AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE



Heavy Menstrual Bleeding Clinical Care Standard

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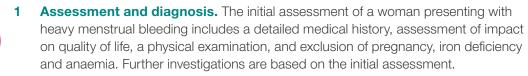
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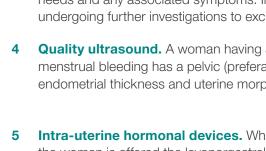
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Heavy Menstrual Bleeding Clinical Care Standard



- 2 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.
- **3 Initial treatment is pharmaceutical.** A woman with heavy menstrual bleeding is offered pharmaceutical treatment, taking into account evidence-based guidelines, her individual needs and any associated symptoms. Initial treatment is provided to a woman who is undergoing further investigations to exclude malignancy and significant pathology.
- Quality ultrasound. A woman having an ultrasound to investigate the cause of her heavy menstrual bleeding has a pelvic (preferably transvaginal) ultrasound, which assesses endometrial thickness and uterine morphology in days 5–10 of her menstrual cycle.
- **Intra-uterine hormonal devices.** When pharmaceutical treatment is being considered, the woman is offered the levonorgestrel intra-uterine system if clinically appropriate, as it is the most effective medical option for managing heavy menstrual bleeding.
- 6 **Specialist referral.** A woman with heavy menstrual bleeding is referred for early specialist review when there is a suspicion of malignancy or other significant pathology based on clinical assessment or ultrasound. Referral is also arranged for a woman who has not responded after six months of medical treatment.
- 7 Uterine-preserving alternatives to hysterectomy. A woman who has heavy menstrual bleeding of benign causes and who is considering surgical management is offered a uterine-preserving procedure, if clinically appropriate. The woman receives information about procedures that may be suitable (such as endometrial ablation or removal of local pathology) and is referred appropriately.
- 8 **Hysterectomy.** Hysterectomy for management of heavy menstrual bleeding is discussed when other treatment options are ineffective or are unsuitable, or at the woman's request. A woman considering a hysterectomy is given balanced information about the risks and benefits of the procedure before making a decision.







About the 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. The quality statements are linked to a number of indicators that can be used by health services to monitor how well they are implementing the care recommended in the clinical care standard. A clinical care standard differs from a clinical practice guideline; rather than describing all the components of care for managing a clinical condition, the quality statements address priority areas for improvement.

Each clinical care standard intends to support key groups of people in the healthcare system in the following ways:

- The public will have a better understanding of what care should be offered by the healthcare system, and will be better able to make informed treatment decisions in partnership with their clinician
- Clinicians will be better able to make decisions about appropriate care
- Health services will be better able to examine the performance of their organisation and make improvements in the care they provide.

This clinical care standard was developed by the Australian Commission on Safety and Quality in Health Care (the Commission) in collaboration with consumers, clinicians, researchers and health organisations, many of whom participated in the Heavy Menstrual Bleeding Clinical Care Standard Topic Working Group. 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 and the indicators, including the evidence base for the quality statements, visit: <u>www.safetyandquality.gov.au/ccs</u>.

Introduction

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

Periods are a very personal experience and women who have always had heavy periods will often consider this is normal. Symptoms such as flooding through clothing, being unable to leave the house on the heaviest days, and having to change pads and tampons frequently (including at night) are indicative of heavy menstrual bleeding.

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 pathology³, and many women who seek medical help do so because of disabling pain.⁴

Despite being a common presentation, the causes of heavy menstrual bleeding are diverse and some women have more than one cause. Terms such as 'dysfunctional uterine bleeding' and 'menorrhagia' are no longer recommended. Instead, abnormal uterine bleeding is described by its presentation (flow, frequency and timing), and categorised into structural and non-structural causes according to the PALM-COEIN classification (Figure 1).^{5,6} Heavy menstrual bleeding is the most common presentation of abnormal uterine bleeding in pre-menopausal women.^{5,7}

The range of management options for heavy menstrual bleeding has expanded and improved since the 1970s and 1980s, when rates of hysterectomy for menstrual disorders were first observed to be relatively high and to vary considerably between regions.^{8,9} Although hysterectomy remains an option, it is not generally recommended for first-line management unless less invasive options are unsatisfactory or are inappropriate.²

Among procedures monitored by the Australian Institute of Health and Welfare, hysterectomy is associated with the second highest rate of unexpected readmissions to hospital after surgery.¹⁰ Short-term complications include infection, bleeding, bowel or urinary tract injury and general surgical complications. Longer-term complications depend partly on the approach to surgery, but include urinary incontinence, pelvic organ prolapse and, if the ovaries are removed, early menopause.^{7,11-14}

