NICE National Institute for Health and Care Excellence

NICE guideline

Heavy menstrual bleeding: assessment and management

Clinical guideline

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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

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.

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This guideline replaces IPG6, IPG7, IPG51 and IPG104.

This guideline is the basis of QS47.

This guideline should be read in conjunction with IPG23.

Overview

This guideline covers assessing and treating heavy menstrual bleeding. It aims to help healthcare professionals offer the right treatments to women with heavy periods (menorrhagia) that affect their quality of life, taking into account the woman's individual preferences.

EMA review of ulipristal acetate (Esmya) and temporary safety measures

In February 2018, the European Medicines Agency (EMA) introduced a number of temporary safety measures as part of an ongoing review of ulipristal acetate (Esmya) for uterine fibroids. Further information is available from the EMA website. The temporary safety measures are:

- **Do not start new treatment courses of Esmya**, including in women who have completed 1 or more treatment courses previously.
- Perform liver function tests at least once a month in all women currently taking Esmya. Stop Esmya treatment in any woman who develops transaminase levels more than 2 times the upper limit of normal, closely monitor and refer for specialist hepatology evaluation as clinically indicated. Liver function tests should be repeated in all women 2 to 4 weeks after stopping treatment.
- Check transaminase levels immediately in current or recent users of Esmya who present with signs or symptoms suggestive of liver injury (such as nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, jaundice). If transaminase levels are more than 2 times the upper limit of normal, stop treatment, closely monitor and refer for specialist hepatology evaluation as clinically indicated.
- Advise women using Esmya on the signs and symptoms of liver injury.

NICE will review its guidance on heavy menstrual bleeding when the EMA review has concluded. In the meantime, the guidance must be read in conjunction with the temporary safety measures above.

Who is it for?

- Healthcare professionals
- Commissioners and providers of heavy menstrual bleeding services
- Women with heavy menstrual bleeding, their families and carers

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

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. [2007]

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. [2007]

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). [2007]

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. [2007]

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). [2007]

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. [2007]

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. [2007]

Examination

1.2.6 A physical examination should be carried out before all:

- LNG-IUS fittings[1]
- investigations for structural abnormalities
- investigations for histological abnormalities. [2007]

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. [2007]

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. [2007]

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. [2007]

1.2.10 A serum ferritin test should not routinely be carried out on women with HMB. [2007]

1.2.11 Female hormone testing should not be carried out on women with HMB. [2007]

1.2.12 Thyroid testing should be carried out only when other signs and symptoms of thyroid disease are present. [2007]

Structural and histological investigations

For suspected cancer see suspected cancer: recognition and referral.

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. [2007]

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. [2007]

1.2.15 Ultrasound is the first-line diagnostic tool for identifying structural abnormalities. [2007]

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. [2007]

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. [2007]

1.2.18 Saline infusion sonography should not be used as a first-line diagnostic tool. [2007]

1.2.19 Magnetic resonance imaging (MRI) should not be used as a first-line diagnostic tool. [2007]

1.2.20 Dilatation and curettage alone should not be used as a diagnostic tool. [2007]

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. **[2007]**

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 the public is available. **[2007]**

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. **[2007]**

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. **[2007]**

1.3.4 Women should be given the following information on potentially unwanted outcomes. **[2007, amended 2016]**

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 **[2007]**	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 **[2007]**	Less common: indigestion; diarrhoea; headaches.
Non-steroidal anti-inflammatory drugs **[2007]**	Common: indigestion; diarrhoea. Rare: worsening of asthma in sensitive individuals; peptic ulcers with possible bleeding and peritonitis.

Combined oral contraceptives [2007]	Common: mood changes; headaches; nausea; fluid retention; breast tenderness. Very rare: deep vein thrombosis; stroke; heart attacks.
Oral progestogen (norethisterone) [2007]	Common: weight gain; bloating; breast tenderness; headaches; acne (but all are usually minor and transient). Rare: depression.
Injected progestogen [2007]	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.
Ulipristal acetate [new 2016] Safety update 2018	Very common: endometrial thickening, amenorrhoea. Common: vertigo, nausea, abdominal pain, hot flushes, headache, fatigue, ovarian cyst, breast pain and tenderness, pelvic pain, musculoskeletal pain, acne, weight increase. Less common: dizziness, dry mouth, constipation, anxiety, urinary incontinence, alopecia, dry skin, hyperhidrosis, back pain, uterine haemorrhage, metrorrhagia, genital discharge, oedema, asthenia, increased blood lipids. Rare: epistaxis, dyspepsia, flatulence, ruptured ovarian cyst, breast swelling,
Gonadotrophin-releasing hormone analogue [2007]	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 [2007]	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 [2007]	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 [2007]	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 [2007]	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 [2007]	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. **[2007]**

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. **[2007]**

1.5 Pharmaceutical treatments for HMB

Fibroids less than 3 cm in diameter or no fibroids

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. [2007]

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). [2007]

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[2]:

- levonorgestrel-releasing intrauterine system (LNG-IUS) provided long-term (at least 12 months) use is anticipated[3],[1]
- 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[4]. [2007]

