AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM: D17-26044

October 2017

Consultation Report

Draft Heavy Menstrual Bleeding Clinical Care Standard

Published by the Australian Commission on Safety and Quality in Health Care
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ISBN: 978-1-925665-03-1

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

> Australian Commission on Safety and Quality in Health Care. Consultation Report: Draft Heavy Menstrual Bleeding Clinical Care Standard. Sydney: ACSQHC; 2017

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Introduction

The role of the Australian Commission on Safety and Quality in Health Care (the Commission) is to lead and coordinate national improvements in the safety and quality of health care. The Commission works in partnership with the Australian Government and state and territory health systems to achieve a sustainable, safe and high-quality health system. In doing so, the Commission also works closely with patients, carers, clinicians, managers, policymakers and healthcare organisations, including those in the private sector.

The National Health Reform Act 2011 established the Commission as an independent statutory authority. It specifies that the Commission will formulate and monitor safety and quality standards and work with clinicians to identify best practice clinical care.

The National Health Reform Agreement 2011 identifies that the Commission will work with clinicians to develop clinical standards for ensuring the appropriateness of care for people with specific clinical conditions, and that the Commission will recommend to Health Ministers the clinical standards suitable for implementation as national clinical standards.

The Commission has been working with consumers, clinicians, health managers and researchers to develop the Heavy Menstrual Bleeding Clinical Care Standard.

This report provides a summary of consultation findings regarding the draft Heavy Menstrual Bleeding Clinical Care Standard.

As a result of the consultation, a number of changes were made to the quality statements. This will account for some differences in the ordering, numbering and naming of the quality statements when comparing the consultation draft with the clinical care standard.

About the consultation

The Heavy Menstrual Bleeding Clinical Care Standard was released for public consultation in 2016. The public consultation period ran from 23 November 2016 to 11 January 2017, with a small number of extensions granted through to 30 January 2017. A total of 60 responses were received by the Commission.

The purpose of the consultation was to determine if the draft clinical care standard was appropriately targeted to make the most difference to routine patient care and outcomes, to assess the relevance of suggested indicators and fact sheets, and to identify strategies that could support the sharing and local implementation of the clinical care standard. Stakeholders across Australia were contacted by mail and email and asked to submit feedback on the draft clinical care standard and draft indicators using an online survey tool available on the Commission's website. The Commission also accepted feedback in writing via mail or email.

Those contacted included medical colleges, organisations with a specific interest in the management of heavy menstrual bleeding, state and territory health departments, Local Hospital Networks, Primary Health Networks, consumer groups and private sector organisations. The Commission also promoted the consultation through its website, Twitter account, On the Radar weekly publication and email bulletin. Members of the Heavy Menstrual Bleeding Clinical Care Standard Topic Working Group (TWG) publicised the consultation among their networks.

The consultation documents for this clinical care standard are described below.

1. Draft Heavy Menstrual Bleeding Clinical Care Standard

This document outlines key components of care that should be received by women of reproductive age who experience heavy menstrual bleeding. It covers management from first recognition of clinically significant heavy menstrual bleeding until its resolution either before or at the menopause. Components of care are organised into eight high-priority areas for quality improvement, called quality statements.

The eight draft quality statements for the Heavy Menstrual Bleeding Clinical Care Standard were:

Quality statement 1: Assessment and diagnosis
Quality statement 2: Specialist referral for women with risk factors
Quality statement 3: Quality ultrasound
Quality statement 4: Informed choice and shared decision making
Quality statement 5: Initial treatment is pharmaceutical
Quality statement 6: Choice of pharmaceutical treatment
Quality statement 7: Uterine-preserving alternatives to hysterectomy
Quality statement 8: When to consider hysterectomy.

This clinical care standard applies to all healthcare settings where care is provided to women with heavy menstrual bleeding, 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.

2. Draft consumer and clinician fact sheets

These documents provide summaries of the eight quality statements for consumers and clinicians.