While hysterectomy rates have fallen worldwide since the 1990s^{9,15-17}, Australia has higher rates than comparable countries. In 2008, there were 230 hysterectomies per 100,000 women in Australia, compared with 178 in New Zealand and 149 in England (for cancer and non-cancer diagnoses).¹⁸

Within Australia, for non-cancer diagnoses, the Commission's Australian Atlas of Healthcare Variation and Second Australian Atlas of Healthcare Variation have identified:

- Variation between local areas in agestandardised rates of hysterectomy and endometrial ablation^{19,20}
- Up to 20.5-fold variation between areas with the highest and lowest rates for endometrial ablation²⁰
- Up to 6.6-fold variation for hysterectomy²⁰
- Higher rates of hysterectomy in regional areas than in metropolitan areas.^{18,20}

These data suggest 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 range of suitable and effective therapeutic options. For some women – for example, women with large fibroids – hysterectomy may be the most suitable option for their clinical circumstances. Many others will make their choice according to their personal circumstances and preferences.

Clinicians and health services can support women to make the choice that is right for them, by providing balanced information about the treatment options and helping women to get access to the care they want.

Appropriate care begins at the first assessment. A comprehensive history and systematic assessment is essential to guide investigation of possible causes and management. Individual factors including age, the duration and nature of bleeding, symptoms and co-morbidity assist in diagnosis.

Some causes of heavy menstrual bleeding can be identified through investigations, but the most common non-structural cause is thought to be a disorder of local blood clotting mechanisms in the endometrium (the lining of the uterus), for which no test exists.⁵ About 30% of women with heavy menstrual bleeding have fibroids, and approximately 10% have polyps.¹¹ Malignancy in these structures or in the endometrium itself is not commonly associated with heavy menstrual bleeding in pre-menopausal women, but the risk is elevated for women with certain characteristics.^{11,21} An appropriately-timed transvaginal ultrasound is the first-line imaging for suspected structural abnormalities. Other diagnostic tests may be warranted when suggested by the history, including laboratory testing for haemostatic disorders (such as von Willebrand's disease), particularly in adolescents and those with a history of heavy bleeding since menarche (the first occurrence of menstruation).⁷

Given that women with heavy menstrual bleeding are a high-risk group for iron-deficiency anaemia^{22,23}, early screening is likely to improve detection and management. Considerable depletion in iron stores may be present with a normal haemoglobin concentration, and iron deficiency – with or without anaemia – should be addressed.^{24,25} This is particularly important in women considering surgery, to avoid post-operative anaemia and the risks of blood transfusion.²⁶

Pharmaceutical treatment is effective for many women, and as many as 80% of women without significant uterine pathology may avoid surgical intervention for at least five years by using the long-acting intrauterine progestogen device²⁷, which is the most effective medical treatment.²⁸ Less invasive procedural interventions include endometrial ablation (surgical removal of the lining of the uterus) and the removal or destruction of fibroids or polyps using surgical or radiological techniques.

As each option has potential benefits and risks, informed choice and shared decision making are essential components of this clinical care standard.

Figure 1: International Federation of Gynecology and Obstetrics (FIGO) classification system for causes of abnormal uterine bleeding (PALM-COEIN)⁵

Abnormal uterine bleeding (including heavy menstual bleeding)*

Structural causes (PALM)	Non-structural causes (COEIN)
P – Polyps	C – Coagulopathy
A – Adenomyosis	o – Ovulatory
L – Leiomyoma (fibroids)	E – Endometrial
M - Malignancy or hyperplasia	I – latrogenic
	N - Not yet classified

*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.

Goal

To ensure that women with heavy menstrual bleeding are offered the least invasive and 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.

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 either before or at the menopause. While the standard is broadly applicable to adolescents with heavy menstrual bleeding, these patients have specific needs and may need earlier specialist review. The standard is relevant to the care provided in primary care settings including general practice, family planning and sexual health services, as well as that provided in public and private specialist gynaecology clinics and practices, hospitals and radiology 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.

Evidence sources

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), and the Society of Obstetricians and Gynaecologists of Canada.^{2,7}

General principles of care

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.²⁹

Clinical care standards support the principles of patient-centred care, namely:

- Treating patients with dignity and respect
- Encouraging patient participation in decision-making
- Communicating with patients about their clinical condition and treatment options
- Providing patients with information in a format that they understand to help them participate in decision-making.³⁰

Carers and families

Carers and family members have an important role in the prevention, early recognition, assessment and recovery of patients' health conditions. They often know the patient very well, and can provide detailed information about the patient's history, routines or symptoms, which may assist in determining the best treatment and ongoing support.²⁹

Although this clinical care standard does not specifically refer to carers and family members, each quality statement should be understood to mean that carers and family members are involved in clinicians' discussions with patients about their care, if the patient prefers carer involvement.

