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1. **Assessment and diagnosis**
   The initial assessment of a woman with symptoms of heavy menstrual bleeding includes a detailed medical history, assessment of impact on quality of life, a physical examination and exclusion of pregnancy and anaemia. Further investigations are based on the initial assessment.

2. **Specialist referral for women with risk factors**
   A woman with heavy menstrual bleeding who has risk factors for, or clinical findings suspicious of malignancy, or who is not responding to medical treatment, is referred to a specialist. Appropriate investigations are performed and initial symptomatic management is provided before the specialist appointment.

3. **Quality ultrasound**
   When the presence of a uterine abnormality is being considered, a woman with heavy menstrual bleeding has a pelvic (preferably transvaginal) ultrasound performed in days 5 to 10 of her menstrual cycle.

4. **Informed choice and shared decision making**
   A woman with heavy menstrual bleeding is provided with consumer-focused information about her treatment options and their potential benefits and risks. She is asked about her preferences in order to support shared decision making for her clinical situation.

5. **Initial treatment is pharmaceutical**
   A woman with heavy menstrual bleeding in whom malignancy and significant pelvic pathology have been ruled out, is offered pharmaceutical treatment initially, taking into account evidence-based guidelines, her individual needs and any associated symptoms.

6. **Choice of pharmaceutical treatment**
   When pharmaceutical treatment is being considered, the woman is offered the levonorgestrel intra-uterine system if clinically appropriate, as it is the most effective option for managing heavy menstrual bleeding.

7. **Uterine-preserving alternatives to hysterectomy**
   A woman who has heavy menstrual bleeding of benign causes and who is considering surgical intervention is offered a uterine-preserving procedure if clinically appropriate (e.g. endometrial ablation, removal of local pathology). The woman receives information about procedures that may be suitable and is referred appropriately.

8. **When to consider hysterectomy**
   Hysterectomy is discussed with a woman who has heavy menstrual bleeding of benign causes when other treatment options fail, are unsuitable or are declined. A woman considering a hysterectomy is given balanced information about the risks and benefits.
Introduction

About Clinical Care Standards

Clinical Care Standards aim to support the delivery of appropriate evidence-based clinical care, and promote shared decision making between patients, carers and clinicians.

A Clinical Care Standard is a small number of quality statements that describe the clinical care that a patient should be offered for a specific clinical condition. It differs from a clinical practice guideline; rather than describing all the components of care for managing a clinical condition, a Clinical Care Standard addresses priority areas for improvement.

Each Clinical Care Standard intends to support:

- people to know what care should be offered by the healthcare system, and to make informed treatment decisions in partnership with their clinician
- clinicians to make decisions about appropriate care
- health services to examine the performance of their organisation and make improvements in the care they provide.

This Clinical Care Standard on heavy menstrual bleeding was developed by the Australian Commission on Safety and Quality in Health Care (the Commission) in collaboration with consumers, clinicians, researchers and health organisations. It complements existing efforts that support care of women with heavy menstrual bleeding, including state and territory-based initiatives.

For more information about the development of this Clinical Care Standard, visit: www.safetyandquality.gov.au/ccs.

1 The evidence base for these statements is available as part of this consultation.
Context

Heavy menstrual bleeding is a common problem affecting 25% of women of reproductive age.\(^1\) It has been 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”.\(^2\)

Heavy menstrual bleeding is the most common presentation of abnormal uterine bleeding in pre-menopausal women who are not pregnant.\(^3,4\) Abnormal uterine bleeding is classified by the type of bleeding and its causes, which may be structural and non-structural. Structural causes can be identified through imaging and/or histopathology (Figure 1). However, women may have more than one cause of heavy menstrual bleeding, while others may have uterine abnormalities that are asymptomatic.

Around 30% of women with heavy menstrual bleeding have fibroids, and approximately 10% have polyps.\(^2\) Malignancy in these structures or the endometrium (the lining of the uterus) itself is not commonly associated with heavy menstrual bleeding in pre-menopausal women, but the risk is elevated for women with certain risk factors.\(^2\)

While some non-structural causes can be detected through laboratory testing (e.g. systemic coagulation disorders), often there is no identifiable cause.\(^2\) The most common non-structural diagnosis, determined through exclusion, is of a disorder in the way blood flow is regulated in the endometrium.\(^4\) Bleeding without a structural cause was previously called ‘dysfunctional uterine bleeding’ or ‘menorrhagia’, but use of these terms is no longer recommended by the International Federation of Gynecology and Obstetrics.\(^4,5\)

Pain and anaemia are relatively common symptoms, in addition to the difficulties associated with heavy menstrual flow. Around 50% of women referred to secondary care for heavy menstrual bleeding experience severe or very severe pain, even when they do not have any uterine pathology,\(^6\) and many women who seek medical help do so because of disabling pain.\(^7\)

Management of heavy menstrual bleeding has changed considerably since the 1980s and 1990s, when the frequency of hysterectomy for the treatment of menstrual disorders first raised concerns that women were being exposed to unnecessary risks.\(^5,9\) Hysterectomy is associated with the second highest rate of unexpected readmissions after surgery, amongst procedures monitored by the Australian Institute of Health and Welfare.\(^10\) Short-term complications include infection, bleeding and bowel or urinary tract injury, while longer term complications include urinary incontinence and early menopause.\(^2,11\)

