NATIONAL INSTITUTE FOR HEALTH AND   
CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1. Quality standard title

Heavy menstrual bleeding update

Date of quality standards advisory virtual committee post-consultation meeting:   
 22 July 2020

1. Introduction

The draft quality standard for heavy menstrual bleeding update was made available on the NICE website for a 4-week public consultation period between 19 November and 16 December 2019. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 14 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

Most of the content of this quality standard was developed before the COVID-19 pandemic arose. It has been reviewed in light of the pandemic and is intended to support quality improvement as services return to normal.

1. Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

4. Do you have an example from practice of implementing the NICE guideline that underpins this quality standard? If so, please provide details on the comments form.

1. General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

* Stakeholders were generally supportive of the quality standard and the areas identified for quality improvement.
* Suggestion to state ‘women’ with heavy menstrual bleeding (HMB) rather than ‘people’.
* Suggestion to state the age of this quality standard’s population.
* Suggestion to refer to menopause in the supporting information of these draft statements and also add menopause to the list of recommended NICE guidelines and quality standards.
* Query raised how the [patient experience in adult NHS services](https://www.nice.org.uk/guidance/qs15) quality standard (QS15) will be implemented in this quality standard?

### Consultation comments on data collection

* HMB data collection was reported as variable and poorly shared.
* A stakeholder raised concern that the draft measures are inadequate and do not make use of available data such as HES.

### Consultation comments on resource impact

* There was a mixed reponse about the resource impact of these draft statements.
* A stakeholder agreed that each statement would be achievable by local services based on the net resources needed to deliver them. The benefits will outweigh the costs such as reducing the:
  + number of repeat appointments
  + number of procedures
  + time required for people with HMB to be absent from work, social and family commitments.
* A stakeholder highlighted how efficient HMB primary and secondary care services with good patient pathways and outpatient assessment could lead to resource savings.
* However another stakeholder raised concern that the statements are excessively expensive to the NHS. They felt the social and wider economic costs to the patient, families and employers, for example, should be considered.
* A stakeholder also reported confusion and barriers when accessing menstrual healthcare services due to fragmented governance and commissioning responsibilities. The increase in GP appointments were also seen as putting pressure on HMB healthcare services. A more joined-up approach between primary and secondary care settings with holistic, integrated commissioning was supported to help streamline services. This approach will ultimately be cost-effective for the NHS.
* Statement 1- Significant resources will be needed in order to audit patient notes or conduct patient questionnaires. However, if detailed histories are taken with appropriate investigation and treatment there will be potential cost savings through streamlined management.
* Statement 2- Query raised about to whether outpatient hysteroscopy (OH) services will be equipped with up-to-date equipment that causes less harm or pain as current services were reported as inadequate to meet demand with limited provision and equipment. Training and education was also highlighted with recommended resources to support these.

1. Summary of consultation feedback by draft statement
   1. Draft statement 1

### People presenting with symptoms of heavy menstrual bleeding have a detailed history taken that includes the impact on their quality of life. [2013, updated 2020]

### Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

* General
  + The statement’s focus on the impact of quality of life (QoL) was supported by a number of stakeholders. Taking a detailed history was also supported as an essential part of HMB diagnosis and treatment.
  + Adenomyosis is an under recognised condition which needs accurate diagnosis.
  + More emphasis is needed on primary care education and training as the statement incorrectly assumes that staff have the appropriate knowledge and awareness of HMB symptoms.
  + Women and girls should also be educated about HMB to reduce stigma.
  + The benefits of prescribed medication prior to treatment was suggested for inclusion.
* Statement
  + Amend the statement wording to ‘People presenting with symptoms of HMB have a detailed history taken, that includes the impact on their QoL to help determine which, if any, examination and investigations are required prior to treatment’. This will help clinicians understand why the detailed history is needed.
* Rationale
  + Change ‘impact on family life’ to ‘daily life’.
* Measures
  + Structure data source a) Include RCGP’s [Menstrual Wellbeing Toolkit](https://www.rcgp.org.uk/menstrualwellbeingtoolkit) and training programmes such as Continuing Professional Development to ensure that primary care staff have the appropriate knowledge to document HMB symptoms.
  + Process and outcome measures – Patient records were reported as inappropriate data collection tools as they do not currently record the correct information about the history and impact on QoL due to the lack of staff training. QoL needs to be specifically defined as it is difficult to quantify in routine clinical practice and could lead to delayed diagnosis and treatment. It was suggested that NICE produces a validated QoL and HMB specific questionnaire to be used a data source. Access to patient records for specific HMB data collection was also reported as difficult.
* Audience descriptors
  + Person – The RCOG [patient information leaflet](https://www.rcog.org.uk/en/patients/patient-leaflets/?q=&subject=Menstrual+disorders&orderby=datedesc) was recommended to be given to women with HMB to ensure informed choice. Developing a national questionnaire involving HMB patient groups was also recommended.
* Definitions
  + Detailed history – Impact on QoL – Add pain intensity, number of sanitary towels or tampons used, length of bleeding, days off work or affected from normal life, inability to continue with normal life, anaemia, sleep deprivation, impact on exercise or sport, overall health and tiredness and fatigue
  + Detailed history – Other factors that may affect treatment options – Add previous sexual abuse, number of vaginal births, previous painful smear tests, previous cervical surgery and dysmenorrhea.

### Issues for consideration

* + Progress this statement to the final quality standard?
  + Can QoL be accurately recorded in patient records?
  + Should we add more definitional detail on the impact on QoL and/ or other factors that may affect treatment options?
  + Should the RCGP’s [Menstrual Wellbeing Toolkit](https://www.rcgp.org.uk/menstrualwellbeingtoolkit) and the RCOG’s [Patient information leaflet](https://www.rcog.org.uk/en/patients/patient-leaflets/?q=&subject=Menstrual+disorders&orderby=datedesc) be included in the supporting information if NICE endorses them?
  1. Draft statement 2

### People with heavy menstrual bleeding and suspected submucosal fibroids, polyps or endometrial pathology have outpatient hysteroscopy. [new 2020]

### Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

* General
  + There was a mixed response about OH and the benefits and risks of this procedure. Monitoring patient safety was highlighted.
  + Informed consent, choice and respecting autonomy were all supported as key to this statement. The rights to choose the hysteroscopy procedure and the option to have the procedure performed in an inpatient setting for appropriate circumstances and preferences were suggested to be added.
  + Significant resources will be needed to increase OH services with data required to inform future planning.
  + As OH is being used to investigate the presence of submucous fibroids or endometrial polyps, the need for data accuracy on HMB diagnosis or classification of cause was emphasised.
  + Key stakeholders should collaborate to help implement this statement.
* Statement
  + Amend wording to ‘offer’ rather than ‘have’ as OH may not be appropriate for all.
  + Endometrial polyps should be specified.
  + More emphasis is needed on education and training as the statement incorrectly assumes that staff and patients have the appropriate knowledge and awareness of all HMB treatment options.
* Measures
  + Structure b) The OH procedure should be pain free for all people rather than minimise discomfort and pain.
  + Structure b data source) The purpose of training records as a data source was queried as patient feedback was felt to be more important. PROMS and pain scores taken before or after the procedure were suggested as alternative measures as hospitals do not currently record these scores.
  + Process – Amend the measure to include ‘proportion of people with suspected submucosal fibroids, polyps or endometrial pathology who had outpatient hysteroscopy as first line instead of ultrasound’.
  + Process measure data source – The data needs to capture all the possible alternatives which have been discussed with the reasons for OH recorded. Also it was suggested first hand patient accounts should be included to provide the full picture of best practice and patient experience.
  + Outcome measure and data source– There was a mixed response to this measure. It was supported as patient satisfaction was felt to be very significant and currently variable. However, how this will be recorded and by who was queried. It was suggested that external auditing will need to happen to ensure objectivity. The British Society of Gynaecological Endoscopy [Outpatient hysteroscopy patient survey](https://www.bsge.org.uk/news/october-national-survey-month-in-outpatient-hysteroscopy/) data source was queried by a stakeholder as being inadequate and inaccurate as the focus is on BSGE members so will not capture patients from every OH clinic.
* Audience descriptors
  + Service providers – There was a mixed response to one-stop diagnostic OH services. These were queried for not following current requirements for informed consent.
  + Service providers – Increasing the number of one-stop therapeutic procedures was supported to reduce the number of repeat appointments, procedures and time required for people with HMB to be absent from work, social and family commitments.
  + Healthcare professionals – Who will assess patient suitability for OH?
  + Healthcare professionals – These should offer sedation, analgesia and anaesthesia. However there were queries raised about over-the-counter oral analgesia or stronger oral analgesia not helping people who experience severe OH pain.
  + Healthcare professionals – Clarification of the nurse post is needed as not all services have nurses in these roles. Also the person will always need an advocate with expertise to help them so this should not be a choice. Whether the person is permitted to bring a partner or friend into the treatment room to act as the patient’s advocate should also be recorded.
  + Commissioners – Query raised on how local commissioners will know that OH services are adequately staffed. The commissioners will need to monitor and measure carefully the cost effectiveness of OH compared to ultrasound and MRI.
  + Person – The facilitation of the advocate during the procedure should be added.
* Definitions
  + OH being carried out without general or regional anaesthesia was queried.

### Issues for consideration

* + Progress this statement to the final quality standard?
  + Change the statement wording from ‘have’ to ‘offer’?
  + Are there sufficient resources available to increase OH services?
  + To ensure OH procedures are carried out in accordance to best practice guidelines should patient feedback (for example PROMs, pain scores) be measured rather training records?
  + Should we refer to local anaesthesia in the definition specifically?
  1. ***Draft statement 3***

People with heavy menstrual bleeding have a discussion with their healthcare professional about all their treatment options. **[2013, updated 2020]**

**Consultation comments**

Stakeholders made the following comments in relation to draft statement 3:

* General
  + The statement was supported for ensuring that information about appropriate treatment options is shared with people with HMB as choice should be at the centre of any treatment pathway.
  + Offering patient information leaflets before outpatient appointments was suggested. This will ensure objective information is provided on all treatment options. The leaflet will also help the person to know what questions to ask at their outpatient appointment and therefore aid effective communication.
  + Formal anonymous patient surveys were also recommended to be included.
* Statement
  + The discussion should also include all investigation options.
* Measures
  + Structure – Clarify the timing of documented discussion with the healthcare professional.
* Audience descriptors
  + Commissioner – Add general anaesthetic to treatment options.
* Definitions
  + Amend ‘where’ to ‘whether’ they want to retain their fertility and/or uterus.

### Issues for consideration

* + Progress this statement to the final quality standard?
  + Can we clarify the timing of the documented discussion?
  + Should general anaesthetic be added to the full range of treatment options?

1. Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

* + **Endometrial biopsy**
  + NICE NG88 recommendations 1.3.10 and 1.3.11 cover this area. This was highlighted at the prioritisation QSAC meeting but not progressed.
  + **Enhanced imaging with ultrasound (with saline infusion)**
  + NICE NG88 recommendation 1.3.16 covers this area. This is a ‘do not do’ recommendation. This has not been discussed during development of this quality standard.
  + **Access and variability in service provision for LNG-IUS for people with no identified pathology**
  + NICE NG88 recommendation 1.5.2 covers this area. This was highlighted at the prioritisation QSAC meeting but not progressed.
  + **Retain the original 2013 quality standard QS47 statement 4 on** [**interim drug treatment**](https://www.nice.org.uk/guidance/qs47/chapter/Quality-statement-4-Interim-drug-treatment)
  + NICE NG88 recommendation 1.5.3 covers this area. This was highlighted at the prioritisation QSAC meeting but not progressed.
  + **Implementation of multi-disciplinary fibroid clinics with interventional radiologists and gynaecologists working together in outpatient settings**
  + This area is outside of scope of this quality standard.
  + **Pre-op assessment screening of OH to assess patient suitability**
  + This area is outside of scope of this quality standard.

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# Appendix 1: Quality standard consultation comments table – registered stakeholders