Competencies and service capability

This clinical care standard recognises that the suitability of a specific surgical procedure or approach depends both on the individual characteristics of the person undergoing surgery as well as the scope of clinical practice of the clinician. Safety and quality of care may be at risk if the workforce does not have the appropriate skills or experience.³¹ The procedural, surgical, imaging and radiological skills required for managing heavy menstrual bleeding should be considered in the context of the clinical service capacity of the organisation and its clinical services planning.^{32,33}

Using the clinical care standard

An integrated approach to delivering care

Central to the delivery of patient-centred care identified in this clinical care standard is an integrated, systems-based approach, supported by individual health services and networks of services with resources, policies, processes and procedures.

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 acute hospital and pre-hospital services, primary care and other community and support services
- Clear lines of communication between 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.

To achieve these aims, systems or organisations implementing the standard may need to:

- Deploy an active implementation plan and feedback mechanisms
- Include agreed protocols and guidelines, decision-support tools and other resource material
- Employ a range of incentives and sanctions to influence behaviours and encourage compliance with policies, protocols, regulation and procedures
- Consider interfaces with risk management, governance, operational processes and procedures, including education, training and orientation.³²

Indicators to support local monitoring

The Commission has developed a set of indicators to support healthcare 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. There are no benchmarks set for any of the indicators. Where comparison to a national reference population would assist in local monitoring, this information will be incorporated into the indicator calculation. This is the case for hysterectomy rates (Indicator 8 in this clinical care standard). However, this does not constitute or imply a national benchmark. For other indicators, healthcare providers can compare their results against themselves during a previous period, or with other healthcare providers with whom they have made such arrangements.

Most of the data underlying these indicators require collection from local sources, chiefly through prospective collection or a retrospective chart review. Some indicators refer to 'local arrangements'. These can include clinical guidelines, protocols, care pathways or any other documentation providing guidance to clinicians on the care of patients with heavy menstrual bleeding.

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 http://www.safetyandquality.gov.au/our-work/assessment-to-the-nsqhs-standards.

The process to develop the indicators specified in this document comprised:

- An environmental scan of existing local and international indicators
- Prioritisation, review and refinement of the indicators with a dedicated sub-committee of the Heavy Menstrual Bleeding Clinical Care Standard Topic Working Group, and review by the Topic Working Group.

Where to find the indicator specifications

In this document, the indicator titles and hyperlinks to the specifications are included with the relevant quality statement under the heading *Indicators for local monitoring*.

Full specifications of the *Heavy Menstrual Bleeding Clinical Care Standard* indicators can be found in the Metadata Online Registry (METeOR) at <u>http://meteor.aihw.gov.au/</u> <u>content/index.phtml/itemld/666572</u>

METeOR is Australia's web-based repository for national metadata standards for the health, community services and housing assistance sectors. Hosted by the Australian Institute of Health and Welfare (AIHW), METeOR provides users with online access to a wide range of nationally endorsed data and indicator definitions.

Supporting documents

The following supporting information for this clinical care standard is available on the Commission's website at **www.safetyandquality.gov.au/ccs**:

- A consumer fact sheet
- A clinician fact sheet
- An evidence sources document
- A link to the set of indicators to support local monitoring.



Quality statement 1 Assessment and diagnosis

The initial assessment of a woman presenting with heavy menstrual bleeding includes a detailed medical history, assessment of impact on quality of life, a physical examination, and exclusion of pregnancy, iron deficiency 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 clinician 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. With your consent, your clinician will carry out an internal physical examination to feel your uterus by placing their fingers inside your vagina. They will recommend a pregnancy test (if there is any chance you are pregnant), and tests for iron deficiency (a lack of iron) and anaemia (a lack of red blood cells). Whether you need any other tests will depend on your individual assessment, but these may include blood tests, a cervical screening test, or an ultrasound.



For clinicians

When assessing a woman with heavy menstrual bleeding, a detailed medical history should take into account the diverse possible causes (listed in Figure 1), and other diagnoses (such as endometriosis or miscarriage). The history should include the following^{2,7}:

- The woman's sexual and reproductive health, her desire for future fertility and cervical screening status
- The duration, timing, heaviness and chronicity of the bleeding and its impact on her daily activities and quality of life (post-coital and inter-menstrual bleeding are different to heavy menstrual bleeding and require investigation)
- Symptoms including pelvic pain or pressure, and fatigue
- Symptoms suggesting a bleeding disorder
- Symptoms associated with polycystic ovary syndrome (PCOS) including acne, hirsutism and irregular bleeding

- Symptoms suggesting thyroid disease (hypothyroidism)
- Risk factors for endometrial cancer³⁴
- Iron deficiency, with or without anaemia.

Conduct a bi-manual pelvic examination to identify any palpable mass or abnormal uterine size, unless this would be clinically inappropriate.

