

Issue date: January 2007

Heavy menstrual bleeding

NICE clinical guideline 44 Heavy menstrual bleeding

Ordering information

You can download the following documents from www.nice.org.uk/CG044

- The NICE guideline (this document) – all the recommendations.
- A quick reference guide – a summary of the recommendations for healthcare professionals.
- ‘Understanding NICE guidance’ – information for patients and carers.
- The full guideline – all the recommendations, details of how they were developed, and summaries of the evidence they were based on.

For printed copies of the quick reference guide or ‘Understanding NICE guidance’, phone the NHS Response Line on 0870 1555 455 and quote:

- N1180 (quick reference guide)
- N1181 (‘Understanding NICE guidance’).

This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, 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.

National Institute for Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk

© National Institute for Health and Clinical Excellence, January 2007. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute.

Contents

Introduction	4
Woman-centred care	5
Key priorities for implementation.....	6
1 Guidance	8
1.1 Impact of HMB on women	8
1.2 History, examination and investigations for HMB	8
1.3 Education and information provision.....	11
1.4 Choice	13
1.5 Pharmaceutical treatments for HMB.....	13
1.6 Non-hysterectomy surgery for HMB.....	15
1.7 Further interventions for uterine fibroids associated with HMB.....	17
1.8 Hysterectomy.....	19
1.9 Removal of ovaries (oophorectomy) with hysterectomy	20
1.10 Competencies.....	21
2 Notes on the scope of the guidance	22
3 Implementation	23
4 Research recommendations	23
5 Other versions of this guideline.....	25
5.1 Full guideline	25
5.2 Quick reference guide.....	25
5.3 'Understanding NICE guidance'	25
6 Related NICE guidance	26
7 Updating the guideline	27
Appendix A: The Guideline Development Group	28
Appendix B: The Guideline Review Panel	29
Appendix C: The algorithms.....	30

Introduction

Heavy menstrual bleeding (HMB) is defined as excessive menstrual blood loss which interferes with a woman's physical, social, emotional and/or material quality of life. It can occur alone or in combination with other symptoms.

HMB is not associated with significant mortality and may be considered unimportant by some healthcare professionals. Many women with HMB consult healthcare professionals in primary care and HMB is a common reason for referral to a specialist.

In the early 1990s, it was estimated that at least 60% of women presenting with HMB went on to have a hysterectomy. This was often the only treatment offered. Hysterectomy is a major operation and is associated with significant complications in a minority of cases. Since the 1990s the number of hysterectomies has been decreasing rapidly. This guideline makes recommendations on a range of treatment options for HMB. It aims to help healthcare professionals provide the right treatments for individual women. Healthcare professionals should be aware that it is the woman herself who determines whether a treatment is successful for her.

Woman-centred care

This guideline offers best practice advice on the care of women with HMB.

HMB has a major impact on a woman's quality of life. Treatment and care should take into account the woman's needs and preferences. Women with HMB should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If women do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines in 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk). From April 2007, healthcare professionals will need to follow a code of practice accompanying the Mental Capacity Act (summary available from www.dca.gov.uk/menincap/bill-summary.htm).

Good communication between healthcare professionals and women is essential. Face-to-face communication should be supported by evidence-based written information tailored to the woman's needs. Treatment and care, and the information women are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Key priorities for implementation

Impact on women

- For clinical purposes, HMB should be defined as excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms. Any interventions should aim to improve quality of life measures.

History taking, examination and investigations

- If appropriate, a biopsy should be taken to exclude endometrial cancer or atypical hyperplasia. Indications for a biopsy include, for example, persistent intermenstrual bleeding, and in women aged 45 and over treatment failure or ineffective treatment.
- Ultrasound is the first-line diagnostic tool for identifying structural abnormalities.