| **ID** | **Stakeholder** | **Statement number** | **Comments[[1]](#footnote-1)** |
| --- | --- | --- | --- |
| 1 | RCOG | General | There is a clear need for a more joined-up approach to women’s healthcare services between primary and secondary care settings, especially in the context of rising number of GP appointments placing pressure on those services and the people that work for them. This had previously been raised as a concern in the RCOG’s advisory report following the conclusion of the Heavy Menstrual Bleeding Audit of 2014 (RCOG, National HMB Audit Final Report 2014).  Heavy menstrual bleeding is estimated to be the fourth most common reason for referral to gynaecological services (RCOG, National Heavy Menstrual Bleeding Audit, Final Report 2014). Furthermore, an estimated one in 20 women aged between 30 and 49 visit their GP each year for help with heavy periods or menstrual problems (NICE, Heavy menstrual bleeding: assessment and management, Information for the public 2018).  However, not all women manage to access their GP for help with the symptoms of HMB. There are several barriers for women accessing primary care services. These include:  • GP services are under extreme pressure meaning that there can be a substantial waiting list to get an appointment. Often primary care services are not open out-of-hours or at weekends. This means that some women are unable to make an appointment due to work and family commitments – women make up 47% of the workforce in the UK. • Fear of pain, embarrassment and stigmas – as discussed above – prevent some women from seeking medical help. • Women who have recently immigrated to the UK might not be registered with a GP or realise what healthcare services they could have access to.  The APPG on Women’s Health in its 2017 report also recommended that “best practice pathway should be endorsed – this would mean that women would be streamlined more quickly into the right care, saving costs from unplanned admissions and ensuring women get access to all treatments” (APPG on Women’s Health, Informed Choice? Giving women control of their healthcare 2017)  This conclusion was reached after a survey of over 2600 women with endometriosis or fibroids found that 40% of those surveyed needed 10 GP appointments or more before being referred to the specialist and 12% of women surveyed with ﬁbroids took 1-2 years from their diagnosis to get their treatment. The report also noted that respondents listed “timely referral to appropriate specialist care” as important and crucial to their care (APPG on Women’s Health, Informed Choice? Giving women control of their healthcare 2017).  Since then, the RCOG, along with others, has called for an end to the fragmentation of commissioning of sexual and reproductive healthcare services.   Currently, the fragmentation of governance and commissioning responsibilities has created confusion and barriers for women when trying to access healthcare services about their menstrual health.  The College believes a holistic, integrated approach to commissioning will help to streamline services, meaning that women will be able to get treatments and be referred to specialists easily and efficiently. This approach will ultimately be cost-effective for the NHS (RCOG, Better for women, 2019). |
| 2 | RCPCH | General | The reviewer was happy with the standards in this document |
| 3 | RCPCH | General | This document is primarily for adults and therefore, it should state so on the document i.e. above 16 years of age. |
| 4 | FTWW | General | Would recommend that ‘Menopause’ be added to the list of recommended guidelines and quality statements. |
| 5 | FTWW | General | Make reference to equivalent bodies in devolved nations |
| 6 | Hysteroscopy Action | General | How will the following Quality Standards from NICE CG138 be implemented?  4 Patients have opportunities to discuss their health beliefs, concerns and preferences to inform their individualised care. 5 Patients are supported by healthcare professionals to understand relevant treatment options, including benefits, risks and potential consequences. 6 Patients are actively involved in shared decision making and supported by healthcare professionals to make fully informed choices about investigations, treatment and care that reflect what is important to them. 7 Patients are made aware that they have the right to choose, accept or decline treatment and these decisions are respected and supported. |
| 7 | FEmISA | General | A quality standard should set the levels to improve patient care standards, diagnosis, treatments and outcomes. It should be patient-centred and ensure patients are fully informed and given informed choice of all diagnostic and treatment procedures available, which suits them. It should take regard of the social and wider economic costs to the patients themselves, their families and employers etc  These standrads do not meet any of the aims of a quality standard. They increase mortality and morbidity for women considerably, where safety should be first consideration. They are unacceptable to women and not evidence based. They replace non-invasive diagnostic procedures with painful endoscopy, which has a high mortality and morbidity rate and is unacceptable to many women, if given informed choice. It is also excessively expensive to the NHS – not safe and not cost effective. The HES ONS data has been considered at all i.e. actual outcomes and it is therefore not evidence based. |
| 8 | FEmISA | General | The suggested measurements and metrics are totally inadequate and do not make use of those already available. Audits of patients notes, which can be changed are inadequate. Much better use should be made of NHS statistics already available and collected regularly- • HES data – diagnoses, in-patient and outpatient numbers Finished Consultant Episodes • Mortality • Readmissions • Litigation • PROMs need to be extended for HMB • PREMs Needs to be extended for HMB • Hospital in-patient surveys New data needs to be collected from patients on the costs to them, their outcomes, time to feeling completely well etc |
| 9 | RCPCH | General | It may also be worth mentioning in the document that any child with this problem should seek help either with their GP or if they are below 10 years of age, by an endocrinologist/paediatrician.  The reviewer noted that they recently had an eight-year-old admitted who was unwell with a HB of 55 due to menorrhagia over the last three months and in spite of contact with their GP nothing had been done and she was brought into ED. |
| 10 | Hysteroscopy Action | Question 1 | Thank you for giving Hysteroscopy Action – the Campaign Against Painful Hysteroscopy this opportunity to comment on NICE’s HMB quality standards. Painful outpatient hysteroscopy is of national and international interest and has been debated several times in the House of Commons by Lyn Brown MP, (Lab, West Ham) most recently in a Westminster Hall debate supported by former Women’s Health Minister, Jackie Doyle-Price. Painful outpatient hysteroscopy https://hansard.parliament.uk/Commons/2018-12-11/debates/9706C757-0DB9-432E-A6BB-8886455923E4/NHSHysteroscopies Lyn Brown, MP has also made a submission of her concerns about NHS hysteroscopy performed with inadequate anaesthesia to United Nations Special Rapporteur Dr Dubravka Simonovic as part of Dr Simonovic’s investigation of obstetric and gynae violence.   With regard to the question “1. Does this draft quality standard accurately reflect the key areas for quality improvement?”  No it does not because comments concerning Outpatient Hysteroscopy on the Briefing Paper asked for means to improve and measure: • Information given to women on all options for hysteroscopy (LA, GA, Sedation, etc); • Fully informed consent (as per Montgomery v. NHS Lanarkshire ruling);  • Pain-scoring; • Patient feedback. None of these are addressed here. |
| 11 | Hysteroscopy Action | Question 1 | With regard to the question “1. Does this draft quality standard accurately reflect the key areas for quality improvement?”   Quality improvement in outpatient hysteroscopy should include proper screening/ pre-op assessment.  As an example, the following criteria are referenced in an audit from NHS North Bristol Trust but are currently being ignored. https://www.whatdotheyknow.com/request/185301/response/460084/attach/3/Cartwright%20Charles%20eSSC%20Dr%20Mears%202.pdf • Can the patient tolerate speculum?  • Will she be happy to attempt LA as ‘rescue anaesthesia’ if necessary? • Has she had previous cervical surgery which might cause severe pain? |
| 12 | Hologic | Question 1 | Yes a detailed history would be an essential part of diagnosis and treatment work-up for a patient with HMB and an important quality standard. |
| 13 | Hologic | Question 1 | Yes outpatient hysteroscopy could improve standards of treatment for HMB |