Exclude pregnancy with a urinary beta HCG if indicated. Routinely exclude iron deficiency and anaemia with serum ferritin and a full blood count. Other investigations will depend on a careful history and presentation, and might include testing for haemostatic disorders (such as von Willebrand's disease), thyroid dysfunction, a cervical screening test³⁵ (if clinically indicated) and ultrasound for assessment of uterine abnormalities. Refer to current guidelines.^{7,11,34}



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, iron deficiency 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. Local protocols or guidelines should clarify when to test for haemostatic disorders or thyroid dysfunction, and when to carry out an appropriate cervical screening test, or request an ultrasound, as these are not required for all women presenting with heavy menstrual bleeding.

Indicator for local monitoring

Indicator 1: Proportion of patients with heavy menstrual bleeding who are tested for iron deficiency and anaemia.

METeOR link: http://meteor.aihw.gov.au/content/index.phtml/itemId/667295

More information about this indicator and the definitions needed to collect and calculate it can be found online in the above METeOR link.



Quality statement 2 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 clinician will give you information about your condition and the options available to you, using plain, non-medical language. You can ask the health service to arrange a translator if this would help you. You may also be given written information. Your clinician will explain the expected benefits as well as the risks for each option, and will ask you questions such as whether you want to become pregnant in the future and what your goals for treatment are. Your preferences are an important part of the decision-making process, which should involve both you and your clinician.



For clinicians

To achieve informed choice and shared decision making:

- Provide women with information about their condition and their treatment options in a way that is suitable to them, using plain language and non-medical jargon
- Ensure that clearly written patient information is available for those who prefer it
- Take into account cultural and religious considerations, and use an interpreter if communicating is difficult
- Inform women of the benefits and risks of possible treatments, including side effects and complications, and the possibility of treatment failure
- Ask women about their quality-of-life concerns and treatment goals to help identify treatment that is both clinically appropriate and acceptable to the woman.



For health services

Ensure that policies and protocols support informed choice and shared decision making. This will include:

- Taking a consumer-focused approach to providing information to women with heavy menstrual bleeding, including women from culturally diverse and non-English-speaking backgrounds
- Ensuring that clearly written patient information resources are available which are clinically accurate, evidence based, easy to understand, suitable for your health service's patient population and which provide information about both benefits and risks
- Supporting clinical staff and patients to participate in shared decision making and clarifying how this applies in the management of women with heavy menstrual bleeding
- Putting in place policies to facilitate referral and access to services that a woman may prefer, but which are not offered in the health service.

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) Standards to support patients to be partners in their care and participate in shared decision making.³²

Indicator for local monitoring

Indicator 2: Local arrangements for the provision of consumer-focused information about heavy menstrual bleeding. METeOR link: <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/667300</u>

More information about this indicator and the definitions needed to collect and calculate it can be found online in the above METeOR link.



Quality statement 3 Initial treatment is pharmaceutical

A woman with heavy menstrual bleeding is offered pharmaceutical treatment, taking into account evidence-based guidelines, her individual needs and any associated symptoms. Initial treatment is provided to a woman undergoing further investigations to exclude malignancy and significant pathology.

Purpose

To ensure that women with heavy menstrual bleeding are offered appropriate pharmaceutical therapy before procedural or surgical options are considered, and that those undergoing further investigations are offered preliminary treatment for symptom relief.

What the quality statement means



For patients

Your clinician will usually suggest medicines to relieve your heavy menstrual bleeding. Which medicine is suitable for you will depend on several factors, such as whether your period is regular, whether you need contraception and your other health conditions. There are several options, including medicines that are swallowed and those delivered in other ways, such as by using a small device placed inside your uterus.

Your clinician will explain the treatment options, their expected benefits and possible side effects, and ask about your preferences. If the first medicine you try is not satisfactory, you can return to your clinician to discuss other options.

Your clinician may want you to have investigations to look for fibroids (non-cancerous growths) or to rule out cancer. If tests are recommended, the treatment provided may be temporary, but should give you relief while you are waiting for the necessary medical appointments. Later, a different treatment may be recommended.



For clinicians

Women with heavy menstrual bleeding may be offered pharmaceutical treatment at their initial presentation to decrease blood loss in subsequent menstrual cycles, even when further investigations are planned. Many women with heavy menstrual bleeding may be effectively managed with pharmaceutical treatment alone. If significant pelvic pathology and malignancy are not suspected, or have been excluded, the choice of therapy will be influenced by whether the bleeding is ovulatory or anovulatory, associated problems (e.g. dysmenorrhoea), whether the woman is trying to conceive, and individual needs and preferences. If both hormonal and non-hormonal therapy are acceptable, consider treatments in the following order, based on evidence of effectiveness and adverse effects:

- Levonorgestrel-releasing intra-uterine system (LNG-IUS)
- Tranexamic acid or non-steroidal anti-inflammatory drugs (NSAIDs) or combined oral contraceptives
- Cyclic norethisterone or injected long-acting progestogens.²

If a woman requires further investigations in order to exclude malignancy or significant pathology, prescribe initial oral treatment to relieve symptoms, bearing in mind that she may need symptom relief while waiting for appointments. Treatment can be reviewed following investigations.