Education and information provision

- A woman with HMB referred to specialist care should be given information before her outpatient appointment. The Institute's information for patients ('Understanding NICE guidance') is available from www.nice.org.uk/CG044publicinfo

Pharmaceutical treatment

- If history and investigations indicate that pharmaceutical treatment is appropriate and either hormonal or non-hormonal treatments are acceptable, treatments should be considered in the following order:
 - levonorgestrel-releasing intrauterine system (LNG-IUS) provided long-term (at least 12-months) use is anticipated
 - tranexamic acid or non-steroidal anti-inflammatory drugs (NSAIDs) or combined oral contraceptives (COCs)

- norethisterone (15 mg) daily from days 5 to 26 of the menstrual cycle, or injected long-acting progestogens.
- If hormonal treatments are not acceptable to the woman, then either tranexamic acid or NSAIDs can be used.

Non-hysterectomy surgery

- In women with HMB alone, with uterus no bigger than a 10-week pregnancy, endometrial ablation should be considered preferable to hysterectomy.

Hysterectomy

- Taking into account the need for individual assessment, the route of hysterectomy should be considered in the following order: first line vaginal; second line abdominal.

Competencies

- Maintenance of surgical, imaging or radiological skills requires a robust clinical governance framework including audit of numbers, decision making, case-mix issues and outcomes of all treatments at both individual operator and organisational levels. These data should be used to demonstrate good clinical practice.

1 Guidance

The following guidance is based on the best available evidence. The full guideline (www.nice.org.uk/CG044fullguideline) gives details of the methods and the evidence used to develop the guidance (see section 5 for details).

1.1 *Impact of HMB on women*

- 1.1.1 Heavy menstrual bleeding (HMB) should be recognised as having a major impact on a woman's quality of life, and any intervention should aim to improve this rather than focusing on menstrual blood loss.
- 1.1.2 For clinical purposes, HMB should be defined as excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms. Any interventions should aim to improve quality of life measures.

1.2 *History, examination and investigations for HMB*

History

- 1.2.1 Initially, a history should be taken from the woman. This should cover the nature of the bleeding, related symptoms that might suggest structural or histological abnormality (see recommendation 1.2.4), impact on quality of life and other factors that may determine treatment options (such as presence of comorbidity).
- 1.2.2 Clinicians should take into account the range and natural variability in menstrual cycles and blood loss when diagnosing HMB, and should discuss this variation with the woman. If the woman feels that she does not fall within the normal ranges, care options should be discussed.
- 1.2.3 If the history suggests HMB without structural or histological abnormality, pharmaceutical treatment can be started without carrying out a physical examination or other investigations at initial

consultation in primary care, unless the treatment chosen is levonorgestrel-releasing intrauterine system (LNG-IUS) (see recommendation 1.2.6).

- 1.2.4 If the history suggests HMB with structural or histological abnormality, with symptoms such as intermenstrual or postcoital bleeding, pelvic pain and/or pressure symptoms, a physical examination and/or other investigations (such as ultrasound) should be performed.
- 1.2.5 Measuring menstrual blood loss either directly (alkaline haematin) or indirectly ('Pictorial blood loss assessment chart') is not routinely recommended for HMB. Whether menstrual blood loss is a problem should be determined not by measuring blood loss but by the woman herself.

Examination

- 1.2.6 A physical examination should be carried out before all:
- LNG-IUS fittings¹
 - investigations for structural abnormalities
 - investigations for histological abnormalities.
- 1.2.7 Women with fibroids that are palpable abdominally or who have intracavity fibroids and/or whose uterine length as measured at ultrasound or hysteroscopy is greater than 12 cm should be offered immediate referral to a specialist.

Laboratory tests

- 1.2.8 A full blood count test should be carried out on all women with HMB. This should be done in parallel with any HMB treatment offered.

¹ See 'Long-acting reversible contraception' (NICE clinical guideline 30), www.nice.org.uk/CG030 for more detail.

- 1.2.9 Testing for coagulation disorders (for example, von Willebrand's disease) should be considered in women who have had HMB since menarche and have personal or family history suggesting a coagulation disorder.
- 1.2.10 A serum ferritin test should not routinely be carried out on women with HMB.
- 1.2.11 Female hormone testing should not be carried out on women with HMB.
- 1.2.12 Thyroid testing should be carried out only when other signs and symptoms of thyroid disease are present.