3. Draft set of indicators

This document outlines a set of suggested indicators that have been developed to assist with local implementation of the clinical care standard. These indicators can be used by health services to monitor the implementation of the quality statements and support improvement as needed.

4. Summary of evidence sources

This document contains the evidence sources used to support the clinical care standard, according to each quality statement.

Consultation process

The following sections of the report provide a summary of the consultation process and responses.

Consultation questions

The Commission asked stakeholders to respond to the following six consultation questions:

1. Which two or three quality statements would make the most difference to routine care and outcomes for patients if implemented nationally? Why?

2. Which two or three quality statements would make the least difference to routine care and outcomes for patients if implemented nationally? Why?

3. Is there a component of patient care for this condition that is not covered by the quality statements that should be included? What evidence is there to support your response?

4. Are the proposed indicators useful for local monitoring of the quality statements in your professional setting?

    a. If no, please explain the barriers you see to using any of the proposed indicators, and any advice the Commission should consider in amending the draft indicators.

5. What opportunities do you know of that could be used to raise awareness of this Clinical Care Standard (e.g. activities, events, publications or distribution lists)?

6. What current or planned initiatives are you aware of that may provide opportunities for the implementation of this Clinical Care Standard?

Submissions received

A total of 60 responses were received by the Commission during the consultation period. There were 42 responses by online survey and 18 by email or mail.

A breakdown of the responses is provided in Table 1.

Table 1: Types of respondents

Respondent type	Number of responses
Individual	**30**
Organisations	**30**
Professional association/college/peak body	5
State or territory response	7
Local hospital network/district or public hospital	9
Private hospital	2
Commonwealth agency	2
Women's health organisation	3
Consumer organisation	1
Private insurer	1
Total responses	**60**

Assessment of submissions

Following the close of consultation, the Commission logged and summarised all responses, noting the submission method (online survey or written).

Comments were analysed by consultation question and by quality statement. For written submissions, comments were classified by subject matter into the equivalent consultation question.

Action categories were determined for each comment:

1. No change
2. Change by the Commission (editorial and minor content changes)
3. For consideration by the Topic Working Group (substantive comments about content).

Themes in each action category mainly related to:

1. Suggestions that were not relevant to the Heavy Menstrual Bleeding Clinical Care Standard or did not align with previous discussions of the Topic Working Group (no change)
2. Clarity of language, terminology, alignment of indicators to quality statements, and supporting evidence (change by the Commission)
3. Suggested changes to the
    a) Scope of the Heavy Menstrual Bleeding Clinical Care Standard
    b) Recommendations for managing heavy menstrual bleeding described in the standard
    c) Relevance or importance of a quality statement in view of existing standards of care (all for consideration by the Topic Working Group).

Factors considered in the analysis of consultation comments included whether the comment:

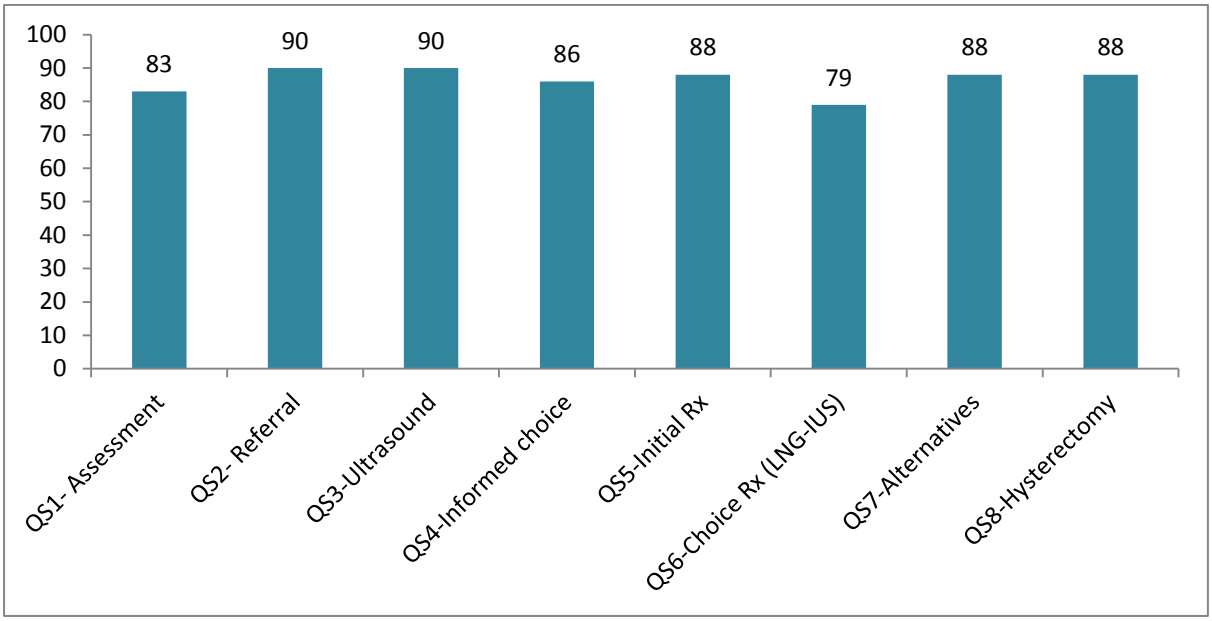
- Was within the scope of the clinical care standard
- Was supported by evidence
- Raised an important point
- Had previously been considered by the Topic Working Group.

Following the assessment, detailed consolidated feedback from the consultation was provided to the Heavy Menstrual Bleeding Clinical Care Standard Topic Working Group for further refinement of the clinical care standard.

Consultation feedback

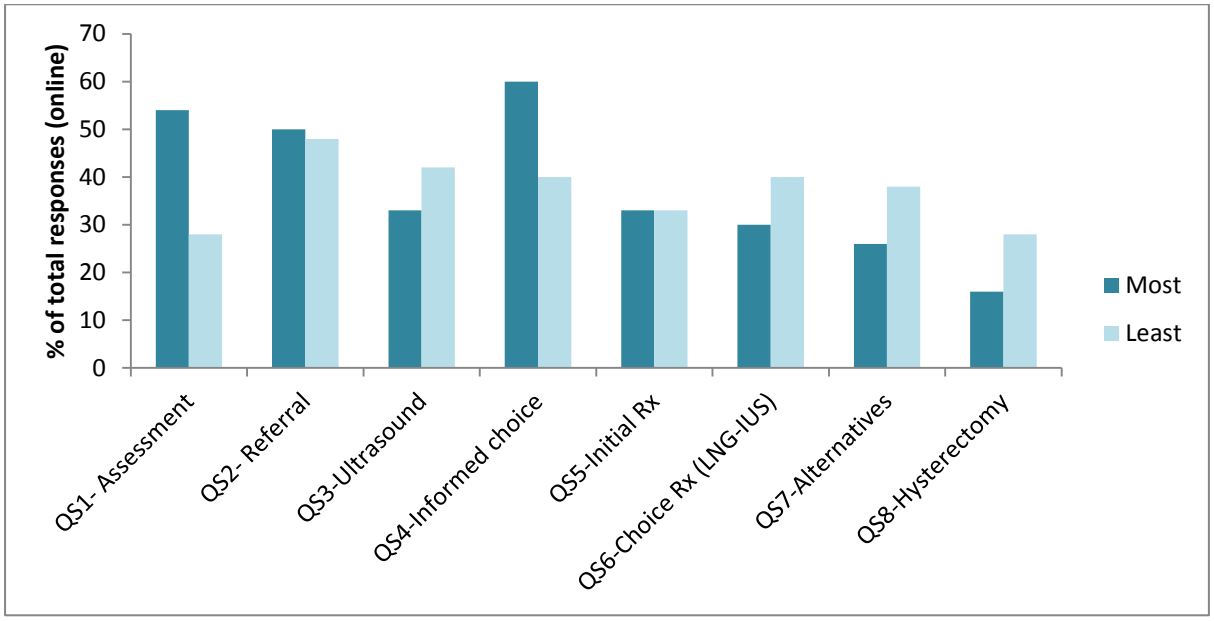
Overall, there was strong support for the development of a clinical care standard for heavy menstrual bleeding and broad agreement with the eight quality statements. Most survey respondents agreed that each quality statement reflected the expected quality of care for women with heavy menstrual bleeding. Agreement was high for all quality statements, ranging from 79% of survey responses for Quality Statement 6 (Choice of pharmaceutical treatment), to 90% for both Quality Statement 2 (Specialist referral for women with risk factors) and Quality Statement 3 (Quality ultrasound) - see Figure 1.