While hysterectomy remains an option, it is not recommended unless less invasive options are unsatisfactory or are inappropriate. For women without significant uterine pathology, effective pharmaceutical treatment allows many women to avoid any form of procedural or surgical intervention. For those considering surgery, surgical and radiological interventions that are lower risk and less invasive than hysterectomy include endometrial ablation (surgical removal of the lining of the uterus) and the removal or destruction of fibroids or polyps. Each option has potential benefits and risks, including a risk of treatment failure, so informed choice and shared decision making are essential.
While hysterectomy rates in Australia and worldwide have fallen since the 1990s,9,12-14 two recent healthcare variation reports released by the Commission found that:

- Australia has higher overall hysterectomy rates than comparable countries: in 2008, the rates for Australia, New Zealand and England were 230, 178, and 149 hysterectomies per 100,000 women, respectively.15
- Within Australia, there is at least three-fold variation across local areas in hospital admissions for hysterectomy and endometrial ablation combined, for women without a cancer diagnosis.16
- Regional areas tend to have higher rates of non-cancer hysterectomy than metropolitan areas.15

This data suggests that therapeutic alternatives to hysterectomy are not being consistently used across Australia for women with heavy menstrual bleeding. The quality statements in this Clinical Care Standard aim to ensure that regardless of where they live, women with heavy menstrual bleeding have the opportunity to choose from the therapeutic options that may be suitable and effective for them and that their choices are guided by balanced information and shared decision-making.

**Figure 1: Federation of Gynecology and Obstetrics (FIGO) classification system for causes of abnormal uterine bleeding (PALM-COEIN)**

<table>
<thead>
<tr>
<th>Structural causes (PALM)</th>
<th>Non-structural causes (COEIN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P – Polyps</td>
<td>C – Coagulopathy</td>
</tr>
<tr>
<td>A – Adenomyosis</td>
<td>O – Ovulatory</td>
</tr>
<tr>
<td>L – Leiomyoma (fibroids)</td>
<td>E – Endometrial</td>
</tr>
<tr>
<td>M – Malignancy or hyperplasia</td>
<td>I – Iatrogenic</td>
</tr>
<tr>
<td></td>
<td>N – Not yet classified</td>
</tr>
</tbody>
</table>

*Abnormal uterine bleeding includes any departure from normal menstruation or from a normal menstrual cycle pattern. Heavy menstrual bleeding is the most common. Other types of abnormal uterine bleeding include intermenstrual bleeding and post-coital bleeding.

Key evidence sources for the Heavy Menstrual Bleeding Clinical Care Standard are clinical guidelines from the United Kingdom’s National Institute for Health and Clinical Excellence (NICE),2 and the Society of Obstetricians and Gynaecologists of Canada.3

Central to the delivery of patient-centred care identified in this Clinical Care Standard is an integrated, systems-based approach, supported by health services and networks of services. Key elements of this approach include:

- an understanding of the capacity and limitations of each component of the health system across metropolitan, regional and remote settings, including pre-hospital, within and across hospitals, through to community and other support services
- clear lines of communication across components of the healthcare system
- appropriate coordination so that patients receive timely access to optimal care regardless of how or where they enter the system.
Scope
This Clinical Care Standard relates to the care of women of reproductive age with heavy menstrual bleeding. It covers management from first recognition of clinically significant heavy menstrual bleeding until its resolution, before, or at the menopause. It is relevant to the care provided in primary care, family planning and sexual health services, as well as that provided in public and private specialist gynaecology clinics.

Heavy menstrual bleeding may be secondary to specific structural abnormalities including malignancy. The detailed management of these conditions is out of the scope of this Clinical Care Standard. The management of acute heavy menstrual bleeding in an emergency context is not covered by this Clinical Care Standard, nor are other presentations of abnormal uterine bleeding including post-coital, intermenstrual and post-menopausal bleeding.

Goal
To ensure that women with heavy menstrual bleeding are offered the least invasive, most effective treatment appropriate to their clinical needs and have the opportunity to make an informed choice from the range of treatments suitable to their individual situation.

Patient-centred care
Patient-centred care is health care that is respectful of, and responsive to, the preferences, needs and values of patients and consumers.17

Clinical Care Standards support the key principles of patient-centred care, namely:

- treating patients with dignity and respect
- encouraging and supporting patient participation in decision making
- communicating and sharing information with patients about clinical conditions and treatment options
- providing patients with information in a format that they understand so they can participate in decision making.18

Carers and family members
Carers and family members have a central role in the prevention, early recognition, assessment and recovery relating to patients’ health conditions. They know the patients very well, and can provide detailed information about their histories, routines or symptoms, which may assist in determining treatment and ongoing support.17

Each quality statement in the Clinical Care Standard should be understood to mean that carers and family members are involved in clinicians’ discussions with patients about their care, if patients prefer carer involvement.
Indicators to support local monitoring of the Clinical Care Standard

The Australian Commission on Safety and Quality in Health Care (the Commission) has developed a set of indicators to support health care providers and local health services to monitor how well they implement the care described in the Clinical Care Standard. The indicators are a tool to support local clinical quality improvement activities.