Structural and histological investigations

For suspected cancer see 'Referral guidelines for suspected cancer.'²

- 1.2.13 If appropriate, a biopsy should be taken to exclude endometrial cancer or atypical hyperplasia. Indications for a biopsy include, for example, persistent intermenstrual bleeding, and in women aged 45 and over treatment failure or ineffective treatment.
- 1.2.14 Imaging should be undertaken in the following circumstances:
- The uterus is palpable abdominally.
 - Vaginal examination reveals a pelvic mass of uncertain origin.
 - Pharmaceutical treatment fails.
- 1.2.15 Ultrasound is the first-line diagnostic tool for identifying structural abnormalities.

² See 'Referral guidelines for suspected cancer' (NICE clinical guideline 27), www.nice.org.uk/CG027 for more detail.

- 1.2.16 Hysteroscopy should be used as a diagnostic tool only when ultrasound results are inconclusive, for example, to determine the exact location of a fibroid or the exact nature of the abnormality.
- 1.2.17 If imaging shows the presence of uterine fibroids then appropriate treatment should be planned based on size, number and location of the fibroids.
- 1.2.18 Saline infusion sonography should not be used as a first-line diagnostic tool.
- 1.2.19 Magnetic resonance imaging (MRI) should not be used as a first-line diagnostic tool.
- 1.2.20 Dilatation and curettage alone should not be used as a diagnostic tool.
- 1.2.21 Where dilatation is required for non-hysteroscopic ablative procedures, hysteroscopy should be used immediately prior to the procedure to ensure correct placement of the device.

1.3 *Education and information provision*

- 1.3.1 A woman with HMB referred to specialist care should be given information before her outpatient appointment. The Institute's information for patients ('Understanding NICE guidance') is available from www.nice.org.uk/CG044publicinfo
- 1.3.2 Although respect for autonomy, and individual choice, are important for the NHS and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost effective.
- 1.3.3 Women should be made aware of the impact on fertility that any planned surgery or uterine artery embolisation (UAE) may have, and if a potential treatment (hysterectomy or ablation) involves the loss of fertility then opportunities for discussion should be made available.

1.3.4 Women should be given the following information on potentially unwanted outcomes.

Treatment	Potential unwanted outcomes experienced by some women (Common: 1 in 100 chance; less common: 1 in 1000 chance; rare: 1 in 10,000 chance; very rare: 1 in 100,000 chance)
Levonorgestrel-releasing intrauterine system	Common: irregular bleeding that may last for over 6 months; hormone-related problems such as breast tenderness, acne or headaches, which, if present, are generally minor and transient Less common: amenorrhoea Rare: uterine perforation at the time of insertion
Tranexamic acid	Less common: indigestion; diarrhoea; headaches
Non-steroidal anti-inflammatory drugs	Common: indigestion; diarrhoea Rare: worsening of asthma in sensitive individuals; peptic ulcers with possible bleeding and peritonitis
Combined oral contraceptives	Common: mood changes; headaches; nausea; fluid retention; breast tenderness Very rare: deep vein thrombosis; stroke; heart attacks
Oral progestogen (norethisterone)	Common: weight gain; bloating; breast tenderness; headaches; acne (but all are usually minor and transient) Rare: depression
Injected progestogen	Common: weight gain; irregular bleeding; amenorrhoea; premenstrual-like syndrome (including bloating, fluid retention, breast tenderness) Less common: small loss of bone mineral density, largely recovered when treatment discontinued
Gonadotrophin-releasing hormone analogue	Common: menopausal-like symptoms (such as hot flushes, increased sweating, vaginal dryness) Less common: osteoporosis, particularly trabecular bone with longer than 6-months' use
Endometrial ablation	Common: vaginal discharge; increased period pain or cramping (even if no further bleeding); need for additional surgery Less common: infection Rare: perforation (but very rare with second generation techniques)
Uterine artery embolisation	Common: persistent vaginal discharge; post-embolisation syndrome – pain, nausea, vomiting and fever (not involving hospitalisation) Less common: need for additional surgery; premature ovarian failure particularly in women over 45 years old; haematoma Rare: haemorrhage; non-target embolisation causing tissue necrosis; infection causing septicaemia