Advise women on the pharmaceutical options available and explain what to expect from therapy, including possible side effects. Informing women and involving them in the treatment choice can assist with patient satisfaction and adherence. Advise women to return for review if the first treatment chosen is unsatisfactory. Refer to the Australian Medicines Handbook³⁶ or clinical guidelines for information regarding efficacy, contraindications, adverse effects and treatment regimens.^{2,37}



For health services

Policies and pathways for the treatment of heavy menstrual bleeding should support pharmaceutical treatment as first-line therapy in the absence of any structural or histological abnormality, and recommend suitable oral medicines for symptom relief in women referred for further investigations. Ensure clinicians have access to relevant evidence-based prescribing guidelines for the choice of therapy and dosing.^{2,37}

Indicator for local monitoring

Indicator 3: Proportion of patients with heavy menstrual bleeding who are offered pharmaceutical treatment. **METeOR link:** <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/667302</u>

More information about this indicator and the definitions needed to collect and calculate it can be found online in the above METeOR link.



Quality statement 4 Quality ultrasound

A woman having an ultrasound to investigate the cause of her heavy menstrual bleeding has a pelvic (preferably transvaginal) ultrasound, which assesses endometrial thickness and uterine morphology in days 5–10 of her menstrual cycle.

Purpose

To optimise the quality of imaging undertaken when screening for uterine and endometrial abnormalities in order to assist clinical decision-making.

What the quality statement means



For patients

You may have 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 ways of obtaining the ultrasound image. One method involves the ultrasound operator placing a narrow ultrasound probe in your vagina. This is called a transvaginal ultrasound, and is preferred because it provides a better view of the uterus and pelvic structures. 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. Ideally, both methods will be used. However a transvaginal ultrasound may not be possible, or you may choose not to have the ultrasound this way.

Whichever method is used, it is important to have the scan done 5–10 days from the first day of your period. This is when the lining of the uterus is thinnest and the reading will be most accurate. Talk to your clinician if timing the scan will be difficult for you for any reason – for example, because your periods are very irregular, or because you live in an area where it is not easy to have an ultrasound. When booking your scan, ask for an appointment that is 5–10 days from when you expect your period.



For clinicians

Transvaginal ultrasound is the first-line imaging when investigating possible structural or histological causes for heavy menstrual bleeding, such as in women who have an increased risk of malignancy, suspected pathology on examination, or who have not responded to a reasonable duration of optimal medical treatment (approximately six months).^{2,7,38}

Transvaginal ultrasound is usually performed in conjunction with a transabdominal ultrasound.³⁹ If transvaginal ultrasound is not available, is inappropriate (for example, for non-sexually active adolescents), or the woman prefers not to have it, then a transabdominal ultrasound may be performed. However, this method is not as accurate as the transvaginal method, particularly when assessing the endometrium.

Ultrasound performed on days 5–10 of the menstrual cycle allows the most accurate measurement of endometrial thickness, which is used in risk assessment for endometrial hyperplasia and malignancy^{34,40} and improves detection of polyps. Identification of structural abnormalities (including the location of polyps and fibroids) is needed to determine the suitability of procedural interventions or insertion of the LNG-IUS. Advise the woman about the timing of the ultrasound, bearing in mind that this may be difficult for some women (for example, those with unpredictable or irregular cycles) and those in areas with limited access to imaging services. Liaise with service providers where necessary to facilitate the best outcome for women.



For health services

Imaging referral protocols and pathways should ensure that when the cause of heavy menstrual bleeding is being assessed, a transvaginal ultrasound conducted on days 5–10 of the woman's cycle is the recommended imaging.⁴⁰ Transvaginal ultrasound should be available when providing gynaecological services⁴¹ and wherever possible, both transvaginal and transabdominal ultrasound should be performed.³⁹ Service policies and procedures should aim to obtain a good-quality ultrasound on the first scan, taking into account the need to accurately measure and report endometrial thickness (in millimetres), uterine dimensions, and the presence and location of structural abnormalities. Protocols for health services conducting ultrasounds should support the appropriate scheduling of appointments and reporting of ultrasounds for abnormal uterine bleeding.