| 14 | Hologic | Question 1 | Yes the patient should be able to have a good discussion with their healthcare provider about all their treatment choices in HMB in line with the NICE-HMB guidelines and similar guidelines in other countries e.g. Netherlands, Canada etc however this would depend on a good level of HMB knowledge for the patient and all healthcare providers from primary care through to secondary care and we do not think this is the case especially for the initial part of those discussions between patient and primary care physician. Education on HMB would be needed to improve this and facilitate these discussions. |
| 15 | NHSE&I | Question 2 | Data collection in relation to the care of women with HMB is of variable quality and is poorly shared. Would NICE consider recommending that DHSC fund the development of national primary data standards for gynaecology and women’s health (possibly by the Professional Records Standards Body). The gynaecology and women’s health data standards would enable formation of a gynaecology secondary users data set by NHD Digital. This would enable GIRFT to monitor provider performance against NICE standards. |
| 16 | Hologic | Question 2 | The education of HMB at a primary care and patient level is an issue for the effective implementation of this NICE-HMB guidance and any quality standard. I do not think a structured system is in place although tolls and education are available e.g. via RCGP, RCOG, BSGE etc Audits and registries would be helpful here but I do not know of any currently in place. |
| 17 | Hologic | Question 2 | There is not enough provision for Outpatient Hysteroscopy to meet the numbers of patients with HMB according to the 1 in 5 data from the RCOG Audit. It seems to be mostly offered in Secondary Care and clinics so not seem to be expanding since NICE-HMB and the statement that around 5,00 hysteroscopies are performed in England annually but around estimates of need are around 15,000. We have also seen no increase in training to meet such demand. |
| 18 | Hologic | Question 2 | Statement 3- No I do not believe that systems are in place to collect data for this and education is needed. |
| 19 | BSGE | Question 2 | The consultation concerning data collection -just to endorse the importance of this area of development.  If activity is being invested in developing structures for data collection then consideration should be given to accumulation of accurate data on diagnosis/ classification of cause of HMB/AUB especially if outpatient hysteroscopy is being utilised to define better the presence of features such as submucous fibroids or endometrial polyps. |
| 20 | Menstrual Health Coalition | Question 3 | The Menstrual Health Coalition welcomes the proposed draft quality standard, as it signifies a move towards a patient-centric approach, which was highlighted as requiring improvement in the inquiry conducted by the Coalition. Findings showed that there is a lack of awareness and education among both healthcare professionals and patients, which are preventing women from receiving appropriate diagnosis and treatment. The Menstrual Health Coalition believes that this issue should be addressed by promoting NICE guidance as a standard practice for patients, including providing information on all treatment options and their potential impact on quality of life. Recommendations for first-line treatments should bear in mind patients’ history and/or pathology expression. As such, the Coalition believes there should be adequate training tools for clinicians, for example through Continuing Professional Development courses, and signposting to relevant resources e.g. Menstrual Health Toolkit. A practical approach to training would ensure that women receive the treatment that is right for them and reduce variability in service provision.  To achieve the improvements the draft quality statements set out to deliver the Coalition proposes the following recommendations: • There needs to be an emphasis on education and awareness of heavy menstrual bleeding to inform patients and empower them to take an active role in their care, as well as among primary care professionals to ensure that they are aware of the symptoms of heavy menstrual bleeding and the national guidelines. The Menstrual Health Coalition’s inquiry highlighted that there is limited awareness and knowledge of guidelines and best practice around heavy menstrual bleeding, which may lead to women presenting with their symptoms being dismissed.  • There should be menstrual health training for primary care professionals. However, respondents to the Coalition’s inquiry acknowledged that time and resource-constrained medical practices would find it difficult to train their staff. Therefore, the Menstrual Health Coalition recommends educating General Practitioners in a clear and efficient way that involves fewer tests and provide clinical pathways to follow. This could be provided through Continuing Professional Development training where relevant guidelines and advice could be updated. Other tools are also available, and awareness needs to be built to signpost clinicians to use these tools. The Coalition believes any pathway should enable identification of heavy menstrual bleeding as an issue, to ensure patients get the right support quickly and sensitively, and enable access to appropriate diagnosis and treatment. These recommendations acknowledge the constraints that healthcare professionals face and provide practical and efficient tools to enable clinicians to deliver better care for women presenting with heavy menstrual bleeding. This would be a step towards ensuring that there is higher rates of awareness of treatment pathway among healthcare professionals, which would in turn have a positive impact on outcomes for patients. |
| 21 | NHSE&I | Question 3 | I think that each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them. |
| 22 | Hologic | Question 3 | As we often hear that primary and secondary care is overloaded clear education and guidance on the NICE-HMB diagnosis and management could help to ensure resources are targeted wisely for maximum effect. Efficient service at both a primary and secondary care level with a good patient pathway and outpatient assessment could lead to resource savings. |
| 23 | Hologic | Question 3 | Current services are not adequate to meet demand training and provision of outpatient hysteroscopy would have to be scaled up to fully implement NICE-HMB guidelines and since they came out in March 2018 I am not aware of any of this having been actioned in the UK by NICE or any of the major GP or Gynae Societies. |
| 24 | Hologic | Question 3 | I do not think patients or primary care are at a level of HMB education to make this QS achievable at present and services and resources are not in place. Education is needed at both a patient and primary care level. Using tools already available such as the RCGP resources could help. |
| 25 | BSGE | Question 3 | The major resource for consideration will be skill-base and equipment and service support for increased ability to offer outpatient hysteroscopy. |
| 26 | RCGP | Additional statement | Can the committee consider keeping the QS statement 4 in QS47 from 2013? This has the potential for immediate improvement on QoL for women. It is measurable, has no extra cost implication and reduces the impact of the HMB on the person while waiting for further investigations or treatments whilst also adding valuable information by assessing the treatment outcome. |
| 27 | BSGE | 1 | Throughout the document there are at times the mention of the structural feature within the uterus of ***adenomyosis***. This is certainly an area where future attention needs to be given for accurate diagnosis. It is an under recognised condition, a major contributor to symptoms of AUB and HMB and attention concerning optimum modes of diagnosis should certainly be addressed. |
| 28 | RCOG | 1 | Information gathering in primary care may be difficult due to the need to access patient records for the specific data collection |
| 29 | RCOG | 1 | ‘Impact on family life’ assumes they have a family or consider themselves part of a family. Would ‘daily life’ be better? QoL is hard to quantify in routine clinical practice, unless NICE also produced a validated QoL and HMB specific questionnaire. No impact, Mild, Moderate or Severe impact. By the definition of HMB as a symptom it is unlikely that there is anyone with No impact on QoL, except perhaps the rare person who presents with symptoms of anaemia. |
