrhagia and one woman with prolonged postmenopausal bleeding. For more details, refer to the Sources of evidence section.

2.3.2 The Specialist Advisors considered photodynamic endometrial ablation to be an experimental procedure not yet ready for routine clinical use.

2.4 **Safety**

2.4.1 The evidence considered by the Advisory Committee was limited – the single study offered no assessment of pain or discomfort during the operation. For more details, refer to the Sources of evidence section.

2.4.2 The Specialist Advisors noted that the photosensitive chemical used in the procedure may cause skin photosensitivity. They commented that the evidence available was too limited to allow accurate assessment of the safety of the procedure.

3 **Further information**

3.1 The Institute has issued guidance on microwave endometrial ablation, balloon thermal endometrial ablation, and free fluid thermal endometrial ablation.

3.2 Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding have been appraised as part of the Institute's technology appraisal work programme. Guidance is being prepared [Now published as 'Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding']
3.3 The Institute is in the process of developing a clinical guideline on hysterectomy and alternative surgical treatments for menorrhagia and other conditions. The expected date of issue of this guideline is September 2005 [Now published as 'Heavy menstrual bleeding: investigation and treatment'].

Andrew Dillon
Chief Executive
March 2004

Sources of evidence
The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of photodynamic endometrial ablation', November 2002.

Information for patients
NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication
The guidance was considered for reassessment in January 2011 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please contact us.

28 January 2012: minor maintenance.

5 About this guidance
NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a
procedure. Funding decisions are taken by local NHS bodies after considering the clinical
effectiveness of the procedure and whether it represents value for money for the NHS. It is
for healthcare professionals and people using the NHS in England, Wales, Scotland and
Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation
by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about
the evidence it is based on is also available.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration
of the available evidence. Healthcare professionals are expected to take it fully into
account when exercising their clinical judgement. This guidance does not, however,
override the individual responsibility of healthcare professionals to make appropriate
decisions in the circumstances of the individual patient, in consultation with the patient
and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or
providers. Commissioners and providers are reminded that it is their responsibility to
implement the guidance, in their local context, in light of their duties to avoid unlawful
discrimination and to have regard to promoting equality of opportunity. Nothing in this
guidance should be interpreted in a way which would be inconsistent with compliance with
those duties.

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National Institute for Health and Clinical Excellence
Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.