

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Hysterectomy and alternative surgical treatments for menorrhagia and other conditions.

1.1 Short title

Hysterectomy

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 hysterectomy 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.
- b) 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) Menorrhagia, also known as heavy menstrual bleeding (HMB), is a common disorder. An estimated 1.5 million women consult their GP each year with HMB in England and Wales. Menstrual disorders account for about 20% of all referrals to specialist gynaecology services, placing a

significant burden on secondary healthcare services. HMB was the presenting complaint for about half of the 47,000 hysterectomies that were carried out in the NHS in England in 2000–2001. About half of all women who have a hysterectomy for HMB are thought to have a normal uterus removed.

- b) Diagnosis of HMB is usually based on subjective evaluation of blood loss by the affected individual. HMB may be caused by conditions such as fibroids, adenomyosis, polyps, infections, pre-cancerous conditions or haematological disorders, but in the majority of cases the cause is unknown. Fibroids occur commonly and are often the reason for a woman to have a hysterectomy or myomectomy.
- c) Treatment of HMB aims to reduce menstrual blood loss and to improve the quality of life of the individuals. Non-surgical treatment options include the use of drugs such as: tranexamic acid (an antifibrinolytic), mefenamic acid (a non-steroidal anti-inflammatory), the combined oral contraceptive pill and the intrauterine levonorgestrel-releasing system.
- d) Surgical treatment is usually offered to patients who do not respond to drug treatment and includes hysterectomy and endometrial ablation techniques. Endometrial ablation techniques were introduced almost 20 years ago as alternatives to hysterectomy. Endometrial ablation techniques are less invasive and require fewer resources than hysterectomy, but do not guarantee complete cessation of menstruation (amenorrhoea). About 15,000 endometrial ablations are performed in England each year.
- e) The most widely used first-generation endometrial ablation technique is transcervical resection of the endometrium, using a loop diathermy electrode and a roller-ball ablation. First-generation endometrial ablation techniques require direct visual examination of the endometrium using a hysteroscope. The success rates of these techniques depend on the skills and experience of the operator. Potential complications include: uterine

perforation (about 12–14 per 1000 procedures), hysterectomy (about 2–6 per 1000 procedures) and death (0.26 per 1000 procedures).

- f) The most common second-generation endometrial ablation techniques are fluid-filled thermal balloon ablation and microwave ablation, but are not suitable for all women. These techniques do not require direct visual examination of the uterine cavity and can be performed under local or general anaesthetic. Compared with first-generation techniques, they rely heavily on the devices for safety and efficacy and less on the skills of the operator. Adverse events with second-generation endometrial ablation techniques include: uterine infection, perforation, visceral burn, bleeding, haematometra, laceration, intra-abdominal injury and cyclical pain. Women who do not respond to initial endometrial ablation may require further ablations, or eventually hysterectomy.
- g) The presence of uterine fibroids is a common reason why women have a hysterectomy or myomectomy, as symptoms of fibroids can include HMB. In this procedure, performed under conscious sedation, both uterine arteries are blocked with particles injected via the femoral and uterine arteries. This procedure has been associated with a reduction in the size of the fibroids and improvement of short-term symptoms. Complications occur in 5–13% of patients and include: pain, infection, fever, ovarian dysfunction and the need for a hysterectomy.
- h) Hysterectomy (removal of the whole, or part of the uterus) is the only treatment for HMB to assure complete cessation of menstrual periods, but has significant resource implications. 1 in every 30 women suffers a major adverse event during, or soon after the operation, which can include damage to the bladder or bowel, infection and heavy bleeding requiring a transfusion. Additionally, the procedure has a mortality rate of 0.4–1.1 per 1000 operations. The rate at which hysterectomies are performed has not changed in recent years and is expected to remain at the current level, or increase, despite the development of alternatives.

- i) 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.

4 The guideline

- j) The guideline development process is described in detail in two publications which 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.
- k) 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).
- l) 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 with heavy menstrual bleeding
- b) Women of reproductive age with uterine fibroids

4.1.2 Groups that will not be covered

- a) The management and treatment of co-morbidities such as adenomyosis will only be covered where they relate to the treatment of HMB, but not beyond this.

- b) Therapeutic interventions will only be discussed as they relate to HMB. For example, intra-uterine systems for contraception, or hysterectomy for other conditions such as prolapse will not be discussed.

4.2 *Healthcare setting*

- a) The guideline will cover the care that is received from primary, community, secondary and tertiary health care

4.3 *Clinical management*

- a) The guideline will cover the diagnostic, medical and surgical management of women through all stages of their care. This will include the following areas (b–g):
 - b) The guideline will provide advice on initial diagnosis and continuing assessment of women who have HMB or uterine fibroids, including guidance on appropriate investigations.
 - c) The guideline will give the indications for hysterectomy, and for the removal of healthy ovaries during the procedure.
 - d) The guideline will examine the competencies required by surgeons performing these operative procedures.
 - e) The guideline will advise on the use of medical and surgical treatment options including: the combined oral contraceptive pill, levonorgestrel-releasing intrauterine system, endometrial ablation techniques, uterine artery embolisation techniques and hysterectomy (including abdominal, vaginal and laparoscopic techniques).
 - f) The guideline will advise on appropriate use of procedures for heavy menstrual bleeding for the following procedures: pre-operative assessment, interventions, or clinical practice likely to reduce morbidity associated with the procedures - including those associated with anaesthesia.

- g) It will provide advice on operative procedures and other techniques used for hysterectomy, including the role of laparoscopically assisted vaginal hysterectomy.
- h) 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.

4.4 Status

4.4.1 Scope

This is the 1st draft of the scope.

4.4.2 Guideline

The development of the guideline recommendations will begin in October 2004.

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

- National Institute for Clinical Excellence (2004). Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding. NICE Technology Appraisal Guidance No. 78.
- National Institute for Clinical Excellence (2004) Free fluid thermal endometrial ablation. NICE Interventional Procedures Guidance No. 51.
- National Institute for Clinical Excellence (2003) Microwave endometrial ablation. NICE Interventional Procedures Guidance No. 7.
- National Institute for Clinical Excellence (2003) Balloon thermal endometrial ablation. NICE Interventional Procedures Guidance No. 6.

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 hysterectomy and alternative surgical treatments for menorrhagia and other conditions. The guidelines should:

- examine the indications for hysterectomy, 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.