Monitoring the implementation of the Clinical Care Standard will assist in meeting some of the requirements of the National Safety and Quality Health Service (NSQHS) Standards. Information about the NSQHS Standards is available at: www.safetyandquality.gov.au/accreditation.

Supporting documents

Fact sheets (for consumers and clinicians) linked to this Clinical Care Standard are available from the Commission’s website. Visit: www.safetyandquality.gov.au/ccb.
Quality statement 1 – Assessment and diagnosis

The initial assessment of a woman with symptoms of heavy menstrual bleeding includes a detailed medical history, assessment of impact on quality of life, a physical examination and exclusion of pregnancy and anaemia. Further investigations are based on the initial assessment.

Purpose

To ensure a comprehensive history and assessment of the bleeding, its likely causes and impact on the woman’s life, in order to guide appropriate investigation, referral, diagnosis, and management.

What the quality statement means:

For patients. If you have heavy menstrual bleeding, your doctor will carry out a thorough assessment to help find the cause. They will ask about your past general health and family medical problems, your sexual health, previous pregnancies and births, current sexual activity, and whether you wish to become pregnant. They will also need to understand your bleeding and how it affects your life. You will have a physical examination, which may be either external (feeling your uterus from the outside) or internal (feeling or looking at the inside of your uterus). Your doctor may recommend tests for pregnancy (if there is any chance you are pregnant) or anaemia (a lack of red blood cells). Whether you need other investigations or referral to another doctor will depend on all the factors discussed.

For clinicians. When assessing a woman with symptoms of heavy menstrual bleeding, take a comprehensive history of the woman’s medical, sexual and reproductive health, including her desire for future fertility, the duration, timing, heaviness and chronicity of the bleeding and its impact on her quality of life. (Post-coital and inter-menstrual bleeding are different to heavy menstrual bleeding and require investigation.) Conduct a physical examination to identify any palpable mass or abnormal uterine size. Pregnancy and anaemia should be excluded routinely. Consider possible structural and non-structural causes (listed in Figure 1, p.7) and investigate appropriately based on the history and presentation. For example, this might include testing for coagulation disorders or thyroid dysfunction, and ultrasound for assessment of uterine abnormalities.

For health services. Guidelines and protocols for assessment of heavy menstrual bleeding should support a thorough medical, sexual and reproductive history, assessment of the nature of the bleeding and its impact on the woman’s quality of life, a physical examination, and exclusion of pregnancy and anaemia. Protocols should support a systematic assessment of the structural and non-structural causes of heavy menstrual bleeding based on the woman’s history and presentation, with relevant investigations conducted according to this assessment.
Indicators for Quality statement 1 – Assessment and diagnosis

**Indicator 1a**
Evidence of local arrangements to ensure that women presenting with symptoms of heavy menstrual bleeding have a detailed medical history, an assessment of impact on quality of life, a physical examination and exclusion of pregnancy and anaemia.

**Data source** Local data collection (i.e. practice or service level audit of the existence of local arrangements).

**Indicator 1b**
Proportion of women presenting with symptoms of heavy menstrual bleeding who have an initial assessment that includes a detailed medical history, an assessment of impact on quality of life, a physical examination and the exclusion of pregnancy and anaemia.

**Numerator** The number of women in the denominator who have an initial assessment that includes a detailed medical history, an assessment of impact on quality of life, a physical examination and the exclusion of pregnancy and anaemia.

**Denominator** The number of women presenting with heavy menstrual bleeding.

**Data source** Local data collection (i.e. chart audit – electronic or paper, depending on data collection by the practice, service or practitioner).
Quality statement 2 – Specialist referral for women with risk factors

A woman with heavy menstrual bleeding who has risk factors for, or clinical findings suspicious of malignancy, or who is not responding to medical treatment, is referred to a specialist. Appropriate investigations are performed and initial symptomatic management is provided before the specialist appointment.

Purpose

To ensure timely, appropriate and efficient referral and specialist review when there is an increased risk of malignancy or inadequate response to medical treatment, and to ensure that symptom relief is provided to previously untreated women awaiting review.

What the quality statement means:

For patients. Heavy menstrual bleeding can often be managed by your general practitioner (GP) or family planning doctor. If your GP determines that you have any risk factors, you will be referred to a specialist gynaecologist to rule out a serious underlying condition, such as cancer. It is rare for heavy menstrual bleeding to be caused by cancer. You might also be referred to a specialist if you are not responding to prescribed medical treatments. If you need to have any tests before your first specialist appointment, your referring doctor will usually arrange these. Your doctor may also prescribe medicines to help your bleeding, period pain and other symptoms, especially if there will be a waiting period before your specialist appointment. Later, a different treatment may be recommended. (Note: you may be referred to a specialist for other reasons not described here, e.g. large fibroids.)

For clinicians. A woman with heavy menstrual bleeding is referred to a gynaecologist at the initial consultation if she has suspicious clinical findings or risk factors for malignancy (these include being aged 45 years or older, having anovulatory cycles, diabetes, obesity, polycystic ovary syndrome, a family history of endometrial or colon cancer, or use of unopposed oestrogen or tamoxifen\textsuperscript{19-21}). Women who have not responded to optimal medical treatment should also be referred for assessment of the cause. Consider any investigations required before the specialist appointment and arrange these concurrently with the referral to reduce avoidable delays in assessment. This will usually include an appropriately timed ultrasound.\textsuperscript{2} If the woman has not previously been treated, prescribe initial symptomatic management for heavy bleeding and dysmenorrhea, bearing in mind the potential waiting time until the first specialist appointment.