Myomectomy	Less common: adhesions (which may lead to pain and/or impaired fertility); need for additional surgery; recurrence of fibroids; perforation (hysteroscopic route); infection Rare: haemorrhage
Hysterectomy	Common: infection Less common: intraoperative haemorrhage; damage to other abdominal organs, such as the urinary tract or bowel; urinary dysfunction – frequent passing of urine and incontinence Rare: thrombosis (DVT and clot on the lung) Very rare: death (Complications are more likely when hysterectomy is performed in the presence of fibroids.)
Oophorectomy at time of hysterectomy	Common: menopausal-like symptoms

1.4 Choice

- 1.4.1 A woman with HMB should be given the opportunity to review and agree any treatment decision. She should have adequate time and support from healthcare professionals in the decision-making process.
- 1.4.2 A woman with HMB and/or her doctor should have the option of gaining a second medical opinion where agreement on treatment options for HMB is not reached.

1.5 Pharmaceutical treatments for HMB

- 1.5.1 Pharmaceutical treatment should be considered where no structural or histological abnormality is present, or for fibroids less than 3 cm in diameter which are causing no distortion of the uterine cavity.
- 1.5.2 The healthcare professional should determine whether hormonal contraception is acceptable to the woman before recommending treatment (for example, she may wish to conceive).
- 1.5.3 If history and investigations indicate that pharmaceutical treatment is appropriate and either hormonal or non-hormonal treatments are

acceptable, treatments should be considered in the following order:³

- a) levonorgestrel-releasing intrauterine system (LNG-IUS) provided long-term (at least 12 months) use is anticipated^{4,5}
- b) tranexamic acid or non-steroidal anti-inflammatory drugs (NSAIDs) or combined oral contraceptives (COCs)
- c) norethisterone (15 mg) daily from days 5 to 26 of the menstrual cycle, or injected long-acting progestogens.⁶

1.5.4 If hormonal treatments are not acceptable to the woman, then either tranexamic acid or NSAIDs can be used.

1.5.5 Women offered an LNG-IUS should be advised of anticipated changes in the bleeding pattern, particularly in the first few cycles and maybe lasting longer than 6 months. They should therefore be advised to persevere for at least 6 cycles to see the benefits of the treatment.⁷

1.5.6 If pharmaceutical treatment is required while investigations and definitive treatment are being organised, either tranexamic acid or NSAIDs should be used.

³ World Health Organization 'Pharmaceutical eligibility criteria for contraceptive use' (WHOMECEC) apply. These criteria can be used to assess the individual's suitability for particular contraceptives. This allows informed decision making by the woman prior to the start of treatment. www.ffprhc.org.uk/admin/uploads/298_UKMEC_200506.pdf

⁴ Check the Summary of Product Characteristics for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

⁵ See 'Long-acting reversible contraception' (NICE clinical guideline 30), www.nice.org.uk/CG030 for more detail.

⁶ Check the Summary of Product Characteristics for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented within the notes. In adolescents and women older than 40 years, refer to CSM advice issued in November 2004. Go to www.mhra.gov.uk and search for Depo Provera.

⁷ See 'Long-acting reversible contraception' (NICE clinical guideline 30), www.nice.org.uk/CG030 for more detail.

- 1.5.7 When HMB coexists with dysmenorrhoea, NSAIDs should be preferred to tranexamic acid.
- 1.5.8 Ongoing use of NSAIDs and/or tranexamic acid is recommended for as long as it is found to be beneficial by the woman.
- 1.5.9 Use of NSAIDs and/or tranexamic acid should be stopped if it does not improve symptoms within 3 menstrual cycles.
- 1.5.10 When a first pharmaceutical treatment has proved ineffective, a second pharmaceutical treatment can be considered rather than immediate referral to surgery. (See also recommendation 1.2.14.)
- 1.5.11 Use of a gonadotrophin-releasing hormone analogue could be considered prior to surgery or when all other treatment options for uterine fibroids, including surgery or uterine artery embolisation, are contraindicated. If this treatment is to be used for more than 6 months or if adverse effects are experienced then hormone replacement therapy (HRT) 'add-back' therapy is recommended.⁸
- 1.5.12 Danazol should not be used routinely for the treatment of HMB.
- 1.5.13 Oral progestogens given during the luteal phase only should not be used for the treatment of HMB.
- 1.5.14 Etamsylate should not be used for the treatment of HMB.