Indicators for local monitoring

Indicator 4a: Local arrangements for conducting investigative pelvic ultrasound in days 5–10 of the menstrual cycle for patients with heavy menstrual bleeding. **METeOR link:** <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/667306</u>

Indicator 4b: Proportion of patients with heavy menstrual bleeding who have appropriate reporting following an investigative pelvic ultrasound. **METeOR link:** <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/667308</u>

More information about these indicators and the definitions needed to collect and calculate them can be found online in the above METeOR links.



Quality statement 5 Intra-uterine hormonal devices

When pharmaceutical treatment is being considered, a woman is offered the levonorgestrel intra-uterine system if clinically appropriate, as it is the most effective medical 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 and can be referred as necessary.

What the quality statement means



For patients

When selecting a pharmaceutical treatment, your clinician may suggest the levonorgestrel intra-uterine system (for example, the brand name Mirena), if it is 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 can also be used as a contraceptive. Studies in large numbers of women show that it is more effective at reducing blood loss compared with other medicines. However, it is not suitable for everyone and you may choose not to have this treatment.

If it is an option for you, your clinician will explain how it works as well as its benefits and possible side effects. The device needs to be placed in the uterus by a health professional who has been trained to insert intra-uterine devices. This means that sometimes you will be referred elsewhere to have the device fitted, for example to a general practice, family planning clinic or a specialist gynaecology service, depending on the services available in your area.



For clinicians

When considering pharmaceutical treatments, offer the levonorgestrel intrauterine system to women whenever it is clinically suitable, in view of the evidence of greater effectiveness and satisfaction compared with other medical treatments.²⁸ If necessary, refer the woman to a trained practitioner for insertion of the device.

Factors to consider in assessing clinical appropriateness include whether a longacting contraceptive is suitable for the woman, 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 – such as initial spotting or irregular bleeding.



For health services

Health services that regularly treat women with heavy menstrual bleeding should have effective, accessible 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 local monitoring

Indicator 5a: Local arrangements for referral of patients with heavy menstrual bleeding for insertion of a levonorgestrel-releasing intra-uterine system. **METeOR Link:** <u>http://meteor.aihw.gov.au/content/index.phtml/itemld/667313</u>

Indicator 5b: Proportion of patients with heavy menstrual bleeding who are deemed clinically suitable for a levonorgestrel-releasing intra-uterine system and have one inserted or are referred for insertion.

METeOR Link: http://meteor.aihw.gov.au/content/index.phtml/itemId/667319

More information about these indicators and the definitions needed to collect and calculate them can be found online in the above METeOR links.



Quality statement 6 Specialist referral

A woman with heavy menstrual bleeding is referred for early specialist review when there is a suspicion of malignancy or other significant pathology based on clinical assessment or ultrasound. Referral is also arranged for a woman who has not responded after six months of medical treatment.

Purpose

To ensure timely and appropriate referral when there is an increased risk of malignancy or inadequate response to medical treatment.

What the quality statement means



For patients

Heavy menstrual bleeding can often be managed in primary care, usually by a general practitioner (GP) or family planning doctor. However, you may be referred to a specialist if your ultrasound or other background suggests further assessment would be helpful. For example, the ultrasound might identify fibroids or polyps, which are common types of non-cancerous growths that may benefit from specialist treatment. While it is rare for heavy menstrual bleeding to be caused by cancer, your clinician may also want to order tests or other investigations to rule this out.

You might also be referred to a specialist if your bleeding is not improving with prescribed medical treatments. It may take six months to try different options properly, so if there is no improvement after six months you should be referred to a specialist. However, if you have any concerns about your treatment or if it is not helping, you can go back to your primary care clinician at any time.



For clinicians

Early referral is warranted for a woman with heavy menstrual bleeding who has suspicious clinical findings on assessment or ultrasound.³⁴ Risk of malignancy is increased in women with anovulatory cycles, polycystic ovary syndrome, a personal or family history of endometrial or colon cancer, use of unopposed oestrogen or tamoxifen, or who are obese (particularly with comorbid diabetes and/or hypertension).^{34,37} Risk of malignancy increases with age, and increased suspicion is warranted in a woman aged over 45.^{21,42}

Women should also be referred if they have significant pelvic pathology on ultrasound (fibroids or polyps). A lack of response to medical treatment requires further investigation, which should take place if six months of optimal treatment has failed to reduce the bleeding. Some women may warrant earlier referral.



For health services

Ensure that protocols for referral of women with heavy menstrual bleeding allow women with possible or suspected malignancy to be referred early to an appropriate specialist for review. Protocols and pathways should also allow for referral and review of women who have evidence of significant pelvic pathology and those who have not responded to medical therapy after six months of optimal treatment. Secondary health services with referral protocols can use those protocols to advise referring doctors of referral requirements and timeframes.

