

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Heavy menstrual bleeding: investigation and treatment.

1.1 Short title

Heavy menstrual bleeding

2 Background

- a) The National Institute for Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Women's and Children's Health to develop a clinical guideline on the diagnosis and management of heavy menstrual bleeding (HMB) for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health and Welsh Assembly Government (see Appendix). The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness. The Institute's clinical guidelines will support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the Framework.

3 Clinical need for the guideline

- a) HMB (or menorrhagia), is a leading cause of diminished quality of life amongst women of reproductive age. At present, the most useful management schedule for HMB is unknown. It is therefore important that guidance is provided on the management of HMB, as improved information on this issue amongst patients and health professionals would clearly be beneficial.

- b) HMB can be considered as heavy, menstrual bleeding over several consecutive cycles. HMB affects quality of life by limiting normal activities, and it is the cause of iron-deficiency anaemia in two thirds of women with clinically defined menorrhagia. An estimated 1.5 million women consult their GP each year with HMB in England and Wales, and menstrual disorders account for about 20% of all referrals to specialist gynaecology services, placing a significant burden on secondary healthcare services.
- c) One in five of all women in the UK have a hysterectomy before the age of 60 years, and HMB was found to be the presenting complaint for 43% of the 37,298 hysterectomies assessed in one study. In 50% of women who undergo hysterectomy there is no visible pathology on examination.
- d) Diagnosis of HMB in primary care is usually based on a woman's own subjective evaluation, but clinical HMB is defined as a total menstrual blood loss of 80 mls or more in each menstruation. However, there is a poor correlation between the reporting of heavy menstrual bleeding and menstrual blood loss (MBL) of ≥ 80 mls. Before starting treatment, HMB must be differentiated from a number of other common gynaecological bleeding disorders such as irregular bleeding. HMB may be associated with conditions such as fibroids, or may exist in the absence of pathology, which is known as dysfunctional uterine bleeding. Associated conditions such as these can influence the management of HMB.
- e) Treatment of HMB aims to reduce menstrual blood loss and to improve the quality of life of the individuals. The provision of information and patient education is an extremely important part of the management process. Treatment recommendations should take account of women's' future fertility plans, as many treatments temporarily or permanently inhibit fertility.
- f) A number of medical and surgical interventions are available to treat HMB. Medical management includes 'watchful waiting', complementary and alternative treatments, ethamsylate, non-steroidal anti-inflammatory drugs (NSAIDs), antifibrinolytic drugs, and hormonal treatments. However, some

of these medical treatments are associated with adverse events, and many medical treatments are not suitable for long-term use. Even with the drug treatments available, surgery has been a commonly used treatment. In 1991, 60% of women referred for HMB in the UK had a hysterectomy within 5 years. However, alternatives to hysterectomy have been developed in recent years. Endometrial ablation (EA) is widely used and uterine artery embolisation (UAE) or myomectomy are often appropriate options for women with uterine fibroids.

- g) An important consideration with myomectomy or hysterectomy, is the route by which the operation should be performed, and whether an abdominal, vaginal, laparoscopic or hysteroscopic procedure should be undertaken. There is a need to determine the long-term outcomes of all these techniques as evidence is currently lacking.
- h) The Royal College of Obstetricians and Gynaecologists published two guidelines in 1998 and 1999 on the management of menorrhagia. These covered the initial investigation and management, and the management in secondary care. However, a review and up-date of these guidelines is now due.
- i) Given the complexity of diagnoses and the range of medical and surgical interventions available, it is important that guidelines are produced to facilitate the diagnosis and management of HMB in the UK.

4 The guideline

- a) The guideline development process is described in detail in two publications that are available from the NICE website (see 'Further information'). *The guideline development process – an overview for stakeholders, the public and the NHS* describes how organisations can become involved in the development of a guideline. *Guideline development methods – information for National Collaborating Centres and Guideline Developers* provides advice on the technical aspects of guideline development.

- b) This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health and Welsh Assembly Government (see Appendix).

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

- a) Women of reproductive age (post-puberty and pre-menopausal) with heavy menstrual bleeding as a result of cyclical ovarian activity, as the major complaint. This may be in association with uterine fibroids, since HMB is commonly the major presenting symptom or dysfunctional uterine bleeding in the absence of visible pathology.

4.1.2 Groups/treatments that will not be covered

- a) Conditions where heavy menstrual bleeding is not the main presenting menstrual symptom. An example is endometriosis, which is often dysmenorrhoea associated with pelvic pain. Such conditions will not be covered even if there is concurrent menorrhagia.
- b) Issues relating to anaesthetics in surgery.
- c) Issues relating to fertility will only be examined as they relate to treatment for HMB but not as a separate issue.
- d) Women with heavy bleeding receiving exogenous steroids (e.g. hormone replacement therapy).
- e) Gynaecological bleeding problems (other than HMB).

4.2 Healthcare setting

- a) The guideline will cover the care that is provided by primary, secondary and tertiary care settings, on an outpatient and inpatient basis.