1.6 *Non-hysterectomy surgery for HMB*

Endometrial ablation

- 1.6.1 Endometrial ablation should be considered where bleeding is having a severe impact on a woman's quality of life, and she does not want to conceive in the future.

⁸ Check the Summary of Product Characteristics for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

- 1.6.2 Endometrial ablation may be offered as an initial treatment for HMB after full discussion with the woman of the risks and benefits and of other treatment options.
- 1.6.3 Women must be advised to avoid subsequent pregnancy and on the need to use effective contraception, if required, after endometrial ablation.
- 1.6.4 Endometrial ablation should be considered in women with HMB who have a normal uterus and also those with small uterine fibroids (less than 3 cm in diameter).
- 1.6.5 In women with HMB alone, with uterus no bigger than a 10-week pregnancy, endometrial ablation should be considered preferable to hysterectomy.
- 1.6.6 All women considering endometrial ablation should have access to a second-generation ablation technique.
- 1.6.7 Second-generation ablation techniques should be used where no structural or histological abnormality is present. The second-generation techniques recommended for consideration are as follows. Providers should ensure that when purchasing any of these that they buy the least expensive available option.^{9,10,11,12}

⁹ NICE have produced 'Fluid-filled thermal balloon and microwave endometrial techniques for heavy menstrual bleeding' (NICE technology appraisal guidance 78) on TBEA and MEA.

¹⁰ This clinical guideline supersedes the following NICE interventional procedure guidances: 'Balloon thermal endometrial ablation' (IPG 6), 'Microwave endometrial ablation' (IPG 7), 'Free fluid endometrial ablation' (IPG 51) and 'Impedance-controlled bipolar radiofrequency ablation for menorrhagia' (IPG 104). However, 'Endometrial cryotherapy for menorrhagia' (NICE interventional procedure guidance 157) is not covered by this guideline.

¹¹ Reference should be made to the limits on uterus size given by the manufacturer of the endometrial ablation device.

¹² It is recommended that the Medicines and Healthcare products Regulatory Agency (MHRA) safety notices on endometrial ablation should be followed (MDA [1998] SN 9812 'Devices used for endometrial ablation achieved by thermal means', and MDA [1999] SN 1999(18) 'Devices used for endometrial ablation').

- Impedance-controlled bipolar radiofrequency ablation (formerly NICE interventional procedure guidance 104)
- Fluid-filled thermal balloon endometrial ablation (TBEA) (formerly NICE interventional procedure guidance 6)
- Microwave endometrial ablation (MEA) (formerly NICE interventional procedure guidance 7)
- Free fluid thermal endometrial ablation (formerly NICE interventional procedure guidance 51).

1.6.8 In TBEA, endometrial thinning is not needed.

1.6.9 In MEA, scheduling of surgery for postmenstrual phase is an alternative to endometrial thinning.

1.6.10 First-generation ablation techniques (for example, rollerball endometrial ablation [REA] and transcervical resection of the endometrium [TCRE]) are appropriate if hysteroscopic myomectomy is to be included in the procedure.

Dilatation and curettage

1.6.11 Dilatation and curettage should not be used as a therapeutic treatment.

1.7 Further interventions for uterine fibroids associated with HMB

1.7.1 For women with large fibroids and HMB, and other significant symptoms such as dysmenorrhoea or pressure symptoms, referral for consideration of surgery or uterine artery embolisation (UAE) as first-line treatment can be recommended.¹³

1.7.2 UAE, myomectomy or hysterectomy should be considered in cases of HMB where large fibroids (greater than 3 cm in diameter) are

¹³ See 'Uterine artery embolisation for the treatment of fibroids' (NICE interventional procedure guidance 94), www.nice.org.uk/IPG094

present and bleeding is having a severe impact on a woman's quality of life.