Indicator for local monitoring

Indicator 6: Local arrangements to ensure timely and appropriate referral to a specialist for patients with heavy menstrual bleeding. **METeOR Link:** <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/667329</u>

More information about this indicator and the definitions needed to collect and calculate it can be found online in the above METeOR link.

Quality statement 7 Uterine-preserving alternatives to hysterectomy

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

If you are considering surgery for heavy menstrual bleeding, 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.

One type of treatment that does not require removing your uterus is called endometrial ablation. This involves removing the tissue lining your uterus, and it is a common and effective procedure for women without large fibroids. After this procedure, it is not safe to get pregnant, so you must avoid any future pregnancy – for example, by using effective contraception.

If the bleeding is caused by fibroids or polyps (non-cancerous growths), there are procedures to remove or destroy these growths without removing your uterus. The risks and benefits will differ for each woman, so discuss these with your doctor, including the impact on your future fertility if you are hoping to become pregnant in the future.

Your doctor will inform you about the options. Some specialists may not conduct these procedures themselves, in which case they may instead 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 procedure appropriate to the woman's clinical situation, including endometrial ablation and/or removal of any local pathology causing the bleeding (fibroids and polyps).

The appropriate technique will depend on the risks and benefits for the woman's specific uterine pathology and clinical presentation, and may include hysteroscopic resection, myomectomy or fibroid-necrosing procedures (such as uterine artery embolisation). If the woman would prefer to consider a treatment choice that you are unable to provide, refer her to a suitably qualified colleague or service 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 of small fibroids or polyps, myomectomy or uterine artery embolisation for women with fibroids, as appropriate according to the specific pathology. When these procedures are not provided within the health service, then policies and systems should support review by an appropriately skilled practitioner.

Indicator for local monitoring

Indicator 7a: Proportion of patients with heavy menstrual bleeding of benign cause(s) who are offered uterine-preserving alternatives to hysterectomy. METeOR Link: <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/667334</u>

More information about this indicator and the definitions needed to collect and calculate it can be found online in the above METeOR link.



Quality statement 8 Hysterectomy

Hysterectomy for management of heavy menstrual bleeding is discussed when other treatment options are ineffective or are unsuitable, or at the woman's request. A woman considering a hysterectomy is given balanced information about the risks and benefits of the procedure before making a decision.

Purpose

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

What the quality statement means



For patients

Hysterectomy (surgery to remove the uterus) is one way to stop heavy menstrual bleeding. While it stops your periods permanently, hysterectomy is a major operation which cannot be reversed. It also has a risk of complications. Hysterectomy will be discussed as an option when alternative treatments are not recommended in your situation, or if alternatives haven't worked for you, or because you have said you would prefer a hysterectomy. Your doctor will explain what the surgery involves, its expected benefits and the possible complications or unwanted effects. This is so you can make an informed choice about the procedure before you decide to go ahead.

After a hysterectomy, you can no longer become pregnant. While many women do not have any complications, there is a risk of infection, blood loss, damage to the bowel or bladder, and other surgical complications. There are different ways to conduct the operation (such as through the abdomen or the vagina). Part or all of the uterus, and less commonly the fallopian tubes and/or ovaries, may be removed. If your ovaries are removed, then you will experience early menopause. Different risks may apply according to your situation and the technique used, which your doctor will discuss with you.



For clinicians

Discuss hysterectomy as a treatment option for a woman with heavy menstrual bleeding of benign causes when alternative medical and procedural options cannot be used for clinical reasons, have proven ineffective or intolerable, or when the woman wishes to consider a hysterectomy.

Provide balanced information so that the woman is aware and informed of the risks and potential benefits, and allow her the time and opportunity to decide, based on this information.

The risks discussed should include: the irreversible nature of the surgery, consequences for childbearing, risk of infection, organ damage and blood loss, as well as the time in hospital and recovery period. Explain any particular risks associated with the type of surgery suggested.



For health services

Ensure that systems and processes are in place to support the use of less invasive 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 a woman who is deciding whether to have a hysterectomy is provided beforehand with information about the risks and benefits in a way that is meaningful to her, so that she can make an informed choice before surgery.

Overall indicators for local monitoring

Indicators for local monitoring

Indicator 8: Hospital rate of hysterectomy per 100 episodes. METeOR Link: <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/667347</u> Note: To enable calculation of this rate, the Commission will supply a tool for use by health services, for calculation of local age-standardised rates and comparison against national reference rates. This tool will be available on the Commission website: see <u>www.safetyandquality.gov.au/ccs</u>

Indicator 9: Local arrangements to measure and act upon patient-reported outcomes related to heavy menstrual bleeding. METeOR Link: <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/667349</u>

More information about these indicators and the definitions needed to collect and calculate them can be found online in the above METeOR links.