Figure 1: Percentage of email respondents (n=42) who agree that the quality statement adequately reflects care that should be provided



When asked to select the quality statements that would make the most difference in routine care and patient outcomes, the statement chosen most often was Quality Statement 4 Informed choice and shared decision making (60%, see Figure 2). The quality statement expected to make the least difference was Quality Statement 2 (Specialist referral for women with risk factors), but respondents often said that they found it difficult to choose, despite being forced to do so by the online survey. Feedback on the indicators confirmed they would be useful for the purpose of local monitoring of the quality statements.

Figure 2: Quality statements that will make the most or least difference in routine care and patient outcomes



The following sections include a summary of the responses that were received rather than an exhaustive description of all the feedback. Note that some individual responses are quoted here to illustrate the feedback only.

Summary of feedback responses for each draft quality statement

Draft 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.

Feedback was generally positive. Most comments focused on how the quality statement aligned with expectations of comprehensive assessment. A few respondents stated that there was room for improvement in assessment, including by GPs and non-specialist medical officers. The quality statement was seen to support the woman's informed choice, which in turn supported her compliance with (medical) treatment. Because there is a lack of recognition about the seriousness of heavy menstrual bleeding, a comprehensive assessment as outlined in the quality statement was seen to be crucial. As one respondent put it:

> [This is] so crucial at the outset and initial presentation as this will drive decision making, investigations and method of management by the woman and her service provider ... to get it right for her!

Key issues raised included what should be included in a comprehensive assessment, such as the need to routinely consider:

- Iron deficiency (with or without anaemia) using serum ferritin as a screening test
- Thyroid function
- Coagulopathy (such as von Willebrand's disease)
- Possible increased risk of endometrial hyperplasia and cancer in obese women, and women with polycystic ovary syndrome (PCOS)
- A Pap smear if required.

Other changes suggested included clarifying:

- Definitions of internal and physical examinations
- The role of hysteroscopy in assessment
- The difference between normal and heavy menstrual bleeding. One such suggestion is provided below.

> Periods are a very personal experience and women who have always had heavy periods will often consider this as normal. A normal period should amount to 35-40ml and last four to seven days. Heavy menstrual bleeding/menorrhagia is a period of an amount greater than 80ml or lasting more than seven days.

Some comments suggested that the indicators for the quality statement would be difficult to measure and suggested revising the statement, while others suggested that the statement was not required because it reflected the standard of care currently provided:

> …This should be current practice for all health professionals.

Draft 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.

There was strong support for the quality statement in feedback, with a number of respondents suggesting that it would particularly support women in rural areas as well as helping to inform clinicians about appropriate care. Several respondents thought that the emphasis on targeted referral was appropriate as this is not done well currently; and therefore this quality statement would support better use of resources. Some noted alignment with other work (such as referral prioritisation criteria).