- 1.7.3 When surgery for fibroid-related HMB is felt necessary then UAE, myomectomy and hysterectomy must all be considered, discussed and documented.
- 1.7.4 Women should be informed that UAE or myomectomy may potentially allow them to retain their fertility.
- 1.7.5 Myomectomy is recommended for women with HMB associated with uterine fibroids and who want to retain their uterus.
- 1.7.6 UAE is recommended for women with HMB associated with uterine fibroids and who want to retain their uterus and/or avoid surgery.¹⁴
- 1.7.7 Prior to scheduling of UAE or myomectomy, the uterus and fibroid(s) should be assessed by ultrasound. If further information about fibroid position, size, number and vascularity is required, MRI should be considered.
- 1.7.8 Pretreatment before hysterectomy and myomectomy with a gonadotrophin-releasing hormone analogue for 3 to 4 months should be considered where uterine fibroids are causing an enlarged or distorted uterus.¹⁵
- 1.7.9 If a woman is being treated with gonadotrophin-releasing hormone analogue and UAE is then planned, the gonadotrophin-releasing hormone analogue should be stopped as soon as UAE has been scheduled.

¹⁴ See 'Uterine artery embolisation for the treatment of fibroids' (NICE interventional procedure guidance 94), www.nice.org.uk/IPG094

¹⁵ Check the Summary of Product Characteristics for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

1.8 Hysterectomy

1.8.1 Hysterectomy should not be used as a first-line treatment solely for HMB. Hysterectomy should be considered only when:

- other treatment options have failed, are contraindicated or are declined by the woman
- there is a wish for amenorrhoea
- the woman (who has been fully informed) requests it
- the woman no longer wishes to retain her uterus and fertility.

1.8.2 Women offered hysterectomy should have a full discussion of the implication of the surgery before a decision is made. The discussion should include: sexual feelings, fertility impact, bladder function, need for further treatment, treatment complications, the woman's expectations, alternative surgery and psychological impact.

1.8.3 Women offered hysterectomy should be informed about the increased risk of serious complications (such as intraoperative haemorrhage or damage to other abdominal organs) associated with hysterectomy when uterine fibroids are present.

1.8.4 Women should be informed about the risk of possible loss of ovarian function and its consequences, even if their ovaries are retained during hysterectomy.

1.8.5 Individual assessment is essential when deciding the route of hysterectomy. The following factors need to be taken into account:

- presence of other gynaecological conditions or disease
- uterine size
- presence and size of uterine fibroids
- mobility and descent of the uterus
- size and shape of the vagina
- history of previous surgery.

- 1.8.6 Taking into account the need for individual assessment, the route of hysterectomy should be considered in the following order: first line vaginal; second line abdominal.
- 1.8.7 Under circumstances such as morbid obesity or the need for oophorectomy during vaginal hysterectomy, the laparoscopic approach should be considered, and appropriate expertise sought.
- 1.8.8 When abdominal hysterectomy is decided upon then both the total method (removal of the uterus and the cervix) and subtotal method (removal of the uterus and preservation of the cervix) should be discussed with the woman.

1.9 Removal of ovaries (oophorectomy) with hysterectomy

- 1.9.1 Removal of healthy ovaries at the time of hysterectomy should not be undertaken
- 1.9.2 Removal of ovaries should only be undertaken with the express wish and consent of the woman.
- 1.9.3 Women with a significant family history of breast or ovarian cancer should be referred for genetic counselling prior to a decision about oophorectomy.¹⁶
- 1.9.4 In women under 45 considering hysterectomy for HMB with other symptoms that may be related to ovarian dysfunction (for example, premenstrual syndrome), a trial of pharmaceutical ovarian suppression for at least 3 months should be used as a guide to the need for oophorectomy.
- 1.9.5 If removal of ovaries is being considered, the impact of this on the woman's wellbeing and, for example, the possible need for hormone replacement therapy (HRT) should be discussed.

¹⁶ See 'The classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care' (NICE clinical guideline 41), www.nice.org.uk/CG041 for more detail.

- 1.9.6 Women considering bilateral oophorectomy should be informed about the impact of this treatment on the risk of ovarian and breast cancer.