4.3 Clinical management

- a) The guideline will provide advice on patient educational interventions and information provision to improve patient satisfaction.
- b) The guideline will provide advice on diagnosis of women presenting with HMB, including guidance on appropriate investigations and referral, and the cost-effectiveness of undertaking such investigations.
- c) The guideline will provide advice on the medical management of HMB, including short- and long-term outcomes, adverse events, cost-effectiveness and subsequent treatment.
- d) The guideline will provide advice on the indications for referral to secondary care management.
- e) The guideline will provide advice to determine if, and when, surgical procedures are most appropriate.
- f) The guideline will provide advice on operative procedures used for endometrial ablation/resection in HMB, including short- and long-term outcomes, cost-effectiveness, adverse events, and subsequent treatment.
- g) The guideline will provide advice on operative procedures used for uterine artery embolisation in HMB, including short- and long-term outcomes, cost-effectiveness, adverse events, and subsequent treatment.
- h) The guideline will provide advice on operative procedures and other techniques used for hysterectomy and myomectomy in HMB, including short- and long-term outcomes, adverse events, and subsequent treatment. This will include guidance on minimal access techniques (laparoscopically).
- i) When hysterectomy is the most appropriate option, issues relating to the removal of healthy ovaries will be examined.
- j) The competencies required by practitioners who wish to carry out surgical techniques and other interventions, such as UAE will be provided.

- k) Advice on treatment options will be based on the best evidence available to the Guideline Development Group. When referring to pharmacological interventions, the guideline will normally recommend use within the licensed indications. Exceptionally, and only where the evidence clearly supports it, the guideline may recommend use of a pharmacological intervention beyond its licensed indications. The guideline recommendations will assume that prescribers will use the Summary of Product Characteristics for prescribing decisions for individual patients. The guideline recommendations will be based on the assessment of short- and long-term outcomes and complications for all treatments.

4.4 Status

4.4.1 Scope

This is the final draft of the scope.

4.4.2 Guideline

The development of the guideline recommendations will begin in January 2005.

5 Further information

Information on the guideline development process is provided in:

- *The guideline development process – an overview for stakeholders, the public and the NHS*
- *Guideline development methods – Information for National Collaborating Centres and Guideline Developers*

These booklets are available as PDF files from the NICE website (www.nice.org.uk). Information on the progress of the guideline will also be available from the website.

6 Related NICE guidance

6.1 Clinical Guidelines

- NICE guideline. Osteoporosis: assessment of fracture risk and prevention of osteoporotic fracture in individuals at high risk (expected publication date February 2006).
- NICE guideline. Referral guidelines for suspected cancer (expected publication date 2005).

6.2 Technology Appraisals

- Technology Appraisal. Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding. 2004. No. 78.
- Technology Appraisal: The clinical effectiveness and cost effectiveness of technologies for the primary prevention of osteoporotic fragility fractures in postmenopausal women (expected publication date September 2005).
- A Technology Appraisal on secondary prevention of osteoporotic fractures in post menopausal women (this is awaiting a response following appeal).
- A Technology Appraisal on strontium ranelate for the prevention of osteoporotic fractures in post-menopausal women with osteoporosis

6.3 Interventional Procedures

- Interventional Procedure Guidance. Impedance-controlled bipolar radiofrequency ablation for menorrhagia. (expected publication date 2004).
- Interventional Procedure Guidance. Laparoscopic hysterectomy (expected publication date February 2005).

- Interventional Procedure Guidance. Free fluid thermal endometrial ablation. 2004. No. 51.
- Interventional Procedure Guidance. Laparoscopic laser myomectomy. 2003. No. 23.
- Interventional Procedure Guidance. Hysteroscopic laser myomectomy (In development).
- Interventional Procedure Guidance. Photodynamic endometrial ablation. 2004. No. 47.
- Interventional Procedure Guidance. Microwave endometrial ablation. 2004. No. 7.
- Interventional Procedure Guidance. Balloon thermal endometrial ablation. 2003. No. 6.
- Interventional Procedure Guidance. Uterine artery embolisation for fibroids. 2004. No. 94.

The published guidelines or updates on progress for guidelines in development are available as PDF files from the NICE website (www.nice.org.uk).

Appendix – Referral from the Department of Health and Welsh Assembly Government

The Department of Health and Welsh Assembly Government asked the Institute:

To prepare clinical guidelines for the NHS in England and Wales on the diagnosis and management of heavy menstrual bleeding (Menorrhagia and other conditions). The guidelines should:

- provide guidance on assessment and diagnosis of heavy menstrual bleeding.
- examine indications for non-surgical clinical management of heavy menstrual bleeding.
- examine the indications for hysterectomy and other surgical interventions, and for removal of healthy ovaries during hysterectomy.
- examine the competencies required by surgeons performing these operative procedures.
- for each indication, examine the evidence for the use of hysterectomy with the availability of alternative procedures together with the contra-indications for various methods.
- provide guidance on technique and operative procedures, including the role of laparoscopically assisted vaginal hysterectomy.