Comments indicating a need for revision suggested that the quality statement was difficult to measure and was inconsistent with existing guidelines, particularly as it appeared to recommend referral on the basis of risk factors alone, rather than investigations of women with risk factors. Others suggested that the referral criteria were too limited:

> GPs should investigate and assess before referring to specialists, even when there is concern about malignancy, referral need not occur at the initial visit/concurrently with investigations.
>
> Age >45 is not sufficient as a risk factor to warrant referral to a gynaecologist and could result in increased referral of women whose only risk factor is age.
>
> The statement conflates referral for risk of malignancy with referral for consideration in view of treatment failure – these should be separated.

A few respondents suggested that this quality statement was not required as it reflected existing standards of care.

While not disagreeing with the statement, some respondents suggested that the statement would be difficult to implement due to limited access to services and specialists, particularly in rural areas. Some suggested it may have unintended consequences in such settings:

> Whilst ideally referral and specialist review should occur in a timely manner, specialist appointments often take many months, and in some centres up to a year, to obtain. Investigations undertaken prior to the specialist appointment may be out-of-date by the time the appointment takes place and will need to be repeated, inadvertently adding to delays in treatment.

Draft 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.

There was strong support for the quality statement in feedback, with a number of respondents suggesting that transvaginal ultrasound is not done well currently, with inconsistency between providers in both skill and reporting. It was also suggested that this quality statement would support better use of resources. Some felt that investigations provide peace of mind for women.

One respondent disagreed with the mention of transabdominal ultrasound, noting its higher false negative rate for detecting cancer.

Several respondents were concerned about their ability to implement the statement, particularly in rural areas, because of the need for women to travel a long way to the ultrasound appointment, compounded by limited availability of providers and appointments. One respondent went further, saying that it would be an inappropriate standard of care for women in rural areas and may be a further disincentive to women to seek medical help. In more general terms, some commented that implementation may be limited by compliance, costs (which vary between providers) and difficulty in identifying quality providers of ultrasound services. Below is a selection of comments from respondents:

> The important word is "quality" as some non-specialist ultrasounds do not adequately assess uterine anatomy and endometrial thickness.
>
> [The respondent] supports the importance of quality pelvic ultrasound when screening for uterine abnormalities, however, in practice, optimal scheduling of these ultrasounds may be difficult to achieve due to delays in obtaining appointments.
>
> Quality ultrasound is not readily available in rural and remote areas and lack of quality ultrasound (particularly those specialising in female health) may significantly impact the quality of care received. However, it is recognised that quality ultrasound is an essential component of diagnosis and treatment.
>
> This [standard] may be a useful guide to clinical investigation, but it is an impractical and unnecessary imperative for investigation and management of heavy or abnormal menstrual bleeding.

Different views regarding the responsibility for ensuring the timing of the ultrasound were presented, with radiology practices, GPs, and patients variously identified as playing the main role. Feedback from one respondent noted:

> The referring medical practitioner should have counselled the patient that a transvaginal scan will be needed and will assist her to schedule the scan at the optimum time of her menstrual cycle, accepting this can be difficult to select in patients with constant bleeding.

Others suggested deleting this quality statement, because it was felt to reflect existing standards of care. Other feedback suggested that this quality statement should specify that investigations, including ultrasound, occur before starting pharmaceutical treatment.

Draft 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.

There was very strong support for this quality statement with feedback that it enables a woman's informed choice, which was especially needed in rural areas. Several respondents felt that informed choice and shared decision making is not done well currently, and that there was a current lack of recognition about the seriousness of heavy menstrual bleeding. Some respondents suggested that informing and involving women in shared decision making could improve compliance. It was noted that this quality statement reinforced the need for clinicians to be up-skilled in shared decision making. As one respondent put it:

> Informed choice and shared decision making empowers women to have control over their lives and bodies, once they have been presented with the relevant facts. Patients who base decisions

> on best available evidence from an expert are more likely to comply with treatments chosen and have fewer complaints/regrets post treatment. This assists in better quality of life outcomes.