1.10 Competencies

Training

- 1.10.1 All those involved in undertaking surgical or radiological procedures to diagnose and treat HMB should demonstrate competence (including both technical and consultation skills) either during their training or in their subsequent practice.
- 1.10.2 The operative competence of healthcare professionals who are acquiring new skills in procedures to diagnose and treat HMB should be formally assessed by trainers through a structured process such as that defined within training schemes of the Postgraduate Medical Education and Training Board, the Royal Colleges and/or the Society and College of Radiographers.
- 1.10.3 Training programmes must be long enough to enable healthcare professionals to achieve competency in complex procedures when these are appropriate (for example, operations for fibroids that are large or in an awkward position, or using laparoscopic techniques). These training programmes will usually be located in units with a particular interest and sufficient workload to allow experience of these procedures.

Maintenance

- 1.10.4 Maintenance of surgical, imaging or radiological skills requires a robust clinical governance framework including audit of numbers, decision making, case-mix issues and outcomes of all treatments at both individual operator and organisational levels. These data should be used to demonstrate good clinical practice.
- 1.10.5 Established healthcare professionals should be able to demonstrate that their training, experience and current practice

meets or exceeds the standards laid out for newly trained professionals.

Governance

1.10.6 If a healthcare professional lacks competence to undertake a procedure then they should refer the woman to a professional with the appropriate skill. Organisations that commission services should be responsible (through service specification based on robust audit data) for identifying and contracting professionals with appropriate skills.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from www.nice.org.uk/page.aspx?o=240825

How this guideline was developed

NICE commissioned the National Collaborating Centre for Women's and Children's Health to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information in the booklet: 'The guideline development process: an overview for stakeholders, the public and the NHS' (second edition, published April 2006), which is available from www.nice.org.uk/guidelinesprocess or by telephoning 0870 1555 455 (quote reference N1113).

3 Implementation

The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health', issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/CG044).

- Slides highlighting key messages for local discussion.
- Costing tools
 - Costing report to estimate the national savings and costs associated with implementation.
 - Costing template to estimate the local costs and savings involved.
- Implementation advice on how to put the guidance into practice and national initiatives which support this locally.
- Audit criteria to monitor local practice.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and care of women in the future.

4.1 What is the epidemiology of women presenting with HMB in primary care?

Why this is important

There are only limited data available on the epidemiological profile of women presenting with HMB in primary care. This is important as the majority of women with HMB will be treated solely within primary care. An epidemiological profile of women presenting with HMB would help

understanding of the presentation of HMB and the requirements from treatment.

4.2 *Investigate routine use of indirect measurements of menstrual blood loss in primary and secondary care*

Why this is important

Evidence shows that direct measurement of menstrual blood loss is accurate but complex to undertake in clinical practice, and that subjective assessment of menstrual blood loss is inaccurate but easy to undertake in clinical practice. An alternative is the use of indirect measures of menstrual blood loss, such as the 'Pictorial blood loss assessment chart'. However, evidence on the use of indirect measures is contradictory and no data are available to show whether they could be used in routine practice. If indirect measures are shown to work then they could be introduced as a simple technique for assessing menstrual blood loss, and from this the management of HMB could be improved.

4.3 *What are the long-term recurrence rates of fibroids after uterine artery embolisation or myomectomy?*

Why this is important

Both UAE and myomectomy are undertaken to reduce symptoms associated with uterine fibroids by directly removing the fibroid(s) or reducing their size. Data exist on short- and medium-term recurrence of fibroids, but no data are available on long-term recurrence.

4.4 *What are the effects of hysterectomy and oophorectomy on the occurrence of cancer?*

Why this is important

One of the arguments surrounding the use of hysterectomy and oophorectomy is the effect on cancer risks. Epidemiological studies are required to investigate the impact of hysterectomy and oophorectomy on cancer. The results of this research will have fundamental implications on the use of these treatments.

4.5 Do volume–outcome relationships exist in gynaecological procedures, taking into account case-mix, hospital and surgeon factors?