1.5.4 If hormonal treatments are not acceptable to the woman, then either tranexamic acid or NSAIDs can be used. [2007]

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[1]. [2007]

1.5.6 If pharmaceutical treatment is required while investigations and definitive treatment are being organised, either tranexamic acid or NSAIDs should be used. [2007]

1.5.7 When HMB coexists with dysmenorrhoea, NSAIDs should be preferred to tranexamic acid. [2007]

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. [2007]

1.5.9 Use of NSAIDs and/or tranexamic acid should be stopped if it does not improve symptoms within 3 menstrual cycles. [2007]

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.) [2007]

Fibroids 3 cm or more in diameter

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- **Do not start new treatment courses of Esmya**, including in women who have completed 1 or more treatment courses previously.
- Perform liver function tests at least once a month in all women currently taking Esmya. Stop Esmya treatment in any woman who develops transaminase levels more than 2 times the upper limit of normal, closely monitor and refer for specialist hepatology evaluation as clinically indicated. Liver function tests should be repeated in all women 2 to 4 weeks after stopping treatment.
- Check transaminase levels immediately in current or recent users of Esmya who present with signs or symptoms suggestive of liver injury (such as nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, jaundice). If transaminase levels are more than 2 times the upper limit of normal, stop treatment, closely monitor and refer for specialist hepatology evaluation as clinically indicated.
- Advise women using Esmya on the signs and symptoms of liver injury.

NICE will review its guidance on heavy menstrual bleeding when the EMA review has concluded. In the meantime, the guidance must be read in conjunction with the temporary safety measures above.

1.5.11 Offer ulipristal acetate 5 mg (up to 4 courses)[5] to women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level of 102 g per litre or below. **[new 2016]**

1.5.12 Consider ulipristal acetate 5 mg (up to 4 courses)[5] for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level above 102 g per litre. **[new 2016]**

All fibroids

1.5.13 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[4]. **[2007]**

1.5.14 Danazol should not be used routinely for the treatment of HMB. **[2007]**

1.5.15 Oral progestogens given during the luteal phase only should not be used for the treatment of HMB. **[2007]**

1.5.16 Etamsylate should not be used for the treatment of HMB. **[2007]**

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. **[2007]**

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. **[2007]**

1.6.3 Women must be advised to avoid subsequent pregnancy and on the need to use effective contraception, if required, after endometrial ablation. **[2007]**

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). [2007]

1.6.5 In women with HMB alone, with a uterus no bigger than a 10-week pregnancy, endometrial ablation should be considered preferable to hysterectomy. [2007]

1.6.6 All women considering endometrial ablation should have access to a second-generation ablation technique. [2007]

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[6],[7],[8],[9].

- 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). [2007]

1.6.8 In TBEA, endometrial thinning is not needed. [2007]

1.6.9 In MEA, scheduling of surgery for postmenstrual phase is an alternative to endometrial thinning. [2007]

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. [2007]

Dilatation and curettage

1.6.11 Dilatation and curettage should not be used as a therapeutic treatment. **[2007]**

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[10]. **[2007]**

1.7.2 UAE, myomectomy or hysterectomy should be considered in cases of HMB where large fibroids (greater than 3 cm in diameter) are present and bleeding is having a severe impact on a woman's quality of life. **[2007]**

1.7.3 When surgery for fibroid-related HMB is felt necessary then UAE, myomectomy and hysterectomy must all be considered, discussed and documented. **[2007]**

1.7.4 Women should be informed that UAE or myomectomy may potentially allow them to retain their fertility. **[2007]**

1.7.5 Myomectomy is recommended for women with HMB associated with uterine fibroids and who want to retain their uterus. **[2007]**

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. **[2007]**

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. **[2007]**

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[4]. **[2007]**

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. **[2007]**

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. [2007]

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. [2007]

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. [2007]

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. [2007]

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. [2007]

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. [2007]

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. [2007]

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. [2007]

1.9 Removal of ovaries (oophorectomy) with hysterectomy

1.9.1 Removal of healthy ovaries at the time of hysterectomy should not be undertaken. [2007]

1.9.2 Removal of ovaries should only be undertaken with the express wish and consent of the woman. [2007]

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[11]. [2007]

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. [2007]

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. [2007]

1.9.6 Women considering bilateral oophorectomy should be informed about the impact of this treatment on the risk of ovarian and breast cancer. [2007]

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. [2007]

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. [2007]

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. [2007]

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. [2007]

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. [2007]

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. [2007]

[1] See the NICE guideline on long-acting reversible contraception for more detail.

[2] World Health Organization Pharmaceutical eligibility criteria for contraceptive use (WHOMEC) 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.

[3] 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.

[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 within the notes. In adolescents and women older than 40 years, refer to CSM advice.

[5] The summary of product characteristics states: 'In case of repeated intermittent treatment, periodic monitoring of the endometrium is recommended. This includes annual ultrasound to be performed after resumption of menstruation during off-treatment period.'

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

[7] 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.

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

[9] 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').

[10] See uterine artery embolisation for fibroids (NICE interventional procedure guidance 367).