For health services. Ensure that protocols for referral of women with heavy menstrual bleeding include identification of women with recognised risk factors for malignancy and those with inadequate response to medical treatment. Any investigations that are usually required before the specialist appointment should be identified and arranged concurrently with the referral (for example an appropriately timed ultrasound). Secondary health services with referral protocols can use these to advise referring doctors of investigations that should be performed before the specialist appointment, in order to avoid unnecessary delays.
Indicators for Quality statement 2 – Specialist referral for women with risk factors

Indicator 2
Evidence of local arrangements to ensure that women presenting with symptoms of heavy menstrual bleeding who have risk factors for, or clinical findings suspicious of malignancy, or who are not responding to medical treatment, are referred in a timely manner for specialist treatment.

Notes
Arrangements should ensure that women with heavy menstrual bleeding who have risk factors for, or clinical findings suspicious of malignancy, are referred to a specialist following the initial assessment.

For women with heavy menstrual bleeding for whom malignancy has been ruled out, but who are not responding to medical treatment, referral to a specialist should occur within six months of unsuccessful medical treatment.

Data source
Local data collection (i.e. practice- or service-level audit of the existence of local arrangements).
Quality statement 3 – Quality ultrasound

When the presence of a uterine abnormality is being considered, a woman with heavy menstrual bleeding has a pelvic (preferably transvaginal) ultrasound performed in days 5 to 10 of her menstrual cycle.

Purpose
To optimise the quality of imaging undertaken when screening for uterine abnormalities and to reduce the delays and costs associated with repeat ultrasounds.

What the quality statement means:

For patients. Your doctor may request an ultrasound of your pelvic area to look for some common causes of heavy menstrual bleeding (such as polyps or fibroids) and to check the size and shape of your uterus. There are two different ways to obtain the ultrasound image. One way is for the ultrasound operator to use a narrow ultrasound probe placed into your vagina. This is called a transvaginal ultrasound, and is preferred because it provides a better view of the uterus and pelvic structures. A transvaginal ultrasound is not always possible – it may not be available at the imaging service, or you may choose not to have the ultrasound this way. The second method involves using the ultrasound probe on the outside of your lower abdomen (tummy), while you have a full bladder. This is called a transabdominal ultrasound. Whichever method is used, it is important to have the scan done 5 to 10 days from the first day of your period. This is when the lining of the uterus is at its thinnest and the reading will be most accurate. If useful images are not obtained, your doctor may ask you to have a second ultrasound. There are a few exceptions, such as women who have irregular or unpredictable periods, who will find it difficult to time the scan. Talk to your doctor if timing the scan will be difficult for you, for any reason.

For clinicians. Ultrasound is the first-line imaging for structural abnormalities of the uterus.2,3,22 Where possible, a transvaginal ultrasound is preferred. However if this is not available, is inappropriate, or the woman prefers not to have it, then a transabdominal ultrasound may be performed. Clinicians should request that the ultrasound be performed on days 5 to 10 of the menstrual cycle to allow the most accurate measurement of endometrial thickness, which is used in risk assessment.19,23 Advise the woman about the timing of the ultrasound, bearing in mind that this may not be possible for some women, for example those with unpredictable or irregular cycles.

For health services. Referral processes and protocols for ultrasound in women with heavy menstrual bleeding should aim to obtain a good-quality ultrasound on the first scan, taking into account the need to accurately measure and report endometrial thickness. Imaging request protocols should ensure that a pelvic (preferably transvaginal) ultrasound is requested and that the provider conducts the ultrasound on days 5 to 10 of the woman’s cycle whenever achievable.23 Protocols for health services conducting ultrasounds should support the appropriate scheduling of appointments and reporting of ultrasounds for abnormal uterine bleeding– for example, the reporting of endometrial thickness and the day of the woman’s cycle on the ultrasound report.
Indicators for Quality statement 3 – Quality ultrasound

Indicator 3
Proportion of women presenting with heavy menstrual bleeding with a possible uterine abnormality, who had a pelvic (transabdominal or transvaginal) ultrasound.

Numerator
The number of women presenting with heavy menstrual bleeding with a possible uterine abnormality, who had a pelvic ultrasound.

Exclusions for the numerator
1. Women who had an ultrasound as second-line imaging for their possible uterine abnormality.
2. Women who did not require imaging for diagnosis of their uterine pathology.

Denominator
The number of women presenting with heavy menstrual bleeding with a possible uterine abnormality.

Exclusions for the denominator
1. Women who did not require imaging for a possible uterine abnormality.

Data source
Local data collection (i.e. chart audit – electronic or paper, depending on data collection by the practice, service or practitioner).

Quality statement 4 – Informed choice and shared decision making

A woman with heavy menstrual bleeding is provided with consumer-focused information about her treatment options and their potential benefits and risks. She is asked about her preferences in order to support shared decision making for her clinical situation.

Purpose
To ensure that whenever treatment options are discussed with a woman with heavy menstrual bleeding, she has the opportunity to participate in shared decision making, based on an informed understanding of each treatment option, and its potential benefits and risks. This quality statement applies to the care described throughout this Clinical Care Standard whenever treatment choices are being considered.