Why this is important

No good evidence was identified for any volume–outcome relationships in gynaecological procedures. If volume–outcome relationships do exist then this would suggest the need for concentration of services.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, ‘Heavy menstrual bleeding’, contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Women’s and Children’s Health, and is available from www.ncc-wch.org.uk, our website (www.nice.org.uk/CG044fullguideline) and the National Library for Health (www.library.nhs.uk).

5.2 Quick reference guide

A quick reference guide for healthcare professionals is also available from www.nice.org.uk/CG044quickrefguide

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number N1180).

5.3 ‘Understanding NICE guidance’

Information for women with heavy menstrual bleeding is available from www.nice.org.uk/CG044publicinfo

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number N1181).

6 Related NICE guidance

- The classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care. NICE clinical guideline 41 (2006). Available from www.nice.org.uk/CG041
- Long-acting reversible contraception. NICE clinical guideline 30 (2005). Available from www.nice.org.uk/CG030
- Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005). Available from www.nice.org.uk/CG027
- Uterine artery embolisation for fibroids. NICE interventional procedure guidance 94 (2004). Available from www.nice.org.uk/PG094
- Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding. NICE technology appraisal guidance 78 (2004). Available from www.nice.org.uk/TA078
- Endometrial cryotherapy for menorrhagia. NICE interventional procedure guidance 157 (2006). Available from www.nice.org.uk/IPG157
- Photodynamic endometrial ablation. NICE interventional procedure guidance 47 (2004). Available from www.nice.org.uk/IPG047
- Magnetic resonance (MI) image-guided percutaneous laser ablation of uterine fibroids. NICE interventional procedure guidance 30 (2003). Available from www.nice.org.uk/IPG030
- Laparoscopic laser myomectomy. NICE interventional procedure guidance 23 (2003). Available from www.nice.org.uk/IPG023

NICE is developing the following guidance (details available from www.nice.org.uk):

- The clinical effectiveness and cost effectiveness of technologies for the primary prevention of osteoporotic fragility fractures in postmenopausal women. NICE technology appraisal guidance (publication date to be confirmed).
- Osteoporosis: assessment of fracture risk and the prevention of osteoporotic fractures in individuals at high risk. NICE clinical guideline (publication date to be confirmed).

- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. NICE technology appraisal (publication date to be confirmed).
- Laparoscopic hysterectomy. NICE interventional procedure guidance (publication date to be confirmed).
- Hysteroscopic laser myomectomy. NICE interventional procedure guidance (publication date to be confirmed).

7 Updating the guideline

NICE clinical guidelines are updated as needed so that recommendations take into account important new information. We check for new evidence 2 and 4 years after publication, to decide whether all or part of the guideline should be updated. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

Appendix A: The Guideline Development Group

Anna-Maria Belli

Consultant Radiologist, St George's Hospital, London

Dianne Crowe

Gynaecology Specialist Nurse Practitioner, Hexham NHS Trust,
Northumberland

Sean Duffy

Clinical Director, Leeds Healthcare Trust

Sarah Gray

General Practitioner, Cornwall

Yasmin Gunaratnam

Patient/Carer Representative

Mary Ann Lumsden

GDG Leader, Professor of Gynaecology and Honorary Consultant
Obstetrician and Gynaecologist, University of Glasgow

Klim McPherson

Visiting Professor of Public Health Epidemiology, University of Oxford

David Parkin

Consultant Gynaecological Oncologist, Aberdeen

Jane Preston

Consultant Obstetrician and Gynaecologist, James Paget Hospital, Norfolk

Mark Shapley

General Practitioner, Staffordshire

Bridgette York

Patient/Carer Representative, Fibroid Network

Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

Jill Freer

Acting Director of Provider Services, Rugby PCT

John Seddon

Chairman V.O.I.C.E.S

Mike Baldwin

Head of Health Technology Appraisals, Sanofi-Aventis

Peter J Robb

Consultant ENT Surgeon Epsom & St Helier, University Hospitals and The Royal Surrey County NHS Trusts

Appendix C: The algorithms

A care pathway can be found on page 6 of the quick reference guide, available from www.nice.org.uk/CG044quickrefguide