Some feedback observed that this quality statement was difficult to measure and was unlikely to have an impact. Others suggested that this quality statement could be deleted because it reflected existing standards of care. Some respondents acknowledged that this quality statement would be difficult to achieve for some women (for example, due to specific language or cultural issues, or because of disadvantage), while other women may rely more on their clinician's advice. One respondent noted:

> Clients with poor health literacy and deprived social backgrounds cannot process this complicated information in the times allowed in a busy outpatient setting. This is particularly true of rural [Aboriginal and Torres Strait Islander] ATSI clients. There needs to be repeated and prolonged education, otherwise appointments for Mirenas and follow up of medication administration are not kept. As a result hysterectomy becomes the only option.

Draft 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.

Feedback noted that this quality statement would help to inform clinicians about evidence-based approaches to appropriate care for women with heavy menstrual bleeding. The view was that this is not done well currently, and GPs would benefit from education and up-skilling. Respondents noted that pharmaceutical treatment is effective for many women, is less invasive than surgery, and avoids risks and complications associated with surgery. They acknowledged that this quality statement supports women to make informed choices and supports better use of healthcare resources. As one respondent said:

> Often patients attend the gynaecology clinic not realising or being aware of the fact that there are good pharmaceutical options available for management of HMB - these guidelines will assist the patient's primary GP to give good options for treatment (with a reliable and evidence based approach).

Other feedback noted that failure of pharmaceutical treatment may delay other treatment options, such as surgery. Some indicated that initial pharmaceutical treatment was the current existing standard and did not warrant a specific quality statement. These respondents noted:

> …initial treatment with pharmaceuticals may be useless in the event that there is abnormal pathology therefore investigation may be warranted in the first instance – ultrasound, colposcopy etc to ascertain the cause of bleeding.

> …given the demonstrated variation in surgical rates for HMB (inclusive of hysterectomy), there should be an assumption of variation in pharmaceutical treatment, as offered, or type of therapy. The reasons for this are multifactorial and include patient factors (such as delay in seeking medical advice) as well as gaps in clinician knowledge and experience in management.

Draft 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.

Comments about Quality Statement 6 were similar to those for Quality Statement 5 in regard to the role of pharmaceutical treatment. Comments included that the levonorgestrel intra-uterine system (LNG-IUS) was an evidence-based treatment that would support better health resource use and help women avoid more invasive treatment.

Feedback noted that for some women hormonal treatments are unacceptable, inappropriate, or not tolerated. Cultural or religious beliefs are barriers for some women and health services. As feedback from one respondent noted:

> For some women pharmaceutical [treatment] and uterine devices are not an option and may be too costly and too challenging or simply unacceptable.

Others disagreed with the quality statement and suggested that surgery may be an appropriate first-line option for women, or that it may be their preference:

> …the omission of surgical treatment options, particularly uterine-preserving options such as endometrial ablation, in the initial discussion on management options appears restrictive.

> [The respondent] recommends that the treatment options initially presented to women with heavy menstrual bleeding, but without evidence of a malignancy, include surgical procedures such as endometrial ablation, in addition to pharmaceutical options.

Some feedback concerned implementation issues, noting that access to services – such as for fitting of the LNG-IUS and the need for prior ultrasound assessment – would limit current implementation of this quality statement due to barriers such as availability and cost.

Several respondents noted that quality statements 5 and 6 were similar and could be combined.

Draft 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.

There was support for this quality statement because it was seen to both support the woman's informed choice and inform clinicians about appropriate care. Respondents felt that it pointed to less invasive treatment, thereby avoiding associated risks and complications:

> Uterine-sparing surgery such as endometrial ablation and hysteroscopic resection of fibroid polyps, endometrial polyps have been shown to be effective in controlling HMB and should be offered as first line surgical treatment, rather than proceeding directly to hysterectomy.