| 30 | RCOG | 1 | Whilst many women have few concerns with their menstrual health, other women can experience a myriad of problems before, during and after their period that can have a huge impact on their physical and mental wellbeing.   One in five women experience unusually heavy periods (Heavy Menstrual Bleeding or HMB). However, despite it being a debilitating condition and may occur as a result of underlying problems -particularly uterine fibroids but also including endometriosis, PID, PC (NHS UK, Heavy periods overview) - one in three women suffering heavy periods have not spoken to their doctor (Wear White Again, The impact of heavy periods)  There are several reasons for this, including a lack of accessible patient information, not realising that HMB is a medical condition, persistent stigmas and embarrassment.  A survey of 1000 women who have experienced HMB in the UK, undertaken by Wear White Again (Wear White Again, The impact of heavy periods), found that:  • 62% did not realise heavy periods are a medical condition. • 74% have experienced anxiety, 69% depression and 49% anaemia. • 72% said it affected their sex life. • 58% feel they are unable to carry out their usual daily routine. • 50% have never been to see a GP about heavy periods.  Considering the above concerning statistics, it is vitally important that women and girls are educated about their health, stigmas are smashed and the healthcare system becomes more easily accessible. |
| 31 | Menstrual Health Coalition | 1 | Draft quality statement 1 relates to the history of a patient presenting with symptoms from heavy menstrual bleeding. The statement places particular emphasis on the impact of heavy menstrual bleeding on the patient’s quality of life rather than focusing on blood loss only. Whilst the Menstrual Health Coalition welcomes this specific inclusion, the draft quality standard makes two assumptions:  1) It assumes knowledge and awareness of heavy menstrual bleeding symptoms by primary care professionals. Findings from an inquiry by the Menstrual Health Coalition showed that there is a lack of knowledge and awareness about the condition among these professionals. This is primarily linked to a lack of education and pressures on primary care services which means that General Practitioners and nurses have little funding for training and are finding it difficult to remain up-to-date with the latest guidance.  2) The statement does not specifically define ‘quality of life’, merely referring to the impact the condition has on patients’ life, including its impact on work, education and family life. This lack of a specific definition within the draft quality statement leaves room for interpretation from healthcare professionals and could result in delayed diagnosis of the condition. Respondents to the Menstrual Health Coalition inquiry commented on the perceived lack of empathy and understanding that primary care professionals often display when speaking with women suffering from heavy menstrual bleeding. If a sufferer were to encounter a less sympathetic General Practitioner it can have a detrimental effect on that woman seeking further help. This could affect timely access to diagnostics and treatment, which would adversely impact the patient’s quality of life.   The Coalition welcomes consideration of the impact of heavy menstrual bleeding on the patient’s quality of life. However, we believe that women’s health should be a more important aspect of primary care provision and thus, argue that the quality statement needs to go further to ensure that primary care professionals are educated and aware of symptoms, as well as predisposed to having a sympathetic ear when diagnosing the disease. |
| 32 | Menstrual Health Coalition | 1 | The proposed data collection for quality statement 1 focuses on training records as a way of evidencing awareness and knowledge of heavy menstrual bleeding by healthcare professionals. However, findings from the Coalition’s inquiry show that there is lack of specialists in women’s health, which has an impact on timely diagnosis of heavy menstrual bleeding. An All Party Parliamentary Group on Women’s Health report found that there is a ‘chronic lack of awareness among healthcare professionals’ of two of the most common causes of heavy menstrual bleeding, fibroids and endometriosis. Therefore, the Coalition does not believe that training records will provide an appropriate way of collecting appropriate data. Instead, there should be an emphasis on educating and training of primary care professionals. However, the Menstrual Health Coalition recognises that it is difficult to keep up to date with updated guidelines, which means that there is a need to take a more practical approach, for example through Continuing Professional Development training. Measuring uptake of this training or usage of signposted tools such as the Royal College of General Practitioners Menstrual Wellbeing Toolkit would be a better measure to ensure that they possess the knowledge required to diagnose heavy menstrual bleeding adequately.  The Coalition also does not believe that auditing patient records as a way to measure the proportion of people presenting with symptoms of heavy menstrual bleeding would enable the accurate collection of data. Auditing patient records would not provide a clear picture of those suffering with heavy menstrual bleeding, as the lack awareness of the illness by primary care professionals, as highlighted in our inquiry, would be reflected in patient records. This means that heavy menstrual bleeding may not have been recorded in the patient record even though in fact the patient might have been suffering from the condition at presentation. This is supported by findings from a survey on endometriosis or fibroids, which found that 40% of the women surveyed needed 10 General Practitioner appointments or more before being referred to the specialist.  As such, the Menstrual Health Coalition urges NICE to consider the above and reflect on the proposed data collection sources, as these may not provide an accurate picture of heavy menstrual bleeding. This would make patient records inappropriate as data collection tools as they would not record correct data. |
| 33 | FTWW | 1 | Add ‘or be suggestive of peri-menopause / menopause’ |
| 34 | FTWW | 1 | Make reference to equivalent bodies in the devolved nations |
| 35 | FTWW | 1 | In section, ‘Symptoms’, add ‘indicators of menopause’ |
| 36 | RCN | 1 | No comments on the statement - however this can be hard to measure especially when including sexual health and emergency departments as the data for this can be difficult to find and audit. |
| 37 | Hysteroscopy Action | 1 | Structure b)  It is important that the impact is recognised as greater than simply blood loss. This is not always recognised by (in particular, male) medical professionals, so it is good to see it stated here. |
| 38 | Hysteroscopy Action | 1 | Some women know with certainty that “over the counter medication” is ineffective for their menstrual, uterine pain and has no impact on it. They find benefit only from prescribed medicines, such as mefenamic acid.  This must be captured so that women are advised, prior to treatment, to use whatever medication is EFFECTIVE for THEM for uterine pain. |
| 39 | Hysteroscopy Action | 1 | In order to consider treatment options, please record whether the woman has given birth vaginally. There is a risk to nulliparous women of severe pain during OPH. |
| 40 | Hysteroscopy Action | 1 | As well as recording evidence, ensure quality information is shared. As per the Briefing Paper, Appendix 4 – Additional Areas, comment 64 from FEMISA “Ensuring Informed Choice for Women”:   There should be a single, comprehensive Patient Information Leaflet for all clinics, caveated where any of the content is not available at that hospital. Hospitals are carrying out the same procedures, so they need to be supported by consistent information. To be developed with patient experience and input. The RCOG PIL is a good example.+  Where the PIL has not been sent to the woman in advance (this happens regularly – see Care Opinion posts), the procedure must NOT go ahead, as it is impossible for her to give informed consent as per the Supreme Court’s Montgomery ruling on informed consent. |
| 41 | Hysteroscopy Action | 1 | As well as recording evidence, ensure quality information is shared. As per the Briefing Paper, Appendix 4 – “Information for women about HMB and treatments”, comment 30 from BSGE.  Provide “all possible treatment options”.   Also provide honest information about the possibility of severe pain during OPH. Unless this is given, women are being steered towards an Outpatient procedure. Too many, after agreeing, experience a traumatic hysteroscopy and realise, too late, that they needed General Anaesthetic. |
| 42 | Hysteroscopy Action | 1 | “Other factors that may affect treatment options” ADD previous sexual abuse, number of vaginal births, previous painful smear tests, previous cervical surgery, dysmenorrhea |