What the quality statement means:

For patients. There are several ways to treat heavy menstrual bleeding and each woman has different needs. When discussing your treatment, your doctor will give you information about your condition and the options available to you, using plain, non-medical language. You may also be given written information. Your doctor will explain the expected benefits as well as the risks for each
option. The benefits and risks can also be different for each woman. Your doctor will ask you some questions to understand what is important to you, for example, whether you want to become pregnant in the future, and your goals in managing the bleeding. Your preferences are an important part of the decision-making process which should involve both you and your doctor. Your treatment needs or wishes may change over time, and you may have more than one discussion about your condition.

For clinicians. Provide women with information about their condition and the treatment options suitable to them using plain language and non-medical jargon. Ensure that clearly written patient information is available for those who prefer it. Inform women of the benefits and risks of possible treatments, including short- and long-term complications, and the possibility of treatment failure. Ask women about their quality of life concerns and treatment goals to help guide shared decision making and identify treatment that is both clinically appropriate and acceptable to the woman.

For health services. Ensure that policies and protocols enable a consumer-focused approach when information is given to women with heavy menstrual bleeding, including women from culturally diverse and non-English-speaking backgrounds. Written patient information resources should be clinically accurate, evidence-based, provide information about both benefits and risks, be suitable to your health service’s patient population and easy to understand. Support clinical staff and patients to participate in shared decision making and clarify how this applies in the management of women with heavy menstrual bleeding. Note: For acute health services, the care described in this quality statement is consistent with the requirements of the National Safety and Quality Health Service (NSQHS) Standards²⁴ to support patients to be partners in their care and participate in shared decision making.
Indicators for Quality Statement 4 – Informed choice and shared decision making

Indicator 4
Evidence of local arrangements to ensure that consumer information is available for heavy menstrual bleeding and it is provided to women presenting with these symptoms and/or diagnosed with this condition.

Notes
Arrangements should specify that the consumer information is available, up-to-date, and is provided to women at an identified point in the care process (e.g. at presentation or following assessment and diagnosis). The information should be from a clinically appropriate source (e.g. the Royal Australian College of General Practitioners or the Royal Australian and New Zealand College of Obstetricians and Gynaecologists), or adapted from such a source (and updated in line with the original source).

Data source
Local data collection (i.e. practice or service level audit of the existence of local arrangements).
Quality statement 5 – Initial treatment is pharmaceutical

A woman with heavy menstrual bleeding in whom malignancy and significant pelvic pathology have been ruled out, is offered pharmaceutical treatment initially, taking into account evidence-based guidelines, her individual needs and any associated symptoms.

Purpose

To ensure that women with heavy menstrual bleeding but without evidence of uterine pathology or malignancy are offered appropriate pharmaceutical therapy before procedural or surgical options are considered.

What the quality statement means:

For patients. If your doctor’s assessment does not suggest any physical abnormality, you will be offered a pharmaceutical treatment. These include medicines that are taken by mouth and delivered in other ways, for example through a device placed inside your uterus. The treatments that are suitable for you will depend on a number of factors such as whether you want to avoid pregnancy, whether you have normal menstrual cycles and any other health conditions. Your doctor will also consider other problems associated with your bleeding, such as period pain. Your doctor will tell you about the treatment options, explain the expected benefits and possible side effects, and ask about your preferences so that you can decide. If the first pharmaceutical treatment you try is not satisfactory, you can return to your doctor to discuss different options.

For clinicians. If structural or histological causes such as large fibroids, malignancy or hyperplasia have been excluded through history, examination and/or investigations, then the first-line treatment of heavy menstrual bleeding is pharmaceutical, and includes hormonal and non-hormonal options. Advise women on the pharmaceutical options available to them based on clinical needs and treatment preferences, taking into account guideline recommendations regarding efficacy, adverse effects and dosing. Choice of therapy will be influenced by the cause of the bleeding (e.g. anovulatory cycles) and associated problems (e.g. dysmenorrhoea or anaemia) and the woman’s contraceptive needs. The UK’s National Institute for Health and Care Excellence states that if both hormonal and non-hormonal are acceptable, treatments can be considered in the following order, based on evidence of effectiveness and adverse effects:

- levonorgestrel-releasing intra-uterine system
- tranexamic acid or nonsteroidal anti-inflammatory drugs (NSAIDs) or combined oral contraceptives
- norethisterone from days 5 to 26 of the menstrual cycle, or injected long-acting progestogens

Explain what to expect from medical therapy and inform women about possible side effects to help with both choice and adherence. Advise women to return for review if the first treatment chosen is unsatisfactory.

For health services. Policies and pathways for the treatment of heavy menstrual bleeding should support pharmaceutical treatment as first-line in the absence of any structural or histological abnormality. Ensure clinicians have access to relevant evidence-based prescribing guidelines for the choice of therapy and dosing.

Indicators for Quality statement 5

No indicators were identified to support this quality statement.
Quality statement 6 – Choice of pharmaceutical treatment

When pharmaceutical treatment is being considered, the woman is offered the levonorgestrel intra-uterine system if clinically appropriate, as it is the most effective option for managing heavy menstrual bleeding.