One specific suggested change was the need to clarify when hysterectomy would and would not be appropriate. For example, that it may be appropriate for women who cannot tolerate hormonal treatment or who prefer this option:

> …in general, uterine-preserving procedures should be offered first, if appropriate to the woman's clinical situation. However, it is crucial to highlight in this context the need for individualisation of treatment. Depending on the specific clinical circumstances, hysterectomy may be the more effective intervention, i.e. in the case of an enlarged uterus with associated prolapse.

The nature of feedback that was less supportive of the quality statement varied widely between respondents. Some said that this quality statement was not required because it reflected existing care. In contrast, others said that this quality statement was unlikely to have an impact. Some thought that treatment failure, for example with endometrial ablation, may delay definitive treatment.

Noting barriers to implementation, some feedback agreed that this quality statement was desirable – even aspirational – but there was concern that it would be difficult to measure and implement because of limited access to services, especially in rural areas. As one respondent commented:

> ….Many of these procedures are not recommended, or not available in smaller units. It is mentioned in the document that hysterectomy rate is higher in regional areas - this can be explained by difficulty in follow up, needing to travel far to get to a specialist or a pharmacy for that matter. Patients are more likely to choose a "100% guarantee" option when remote.

Draft 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.

There was support for this quality statement for several reasons: it supported less invasive treatment, encouraged informed choices for women and was measurable. Two respondents said:

> [This] reminds clinicians and patients that this should be reserved for use only when all other methods are ineffective or unsuitable. There is a place for this surgery but not before other options have been considered and/or implemented.

> [S]urgical intervention with hysterectomy is likely to be the last option. It is more around how the patients are fully informed and their understanding of the impact and the likely improvements that intervention may have that is the real issue.

In contrast, other feedback included that hysterectomy should be discussed earlier and called for clarification of when it was the most suitable option. Some disagreed with the statement and said that procedural interventions may be either an appropriate first line option for some women or may be their first preference. Some suggested that the quality statement should make it clear that anaemia and iron deficiency status should be assessed before surgery. One respondent said:

> Hysterectomy should be made available to women, who are informed and do not wish to take up other options. Their choice should be respected and surgery offered without undue delay.

Feedback on indicators

Of the 60 responses received by the Commission during the public consultation process, 47 responses provided feedback on the proposed indicators. Respondents were asked questions relating to the proposed indicators overall, and about each individual indicator.

With regard to the overall utility of the indicators, respondents were asked to rate “how useful the indicators are for local monitoring in their professional setting”. They were given the opportunity to provide written comments. Of the 42 responses to this question, over 70% of respondents rated the indicators as somewhat or very useful. Feedback provided was around three general areas including:

- Feasibility of data collection
- Implementation of indicators
- Supporting quality practice.

Nine respondents also provided specific feedback on individual indicators. The written feedback received suggested that the indicators can be used to support local monitoring of the quality statements. Some concerns were raised that the feasibility of collecting data from medical records may be a potential challenge to implementing the indicators in primary care.

Next steps

Feedback from the consultation process was collated and analysed, and a summary of key findings was presented to the Heavy Menstrual Bleeding Clinical Care Standard Topic Working Group. Following this, the clinical care standard was revised and finalised for submission to the Commission's various committees.

The endorsement process for clinical care standards involves passage through the Commission's governance committees, and then noting by the Australian Health Ministers' Advisory Council, a national committee that is instrumental in leading the coordination of health services across Australia.

It is envisaged that the Commission will provide high-level implementation support for this clinical care standard, with activities and resources to be identified and organised in the coming months. This clinical care standard will be launched in the second half of 2017.

Further information about the Heavy Menstrual Bleeding Clinical Care Standard can be found at www.safetyandquality.gov.au/ccs.

If you would like to be kept informed about the work of the Commission, sign up to the Commission's newsletter online, or follow the Commission on Twitter @ACSQHC.

Additionally, if you would like to be advised of the publication of this clinical care standard and associated resources, please send your contact details to ccs@safetyandquality.gov.au.

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