| 43 | RCGP | 1 | It would help clinicians to understand why the detailed history is required and so adding in the reason for this may focus the measurements undertaken.  Can the committee therefore consider altering the statement to: ‘People presenting with symptoms of HMB have a detailed history taken, that includes the impact on their QoL to help determine which, if any, examination and investigations are required prior to treatment’ |
| 44 | RCGP | 1 | This can be measured but will require an audit of clinical notes to determine if the history and impact on quality of life has been undertaken, or a patient questionnaire/ survey, and so is more likely to be performed in individual GP practice/ hospitals for local quality improvement, rather than across a wider network such as a CCG/ STP |
| 45 | RCGP | 1 | Resources would be significant to audit notes or to produce a patient questionnaire and collate the responses in order to measure this QS, however, if detailed histories were taken and appropriate investigation and treatment implemented there are possible cost savings including: • Streamlining management and reducing numbers of primary care visits by managing HMB more efficiently,  • Reducing numbers of unnecessary ultrasound scans, Social impact of improved management including reduced time away from the workplace |
| 46 | FEmISA | 1 | Measurable effects on the woman’s life should be taken including – • Intensity of pain • No of sanitary towels/tampons used • Length of bleeding – number of days per month • Days off work/away from normal life • Inability to continue with normal life • Anaemia • Sleep deprivation • Effect on exercise/sport • Overall healthiness • Tiredness and fatigue A questionnaire should be developed with patient groups for HMB so the same format is used for all and can be used nationally |
| 47 | Hologic | 1 | There is a wide variation in understanding and knowledge of HMB in terms of symptoms, impact on the individual and treatment especially at the primary care level. Statement 1 would need education on HMB at both a patient and primary care HCP level in order to take a detailed history. We have not seen any plans for such education but it would be essential in order for this statement and NICE-HMB ng88 to be fully implemented and effective. Further guidance could be given to define the history needed e.g. 3-6months menstrual record such as a period diary or use of an app and definition of the impact on quality of life which would help this to be useful. Referral on to secondary care with a detailed history would enhance patient treatment for HMB so should be encouraged at first patient-primary care visits as the NICE-HMB workup suggests. Primary Care physicians should be educated and given clear guidance on what the diagnosis and treatment pathways are according to NICE-HMB ng88 as they are very clearly described also the RCGP has just completed an HMB toolkit for GPs and use of this and the accompanying modules should be encouraged. |
| 48 | Hologic | 1 | More detail on what the ‘detailed history looks like for guidance would be useful here |
| 49 | RCOG | 2 | The advice for outpatient hysteroscopy in preference to ultrasound will increase numbers of referral form primary care. This will therefore require an increase in infrastructure to those units already providing outpatient hysteroscopy. |
| 50 | RCOG | 2 | As outpatient hysteroscopy is stated to be better first line that ultrasound, this data collection should suggest ‘proportion of people with suspected submucosal fibroids, polyps or endometrial pathology who had outpatient hysteroscopy as first line instead of *ultrasound* |
| 51 | RCOG | 2 | A direct referral to hysteroscopy rather than ultrasound scan, will require an increase in resources to implement. |
| 52 | RCOG | 2 | There continues to be anecdotal reports of patients having distressing experiences owing to units not following the best practice guidance in the NICE guidelines (which were taken from the RCOG outpatient hysteroscopy guideline). The other main area was in variation of access to, and route of, hysterectomy. Although the NICE guidelines found hysterectomy to be both clinically and cost effective, and should be offered as first line treatment where appropriate, many CCGs restrict access and rate it as a procedure of low clinical value. Where it is done, too many are not through minimal access routes (laparoscopic or vaginal hysterectomy) but continue to be through open surgery. The RCOG published its clinical indicators project – Patterns of Benign Gynaecology Care – in 2016 which listed good outcome measures that could be used. The RCOG also published its HMB national audit in 2014 which showed significant variations in hysterectomy rates, with some areas being too high suggesting poor provision of conservative measures like endometrial ablation, and others too low likely due to restrictions from commissioning. |
| 53 | RCOG | 2 | I am unsure about the term HAVE outpatient hysteroscopy. Maybe offered outpatient hysteroscopy first line would be better and in keeping with statement 3. |
| 54 | RCOG | 2 | Proportion of people with heavy menstrual bleeding and suspected submucosal fibroids, polyps or endometrial pathology who report satisfaction with outpatient hysteroscopy. This is an excellent standard to audit as the patient experience is also a major factor. This may be different with different operators and how the patient is counselled pre procedure eg to take oral analgesia prior to the procedure. |
| 55 | FTWW | 2 | Change wording to, ‘be offered hysteroscopy’: Hysteroscopy in an outpatient setting may not be appropriate for all; making this descriptor as categorical as it is obviates patient choice, ie for those patients who may prefer (or need) hysteroscopy to be performed under general anaesthetic. Similarly, an outpatient setting may not be suitable for all disabled people. |
| 56 | FTWW | 2 | Would recommend ‘Outpatient’ being in parentheses |
| 57 | FTWW | 2 | Would amend to, ‘People with heavy menstrual bleeding and suspected submucosal fibroids, polyps or endometrial pathology be offered outpatient hysteroscopy’. |
| 58 | FTWW | 2 | Would recommend amending to, ‘Before carrying out hysteroscopy, the healthcare professional should discuss the procedure with the person, discuss and offer sedation / analgesia / anaesthesia and advise on the possible alternatives to the procedure’ |
| 59 | FTWW | 2 | The QS in its current form fails to take into account the not insignificant number of women who experience pain as a consequence of hysteroscopy without sedation or adequate analgesia, have previous / existing trauma, or who have impairments which may necessitate hysteroscopy in an in-patient setting. Patient choice should be a key part of the quality standard, so making Quality Statement 2 as categorical as ‘Outpatient Hysteroscopy’ obviates patient autonomy, choice, and circumstances. The option to have the procedure performed in an in-patient setting, for those whose circumstances and preferences warrant it, should be factored into the QS accordingly. |
| 60 | FTWW | 2 | Add, ‘or, if the person has brought an advocate or supporter with them, their presence at the procedure should be facilitated if the patient requests it’. |
| 61 | FTWW | 2 | Would amend sentence to ‘are offered a procedure called hysteroscopy, most usually carried out in an outpatient hysteroscopy service’. |
| 62 | RCN | 2 | The facility for outpatient hysteroscopy is not present in all locations and not always in outpatients, this will significantly impact on the resources and the access to this. There needs to be more training and provision.   It is not clear how the data would be collected, as an example in clinical practice, the procedure in outpatients are coded but not the reason for it. |
| 63 | RCN | 2 | “A nurse is also available to act as the person’s advocate if needed” - could this be a nurse, nursing associate or healthcare assistant? This statement needs to be clearer, if it means a registered nurse, the statement needs to say so. |
| 64 | RCN | 2 | “Outcome Proportion of people with heavy menstrual bleeding and suspected submucosal fibroids, polyps or endometrial pathology who report satisfaction with outpatient hysteroscopy. Numerator – the number in the denominator who report satisfaction with outpatient hysteroscopy.” What is satisfaction? Is it pain score or willingness to have the procedure again, is it the outcome for the procedure? This needs to be made clear in the standard. |