Purpose

To ensure that the levonorgestrel intra-uterine system is offered to a woman if it is clinically appropriate, so that she has the opportunity to choose this treatment if she wishes.

What the quality statement means:

For patients. When selecting a pharmaceutical treatment, your doctor will consider whether the levonorgestrel intra-uterine system (brand name Mirena®) may be suitable for you. This is a hormonal treatment that is released from a small plastic device placed inside your uterus, which can be left in place for up to five years. It is also a contraceptive. Studies in large numbers of women show that it is effective compared with other treatments. However, it is not suitable for everyone. If it is an option for you, your doctor will suggest it, explain how it works, its benefits and possible side effects. You may choose not to use this treatment. The device needs to be inserted by a trained health professional, so sometimes you will be referred to another doctor or service for this to occur.

For clinicians. When considering pharmaceutical treatments, offer the levonorgestrel intra-uterine system to women whenever it is clinically suitable, in view of its evidence of greater effectiveness and satisfaction compared to other prescribed treatments.26 Factors to consider in assessing clinical appropriateness include whether a long-acting contraceptive is suitable for the woman considering her desire for pregnancy in the next few years, her age, parity, contraindications and precautions to use, adverse effects, the size and shape of the uterine cavity and the acceptability of treatment to the woman. Explain what to expect and inform women about possible side effects when discussing this treatment option. If necessary, refer the woman to a trained practitioner for insertion of the device.

For health services. Health services that regularly treat women with heavy menstrual bleeding should have effective and appropriate arrangements in place for providing women with the levonorgestrel intra-uterine system, either on-site or through referral if there is no suitably trained clinician within the service.
Indicators for Quality Statement 6 – Choice of pharmaceutical treatment

Indicator 6a
Evidence of local arrangements to ensure that service providers have networks in place to refer women for the fitting of a levonorgestrel-releasing intra-uterine system if this is not provided within the referring service.

Data source
Local data collection (i.e. practice- or service-level audit of the existence of local arrangements).

Indicator 6b
The proportion of women who have been assessed as being suitable for a levonorgestrel-releasing intra-uterine system and have agreed to have one fitted, who have one fitted locally or are referred to an alternative provider to have one fitted.

Numerator
The number of women with heavy menstrual bleeding assessed as being suitable for a levonorgestrel-releasing intra-uterine system and have agreed to have one fitted, who have one fitted locally or are referred to an alternative provider to have one fitted.

Exclusions
1. Women with suspected or confirmed structural or histological abnormalities.

2. Women who are not suitable for a levonorgestrel-releasing intra-uterine system for other reasons or do not agree to have one fitted.

Denominator
The number of women with heavy menstrual bleeding assessed as being suitable for a levonorgestrel-releasing intra-uterine system and who have agreed to have one fitted.

Exclusions
1. Women with suspected or confirmed structural or histological abnormalities.

2. Women who are not suitable for a levonorgestrel-releasing intra-uterine system for other reasons or do not agree to have one fitted.

Data source
Local data collection (i.e. chart audit – electronic or paper, depending on data collection by the practice, service or practitioner).
Quality statement 7 – Uterine-preserving alternatives to hysterectomy

A woman who has heavy menstrual bleeding of benign causes and who is considering surgical intervention is offered a uterine-preserving procedure if clinically appropriate (e.g. endometrial ablation, removal of local pathology). The woman receives information about procedures that may be suitable and is referred appropriately.

Purpose

To ensure that when surgical options are being considered by a woman, she is informed about the least invasive procedures that may be appropriate in her clinical situation – and if necessary, she is referred to a suitable practitioner for individual assessment and treatment.

What the quality statement means:

For patients. Most women will be able to successfully manage their heavy menstrual bleeding without surgery. However, in some circumstances, you may want or need to find out about the surgical options. The first procedures to consider are those that will leave your uterus in place. The procedures that may be suitable for you will depend on the cause of your bleeding, and whether you wish to become pregnant in the future. For example:

- Endometrial ablation (removal of the tissue lining your uterus) is a common and effective procedure for heavy menstrual bleeding, but is not suitable if you may want to become pregnant in the future.
- If the bleeding is caused by growths in your uterus, such as fibroids or polyps, it may be possible to have a procedure to remove or destroy these without removing your uterus. However, if you are hoping to become pregnant in the future, talk to your specialist about the possible effects of these procedures on your fertility.

Your doctor will provide you with information about procedures which may be suitable for you. In some cases they may not conduct these procedures themselves but refer you to another specialist for further assessment and treatment.

For clinicians. When surgical options are being considered, assess the suitability of the least invasive procedures appropriate to the woman’s clinical situation, including endometrial ablation and/or removal of any local pathology causing the bleeding (leiomyoma and polyps). Where uterine pathology is present, the appropriate technique will depend on the woman’s individual circumstances and may include hysteroscopic resection, myomectomy or fibroid-necrosing procedures (e.g. uterine artery embolisation). If the woman would prefer a treatment choice that you are unable to provide, refer her to a suitably qualified practitioner for assessment.