[11] See the NICE guideline on familial breast cancer for more detail.

Putting this guideline into practice

NICE has produced tools and resources to help you put this guideline into practice.

Putting recommendations into practice can take time. How long may vary from guideline to guideline, and depends on how much change in practice or services is needed. Implementing change is most effective when aligned with local priorities.

Changes recommended for clinical practice that can be done quickly – like changes in prescribing practice – should be shared quickly. This is because healthcare professionals should use guidelines to guide their work – as is required by professional regulating bodies such as the General Medical and Nursing and Midwifery Councils.

Changes should be implemented as soon as possible, unless there is a good reason for not doing so (for example, if it would be better value for money if a package of recommendations were all implemented at once).

Different organisations may need different approaches to implementation, depending on their size and function. Sometimes individual practitioners may be able to respond to recommendations to improve their practice more quickly than large organisations.

Here are some pointers to help organisations put NICE guidelines into practice:

1. **Raise awareness** through routine communication channels, such as email or newsletters, regular meetings, internal staff briefings and other communications with all relevant partner organisations. Identify things staff can include in their own practice straight away.

2. **Identify a lead** with an interest in the topic to champion the guideline and motivate others to support its use and make service changes, and to find out any significant issues locally.

3. **Carry out a baseline assessment** against the recommendations to find out whether there are gaps in current service provision.

4. **Think about what data you need to measure improvement** and plan how you will collect it. You may want to work with other health and social care organisations and specialist groups to compare current practice with the recommendations. This may also help identify local issues that will slow or prevent implementation.

5. **Develop an action plan**, with the steps needed to put the guideline into practice, and make sure it is ready as soon as possible. Big, complex changes may take longer to implement, but some may be quick and easy to do. An action plan will help in both cases.

6. **For very big changes** include milestones and a business case, which will set out additional costs, savings and possible areas for disinvestment. A small project group could develop the action plan. The group might include the guideline champion, a senior organisational sponsor, staff involved in the associated services, finance and information professionals.

7. **Implement the action plan** with oversight from the lead and the project group. Big projects may also need project management support.

8. **Review and monitor** how well the guideline is being implemented through the project group. Share progress with those involved in making improvements, as well as relevant boards and local partners.

NICE provides a comprehensive programme of support and resources to maximise uptake and use of evidence and guidance. See our into practice pages for more information.

Also see Leng G, Moore V, Abraham S, editors (2014) Achieving high quality care – practical experience from NICE. Chichester: Wiley.

Context

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.

New evidence on progesterone-receptor modulators (mifepristone and ulipristal acetate) as a medical treatment for fibroids was reviewed in 2016 and recommendations added.

More information

To find out what NICE has said on topics related to this guideline, see our web pages on heavy menstrual bleeding and endometriosis and fibroids.

Recommendations for research

The guideline committee has made the following recommendations for research. The committee's full set of research recommendations is detailed in the full guideline.

As part of the 2016 update, the standing committee made an additional research recommendation on prolonged ulipristal acetate treatment. Details can be found in the addendum.

1 Prolonged ulipristal acetate treatment for women with heavy menstrual bleeding and fibroids of 3 cm or more

What is the efficacy and safety of ulipristal acetate 5 mg for a duration of more than 4 courses for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, compared with other uterus-sparing treatments?

Why this is important

The current evidence suggests that ulipristal acetate 5 mg is an effective treatment for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter. The evidence covers a period of 4 courses (20 months). Research is needed on the efficacy and safety of ulipristal acetate 5 mg over a period of more than 4 courses, compared with other uterus-sparing treatments.

2 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.

3 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 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 fibroids or reducing their size. Data exist on short- and medium-term recurrence of fibroids, but no data are available on long-term recurrence.

5 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.

6 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.

Update information

February 2018: Text has been added before recommendations 1.5.11 and 1.5.12 and to the table in recommendation 1.3.4 to highlight the European Medicines Agency temporary safety measures on ulipristal acetate (Esmya).

September 2016: A change was made to research recommendation 1 to correct the period covered by 4 courses of ulipristal acetate from 16 months to 20 months.

August 2016: This guideline is an update of NICE guideline CG44 (published January 2007).

New recommendations have been added on treatments for women with heavy menstrual bleeding associated with uterine fibroids. These are marked as **[new 2016]**.

Where recommendations end **[2007]**, the evidence has not been reviewed since the original guideline.

Where recommendations end **[2007, amended 2016]**, the evidence has not been reviewed but changes have been made to the recommendation wording that change the meaning. An explanation of the reasons for the changes is given in the table below.

Recommendations that have been changed

Amended recommendation wording (change to meaning)

Recommendation in 2007 guideline	Recommendation in current guideline	Reason for change
1.3.4	1.3.4	A row has been added to the table in recommendation 1.3.4 that includes information about the potential unwanted outcomes for ulipristal acetate (see **[new 2016]** recommendations 1.5.11 and 1.5.12). Date labels have been included in each row of the table to denote when the information was added (that is, a label of **[2007]** means that the information about potential unwanted outcomes has not been updated since 2007).

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