| 65 | Hysteroscopy Action | 2 | Why is the focus only on Outpatient Hysteroscopy? Why not offer equally with GA / LA / sedation, etc and ALL benefits and risks explained (including severe pain) as per Montgomery informed consent? The suggestion that all women have outpatient hysteroscopy without offering the explicit option of GA (or IV sedation if available) is almost certainly clinically negligent. See ‘A guide to consent in clinical negligence post-Montgomery’, Lauren Sutherland, QC.   The Briefing Paper, at 4.5 “Additional areas” required “…access to a choice of out-patient or in-patient procedures”. Are there no next steps on this aspect? It has not been developed at all here. |
| 66 | Hysteroscopy Action | 2 | At 2.4, the Briefing Paper states, “…hysteroscopy has become more widely available and is more acceptable to women”. Before collecting data on the implementation of Trial by Outpatient Hysteroscopy for all, NICE must stop and reframe Quality Standard 2, “People with HMB and suspected submucosal fibroids, polyps or endometrial pathology have outpatient hysteroscopy. “ PLEASE DELETE THE WORD ‘OUTPATIENT’.    The mantra “Outpatient hysteroscopy is more acceptable to women” is based on incomplete data, including a landmark UCLH clinical trial with a shrinking denominator; none of the trial participants who declined OPH upfront appear in the final % of acceptability. Similarly, the Cardiff SHINE project which studied the ‘acceptability’ of OPH polypectomy and myomectomy recorded 122 attempted procedures but only 79 independently validated pain-scores. Hmm.   Very few NHS OPH audits publish the full range of pain-scores experienced. A median or mean score is usually published which conveniently conceals the incidence of severe pain. NICE must insist that the full range of pain-scores are published for each clinic. Pain-scores must be measured INDEPENDENTLY of the operating team. The team may take pain-scores during and after the procedure but the patient must be allowed to input her OWN score anonymously once she is at home. The Campaign Against Painful Hysteroscopy has received accounts of hysteroscopy teams fabricating over-optimistic pain-scores, and of a nurse pressurising a patient to give a good rather than a truthful pain score.   One trial of OPH rather amusingly only records a vaso-vagal reaction if a woman is unable to stand up from the bed/chair after 5 minutes have elapsed!    www.whatdotheyknow.com ‘Outpatient Hysteroscopy/biopsy’ lists Freedom of Information Act replies from English NHS Trusts asked for audits of OP hysteroscopy pain scores. Typically 1 in 4 patients reported a pain-score of 7/10 or more: • Frimley 24% severe pain =/> 8/10;  • Ashford & St Peters 30% severe pain =/> 8/10;  • Derby 35% 7/10;  • Croydon 40% severe pain.   Less than 5% patients who contacted Hysteroscopy Action - the Campaign Against Painful Hysteroscopy were asked for a pain-score. Some women who had suffered appalling pain read that they had ‘tolerated the procedure’ well in the notes to the GP.   OPH is more acceptable to some women. GA is more acceptable to some women.  We need data to quantify the statement that it is “more acceptable”. What is used to measure “acceptability”? It does not sound objective, only anecdotal. There is a clear lack of pain scores, Patient Reported Outcomes and patient feedback. Also, postings to the Care Opinion site show that too many women find it completely UN-acceptable.   Is “acceptability” currently based on clinicians’ measures / opinions?   Women who haven’t experienced OPH with AND without anaesthetic cannot choose which they prefer. You cannot make that judgement unless you have experienced both.   Also, LA and GA are often presented to women as being risky, so they are encouraged to “try” with no pain relief and “see how it goes”. Women are led to believe that their only choice is 'vocal local' (with rescue LA) or GA. By the time severe pain hits them, it is too late. |
| 67 | Hysteroscopy Action | 2 | The rationale for offering Outpatient Hysteroscopy is incomplete.   The Briefing Paper, at 2.5 states, “ …cost of additional hysteroscopy is likely to be offset by savings from fewer ultrasound investigations and fewer appointments required for treatment following the diagnostic test”  • For those who suffer severe pain and trauma, the impact can last for weeks, months or even years. • There are cases of women requiring counselling for PTSD. 10% of patients who replied to CAPH’s ongoing survey report being diagnosed with PTSD. https://docs.google.com/forms/d/e/1FAIpQLSc2XTOe81rEy7zV2ARNPECceYyE--wTtR0mA10XHIxNQVOBrw/viewform?fbclid=IwAR1mY2kiA2IFfVaGSk4vDzhoLcMDCL3d9AglWBWr7h\_SFuI1HcRh24eD66g • No reference to this was included in the “offset”. • Trauma caused by extreme pain at Outpatient Hysteroscopy leaves some women unable to present for future gynaecological screening to the detriment of their health. CAPH’s survey lists several cases of women so traumatised by OPH that they say they won’t return to a gynae department, even if they suspect, or have, cancer. There was no reference to this in the “offset”. • Women being investigated for womb cancer normally have a TVU scan. Although cost effective and normally pain free they are difficult to interpret. For HMB you propose to go straight to Outpatient Hysteroscopy. Some of these patients may not have been sexually active, many will not have had children - women who are at a greater risk of a painful and traumatic experience. • Increase in Outpatient Hysteroscopy without option of GA will increase demands on PALS services, NHS Resolution, Care Opinion, complaints processes.  The “Best Practise Tariff” for Outpatient Hysteroscopy must be discontinued. It is a financial incentive to push women who are unsuitable into an outpatient procedure. |
| 68 | Hysteroscopy Action | 2 | The QS states, “..discuss the procedure …and advise on the possible alternatives”.  NICE should measure whether Quality Standard 2 incorporates the ‘best practice’ RCOG advice to women: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg59/ 1. The option to be treated under GA, or procedural sedation with analgesia – already available in certain gynae clinics but not always offered. . 2. The fact that nulliparous and post-menopausal women with cervical stenosis have a higher risk of developing severe or intolerable pain. 3. Other things to consider when deciding whether OPH is the right choice for you, such as:  • if you faint during your periods because of pain  • if you have experienced severe pain during a previous vaginal examination  • if you have experienced difficult or painful cervical smears  • if you have had any previous traumatic experience that might make the procedure difficult for you  • if you do not wish to have this examination when awake.  The British Society for Gynaecological Endoscopy published this statement in December 2018: "Diagnostic hysteroscopy is a commonly performed investigation; it is safe and of short duration. Most women are able to have the procedure in an outpatient setting, with or without local anaesthesia, and find it convenient and acceptable. However, it is important that women are offered, from the outset, the choice of having the procedure performed as a day case procedure under general or regional anaesthetic. Some centres are also able to offer a conscious sedation service in a safe and monitored environment. It is important that the procedure is stopped if a woman finds the outpatient experience too painful for it to be continued. This may be at the request of the patient or nursing staff in attendance, or at the discretion of the clinician performing the investigation"   Be honest about the effectiveness of Local Anaesthesia.  • The injection itself can be painful.  • It numbs ONLY the cervix, not the uterus. As per RCOG guidelines “Instillation of local anaesthetic into the cervical canal does not reduce pain during diagnostic outpatient hysteroscopy but may reduce the incidence of vasovagal reactions”.  Some women know with certainty that “over the counter medication” is ineffective for their menstrual, uterine pain and has no impact on it. They find benefit only from prescribed medicines, such as mefenamic acid. Women must be advised to use whatever medication is EFFECTIVE for THEM for uterine pain.  Women also need honest info of the risks and benefits of different options of anaesthetic. Many hospitals are not even using the RCOG December 2018 statement, preferring to omit information vital in order to give a Montgomery-compliant informed consent.  The Royal College of Anaesthetists, in conjunction with the Royal College of Surgeons, have a good patient information leaflet, giving information on hysteroscopy anaesthetics, RCOG appear not to have been involved. We have no evidence that this leaflet is being given to any patients.  The Briefing Paper, at 4.3.1 refers to “Discussing all options with explanation of benefits and risks”. This MUST include the risk of severe pain.   The Briefing also regards “Involving patients in treatment decisions”, which is not only required for “treatment adherence and patient satisfaction”. It is now required in law as per Montgomery.  The Briefing Paper, in a comment from Bayer, stated that in a Women’s Health APPG survey “42% ..said they were not treated with dignity and respect”. Being honest about the potential for pain would help women feel respected as adults rather than being subjected to paternalism. This attitude has led to >49,000 people signing a petition to the Health Secretary, “to change the barbaric manner in which many NHS hysteroscopies are currently performed”.  VAS 1 to 10 pain scoring is used worldwide, it is the best we have and is accepted method for research and administering of pain relief within the NHS.” Pain scores have a good evidence base and lead well to benchmarking“. It doesn’t make sense that these haven’t been used. Patients could then be given a personalised risk of suffering high pain levels (years of useful data is already missing). A missed opportunity.  Informing patients is key – as is BELEIVING them. The Green top guidelines 2011 were unsuitable due to lack of patient involvement.   Women referred for hysteroscopy may have already managed uterine pain for decades. Ask them about it, then use their knowledge and experience of their own bodies to improve their treatment. |