For health services. Health services that provide hysterectomy to women with heavy menstrual bleeding should have protocols and systems in place to provide women with access to less invasive procedural alternatives, taking into account individual clinical appropriateness and current recommendations of best practice. These procedures might include endometrial ablation, hysteroscopic resection, myomectomy or uterine artery embolisation for women, according to the specific pathology. When these procedures are not provided within the health service, then policies and systems should support referral to an appropriately qualified practitioner.
Indicators for Quality Statement 7 – Uterine-preserving alternatives to hysterectomy

Indicator 7
Local arrangements are in place to regularly measure women’s satisfaction with the decision-making process when choosing surgical treatment for heavy menstrual bleeding, and to act on the results.

Data source
Local data collection (i.e. practice- or service-level audit of the existence of local arrangements).
Quality statement 8 – When to consider hysterectomy

Hysterectomy is discussed with a woman who has heavy menstrual bleeding of benign causes when other treatment options fail, are unsuitable or are declined. A woman considering a hysterectomy is given balanced information about the risks and benefits.

Purpose

To ensure the judicious use of hysterectomy for women with heavy menstrual bleeding and that women understand the risks and benefits before electing to have the procedure.

What the quality statement means:

For patients. Hysterectomy (surgery to remove the uterus, or womb) is one way to stop heavy menstrual bleeding. Although it is effective, a hysterectomy is a major operation which cannot be reversed and has short- and long-term risks. While the chances of a complication are generally low, the short-term risks include infection, blood loss requiring a transfusion, and other surgical complications. Long-term risks include urinary incontinence and the hormonal changes and consequences of early menopause, especially if your ovaries are removed.

If other treatments might be suitable, your doctor will explore these options with you first. However if the alternative treatments are not recommended in your situation, haven’t worked for you, or you would prefer not to have them, your doctor may talk with you about having a hysterectomy. If you are thinking about having a hysterectomy for any reason, your doctor will explain what is involved in having the procedure, its potential benefits and possible complications or unwanted effects. This is so that you can make an informed choice about whether you want to have the procedure.

For clinicians. Before considering a hysterectomy, offer less invasive, clinically appropriate treatment options, referring women accordingly if required. Discuss hysterectomy as a treatment option when a woman has heavy menstrual bleeding of benign causes, and alternative medical and procedural options cannot be used for clinical reasons, have proven ineffective or intolerable, or the woman prefers not to have them. When a woman is considering a hysterectomy, provide balanced information so that she is fully informed of the short- and long-term risks and potential benefits, and is given the opportunity to decide based on this information.

For health services. Ensure that systems and processes are in place to support the use of less invasive medical and procedural treatment alternatives to hysterectomy for women with heavy menstrual bleeding, and that these are systematically considered and offered before hysterectomy, as appropriate to the woman’s clinical needs. Ensure that women who are considering a hysterectomy, or making a decision about having the procedure, are provided with information about the risks and benefits in a way that is meaningful to them, to enable them to make an informed decision.
**Indicators for Quality statement 8 – When to consider hysterectomy**

**Indicator 8a**
The proportion of women who are offered medical, surgical or other interventions as an alternative to hysterectomy for their heavy menstrual bleeding.

<table>
<thead>
<tr>
<th>Numerator</th>
<th>The number of women with documented evidence of being offered medical, surgical or other interventions as an alternative to hysterectomy for their heavy menstrual bleeding.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>The number of women undergoing treatment for heavy menstrual bleeding.</td>
</tr>
<tr>
<td>Data source</td>
<td>Local data collection (i.e. chart audit – electronic or paper, depending on data collection by the practice, service or practitioner)</td>
</tr>
</tbody>
</table>

**Indicator 8b**
Hysterectomy rate.

| Notes | Hysterectomy procedures associated with a cancer diagnosis will not be included in the rate. Any non-cancer-related hysterectomy will be included. |
| Numerator | The number of hysterectomy episodes that would occur if the age-specific rates of hysterectomy from this hospital were applied to the national reference population (by peer hospital group), multiplied by 100. |
| Denominator | The number of episodes from the national reference population (by peer hospital group). |

**Note**
The Commission will provide the national rates for the denominator, which can be used by hospitals for peer group comparison. The national rates are not benchmarks, and are not the desired results for this indicator. They are provided as a reference to allow hospitals to review their hysterectomy rate compared with other Australian hospitals, and to consider the possible reasons for any differences.

| Data source | Hospital patient administration systems. |

**Additional indicator to support local monitoring of the Clinical Care Standard**

**Indicator 9**
Local arrangements are in place to regularly measure women’s satisfaction with symptom control and quality of life related to their heavy menstrual bleeding, and to act upon these results.

| Data source | Local data collection (i.e. practice- or service-level audit of the existence of local arrangements). |
Glossary

Abnormal uterine bleeding
Any variation from the normal menstrual cycle, including changes in regularity and frequency of menses, duration of flow, or amount of blood loss. It may be acute or chronic.1-5

Acute abnormal uterine bleeding is an episode of bleeding in a woman of reproductive age who is not pregnant, that is of sufficient quantity to require immediate intervention to prevent further blood loss.

Chronic abnormal uterine bleeding is bleeding from the body of the uterus (corpus) that is abnormal in duration, volume, and/or frequency and has been present for the majority of the last six months.4

Adverse effects
See ‘side effects’.