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.⁵⁻⁷

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.⁵

Adverse effects

See 'side effects'.

Anovulatory

An anovulatory cycle is a menstrual cycle in which ovulation fails to occur.¹¹

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).⁴³

Benign

Not malignant (that is, not cancerous).

Bi-manual examination

An internal examination of the pelvis, using both hands. With one hand placed on the outside of the woman's lower abdomen, the fingers of the other hand are inserted into the uterus, allowing the clinician to feel the size, shape and position of the uterus using both hands.

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.³²

Clinician

A qualified and trained health professional who provides direct patient care (that is, the diagnosis and/or treatment of patients including recommending preventative action). In this document it may refer to a doctor, nurse or nurse practitioner, depending on the care that is being described and the individual's scope of professional practice.^{43,44}

Doctor

See 'medical practitioner'.

Endometrial ablation

The targeted destruction or removal of the entire endometrial surface (inner lining of the uterus), using one of several surgical techniques or devices.^{7,11}

Endometrium

The glandular inner layer of the uterus.¹¹

Fibroids

Benign, smooth muscle tumours, also called myomas or leiomyomas, 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.¹¹ The chance that a woman with uterine fibroids has a cancerous type of tumour (called a leiomyosarcoma) is very small.⁴⁵

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. It can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms.³²

Hospital

A licensed facility providing healthcare services to patients for short periods of acute illness, injury or recovery.⁴⁶

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 telescope of 5–10mm 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.⁴⁷

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).¹¹

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 intra-uterine), are included.³²

Menarche

When a woman starts having menstrual periods, during puberty.

Pharmaceutical treatment

See 'medicine'.

Nurse practitioner

A nurse practitioner (NP) is a registered nurse with the experience and expertise to diagnose and treat people of all ages with a variety of acute or chronic health conditions. NPs have completed additional university study at Master's degree level and are the most senior clinical nurses in our health care system.⁴⁸

Primary care

The first level of care or entry point to the healthcare system for consumers. It is multidisciplinary and incorporates office-based practices (such as general practice clinics, family planning clinics and sexual health services), community health practice (such as clinics, outreach or home-visiting services), emergency services (such as ambulance services), community-based allied health services (such as pharmacists), services for specific populations (such as Aboriginal and Torres Strait Islander or refugee health services, or school health clinics).⁴⁹

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.⁴³

Risk factor

A characteristic, condition, or behaviour that increases the possibility of disease or injury.⁴³

Side effect

An effect from a medicine or treatment that is unintended. $^{\mbox{\tiny 50}}$

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.³²

Transabdominal ultrasound

A method of imaging the genital tract and pelvic organs in women. With the transabdominal technique, the ultrasound transducer (a handheld probe with a broad flat end) is applied on the outside of the abdomen (tummy).¹¹ The bladder should be comfortably full as this helps the pelvic organs to be seen on the scan.

Transvaginal ultrasound

A method of imaging the genital tract and pelvic organs in women. With the transvaginal technique, the ultrasound transducer (a handheld probe that is narrow and about the width of the thumb) is gently placed into the vagina. It is therefore closer to pelvic structures than with the transabdominal technique and produces better-quality images to aid diagnosis.¹¹

Ultrasound

A method of imaging parts of the body. The ultrasound machine sends out highfrequency sound waves that bounce off body structures to create a picture on a screen.¹¹

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.¹¹

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 neck); the broader, upper part is the corpus (the body). The corpus is made up of two layers of tissue (myometrium and endometrium).¹¹

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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE











The Royal Australian and New Zealand College of Obstetricians and Gynaecologists 's Healtl





Australian Commission on Safety and Quality in Health Care

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Figure 1: International Federation of Gynecology and Obstetrics (FIGO) classification system for causes of abnormal uterine bleeding (PALM-COEIN)⁵

Abnormal uterine bleeding (including heavy menstual bleeding)*

Structural causes (PALM)	Non-structural causes (COEIN)
P – Polyps	C – Coagulopathy
A – Adenomyosis	o – Ovulatory
L – Leiomyoma (fibroids)	E – Endometrial
M - Malignancy or hyperplasia	I – latrogenic
	N - Not yet classified

*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.

Goal

To ensure that women with heavy menstrual bleeding are offered the least invasive and 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.

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 either before or at the menopause. While the standard is broadly applicable to adolescents with heavy menstrual bleeding, these patients have specific needs and may need earlier specialist review. The standard is relevant to the care provided in primary care settings including general practice, family planning and sexual health services, as well as that provided in public and private specialist gynaecology clinics and practices, hospitals and radiology 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.

Evidence sources

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), and the Society of Obstetricians and Gynaecologists of Canada.^{2,7}

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE











The Royal Australian and New Zealand College of Obstetricians and Gynaecologists 's Healtl





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