Anovulatory
An anovulatory cycle is a menstrual cycle in which ovulation fails to occur.2

Assessment
A clinician’s evaluation of the disease or condition, based on the patient’s report of the symptoms and course of the illness or condition, on information reported by family members and other healthcare team members, and on the clinician’s objective findings (including data obtained through tests, physical examination, medical history, and information reported by family members and other healthcare team members).27

Benign
Not malignant (that is, not cancerous).

Carers
People who provide care and support to family members and friends who have a disease, disability, mental illness, chronic condition, terminal illness or general frailty. Carers include parents and guardians caring for children.24

Clinician
A qualified and trained health professional who spends most of their working hours engaged in clinical practice (that is, in diagnosis and/or treatment of patients including recommending preventive action), for example as a doctor, nurse or allied health professional.27,28

Doctor
See ‘medical practitioner’.

Endometrial ablation
The targeted destruction or removal of the endometrial surface (inner lining of the uterus), using one of several surgical techniques or devices.2,3

Endometrium
The glandular inner layer of the uterus.2

Fibroids
Benign, smooth muscle tumours, most often of the uterus. They vary greatly in size, from millimetres to tens of centimetres, and are associated with heavy periods, pressure symptoms and, occasionally, pain.2 The chance that a woman with uterine fibroids has a cancerous type of tumour (called a leiomyosarcoma) is very small.29

Health service
A service responsible for the clinical governance, administration and financial management of unit(s) providing health care. A service unit involves a grouping of clinicians and others working in a systematic way to deliver health care to patients and can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients’ homes, community settings, practices and clinicians’ rooms.24

Hospital
A licensed facility providing healthcare services to patients for short periods of acute illness, injury or recovery.30
Hysterectomy
Surgical removal of the uterus. There are different types of surgery. Surgery may be performed through an incision in the abdomen, via the vagina or laparoscopically ('keyhole surgery', where the surgery is conducted with the assistance of a small camera probe inserted through small incisions in the abdomen). Hysterectomy may involve the removal of part, or all of the uterus. The fallopian tubes, ovaries, cervix and surrounding tissue are sometimes removed at the same time, depending on the type of operation.31

Hysteroscopy, hysteroscopic
A hysteroscopy is an examination of the uterus using an instrument that allows the doctor to see the inside of the uterus, called a hysteroscope. The hysteroscope is carefully passed through the vagina and cervix, and into the uterus.

Hysteroscopic techniques and procedures are performed using the hysteroscope to view the inside of the uterus while conducting the procedure (e.g. hysteroscopic resection).2

Leiomyomas
See ‘fibroids’.

Levonorgestrel
A synthetic form of the hormone progesterone, a female hormone that plays a role in the menstrual cycle.

Medical practitioner
A medically-qualified person whose primary role is the diagnosis and treatment of physical and mental illnesses, disorders and injuries. This could include general practitioners, medical specialists and non-specialists.

Medicine
A chemical substance given with the intention of preventing, curing, controlling or alleviating disease, or otherwise improving the physical or mental welfare of people. Prescription, non-prescription and complementary medicines, regardless of administration route (e.g. oral, intravenous, intra-articular, transdermal or intrauterine), are included.24

Pharmaceutical treatment
See ‘medicine’.

Primary care
The first level of care or entry point to the healthcare system for consumers. It is multidisciplinary and incorporates office-based practices (e.g. general practice clinics, family planning clinics and sexual health services), community health practice (e.g. clinics, outreach or home-visiting services), emergency services (e.g. ambulance services), community-based allied health services (e.g. pharmacists), services for specific populations (e.g. Aboriginal and Torres Strait Islander or refugee health services, or school health clinics).32

Quality of life
An overall assessment of a person's wellbeing, which may include physical, emotional, and social dimensions, as well as stress level, sexual function, and self-perceived health status.27

Risk factor
A characteristic, condition, or behaviour that increases the possibility of disease or injury.27

Side effect
An effect from a medicine or treatment that is unintended.33

System
The resources, policies, processes and procedures that are organised, integrated, regulated and administered to accomplish the objective of a standard. The system:
- interfaces risk management, governance, operational processes, policies and procedures, including education, training and orientation
- deploys an active implementation plan and feedback mechanisms
- includes agreed protocols and guidelines, decision-support tools and other resource material
- employs a range of incentives and sanctions to influence behaviours and encourage compliance with policy, protocol, regulation and procedures.24
| **Transabdominal ultrasound** | A method of imaging the pelvic organs with the probe applied to the outside of the abdomen (tummy).

| **Transvaginal ultrasound** | A method of imaging the genital tract and pelvic organs in women. With the transvaginal technique, the ultrasound transducer (a handheld probe) is inserted directly into the vagina. It is therefore closer to pelvic structures than with the transabdominal technique.

| **Ultrasound** | A method of imaging parts of the body. The ultrasound machine sends out high-frequency sound waves that bounce off body structures to create a picture on a screen.

| **Uterine artery embolisation** | A procedure for treating uterine fibroids that preserves the uterus. Both uterine arteries are blocked with particles injected via the femoral and uterine arteries. This causes the fibroids to shrink. Uterine artery embolisation is a non-surgical procedure performed by an interventional radiologist.

| **Uterus** | The womb. It is located in a woman’s pelvis, between the bladder and the rectum. The narrow, lower portion of the uterus is the cervix; the broader, upper part is the corpus. The corpus is made up of two layers of tissue (myometrium and endometrium).
References