| 69 | Hysteroscopy Action | 2 | Measurement is needed of whether Information about the procedure is provided at least 2 days before the appointment unless a pre-procedure appointment is taking place, allowing enough time for a patient to be able to reflect upon her options and give informed consent. |
| 70 | Hysteroscopy Action | 2 | There must be data captured confirming that all possible alternatives have been discussed. |
| 71 | Hysteroscopy Action | 2 | How will local commissioners know that hysteroscopy services are adequately staffed when patients start requesting GA or procedural sedation?  Will outpatient hysteroscopy services be equipped with up-to-date equipment that causes less harm/pain, e.g. no electro-thermal surgery to be used for resection of polyps? See MERT trial.  Will local data collection include pain scores taken before/after the procedure and at a later date if the patient is too unwell to complete pain scores at end of procedure? We don’t see how this can currently work as a quality measure since most hospitals don’t carry out or record pain-scores. |
| 72 | Hysteroscopy Action | 2 | Data Source – training records.  Who will be responsible for this training and collection of evidence since it’s clearly not currently working for at least 25% women undergoing outpatient hysteroscopy.   In 2019 should we be referring to “minimise discomfort and pain”? Surely the procedure should be painfree for all women, as it would be for a man having polyps removed from his urinary tract or other penile endoscopy.   Training undertaken is not proof of skill in application. Patient feedback is essential e.g, pain scores, PROMs etc. |
| 73 | Hysteroscopy Action | 2 | Data Source – audit of patient records. This is incomplete. Best practice must be assessed through first hand patient accounts also. Some women have accessed their medical records after a traumatic Outpatient Hysteroscopy, to find them noted that the OPH was “Successful”, i.e. it was completed, despite the fact they have suffered severe pain and trauma during the procedure. Patient records alone do not give the full picture. How will patient groups be involved in the audit of patient experience? |
| 74 | Hysteroscopy Action | 2 | Service Providers – one-stop shop:  One-stop shop, or See-and-Treat, does not follow current requirements for informed consent. Women must have time to obtain information, ask questions and reflect. There needs to be measurement of pre-op assessment screening of suitability for and acceptance of OPH.  Best practice guidelines should include patients being given detailed information about the procedure at least 2 days in advance to allow informed consent to be given or for them to choose a different procedure. Please ensure this happens as part of Best Practice. Information should be the RCOG leaflet or Dr Mary Connor’s Sheffield leaflet at minimum.  Currently ‘See then Treat’ is administered akin to ‘Trick ‘n Treat’. Women are told that they will only feel the discomfort similar to a smear test. They confidently agree to OPH and are then shocked to the core when the pain is 8/10. Trust in healthcare professionals is destroyed. It does not cater for women who are happy to attend to DISCUSS possible treatment options but cannot endure examination, for example due to previous trauma. RCOG guidance refers, “We understand that for some people, particularly those who may have anxiety or who have experienced trauma, physical or sexual abuse, such examinations can be very difficult”.  Service providers should not audit themselves (mark their own homework). There are some very poor NHS outpatient hysteroscopy clinics which cause considerable harm to patients. |
| 75 | Hysteroscopy Action | 2 | Healthcare professionals as advocate “…if required”. In what scenario would an advocate not be required? The woman does not know that the procedure is going to be problematic, or how, until it IS problematic. She needs someone with expertise to help her.  The woman needs to KNOW that this is the nurse’s function during OPH. Many women report the nurse’s role as providing “vocal local” only. They did not know that they had an advocate.  There needs to be a record of whether a patient is permitted to bring a partner or friend into the treatment room to act as the patient’s advocate. |
| 76 | Hysteroscopy Action | 2 | Over-the-counter oral analgesia or even stronger oral analgesia will not help women who experience severe OPH pain. When world expert Prof A. di Spiezio Sardo was asked at the BSGE 2019 what analgesia was best for OPH he explained that he’d tried using everything and no drug works.   Hundreds of patients who have contacted Hysteroscopy Action – the Campaign Against Painful Hysteroscopy report severe pain on a par or worse than childbirth. NHS audits obtained under the Freedom of Information Act and in the public domain labelled ‘Outpatient hysteroscopy’ at www.whatdotheyknow.com show that up to 40% (!) of patients at a given clinic report severe pain during OPH. The mean % of severe pain for an NHS OPH clinic is 25%. Data is incomplete across the NHS since most clinics fail to publish their range of pain-scores and only give the mean score of those patients who completed a survey. Just as with the vaginal mesh scandal, long-term Patient Reported Outcomes of outpatient hysteroscopy have never been measured by the Department of Health.   We cannot stress enough the inadequacy and inaccuracy of the BSGE ‘satisfaction’ survey of Nov & Dec 2019 being adopted as a national benchmark standard for ‘acceptable’ outpatient hysteroscopy. The BSGE survey will only go to BSGE members’ patients and not to every NHS OPH clinic. The survey is unlikely to capture evidence of the full range of pain scores since patients are being asked to complete a survey immediately after the procedure, at a time when women who’ve been traumatised by the procedure will be unable to take part. There is no independent monitoring of denominator and numerator. |
| 77 | Hysteroscopy Action | 2 | Which healthcare professionals will assess whether a patient is suitable for outpatient hysteroscopy? Which HCPs will be responsible for screening out women at high risk of severe pain, e.g. have had a previous bad OPH, have never given birth vaginally, have suffered sexual abuse, have vaginismus, have never had a sexual partner. Who will prevent ALL women from being put through ‘Trial by Outpatient Hysteroscopy’? |
| 78 | Hysteroscopy Action | 2 | PLEASE ADD: Commissioners must ensure that ‘best practice guidelines’ include provision for general anaesthetic (and procedural IV sedation with analgesia) for those patients who prefer not to undergo Trial by Outpatient Hysteroscopy. SEE BSGE/RCOG STATEMENT 2018. https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg59/ See Supreme Court ruling in Montgomery v. NHS Lanarkshire 2015 https://www.supremecourt.uk/cases/uksc-2013-0136.html |
| 79 | Hysteroscopy Action | 2 | “A nurse is also available to act as the person’s advocate..” The nurse must be trained and empowered to tell the hysteroscopist to stop if the patient is passing out, crying etc. Evidence collected by the Campaign Against Painful Hysteroscopy’s survey shows multiple instances of nurses ignoring a patient’s distress or of hysteroscopists ignoring a nurse’s advocacy on behalf of the patient. We have many reports of patients being in so much pain, or on the verge of fainting that they are unable to speak and unable to indicate their distress. How will this be recorded? |
| 80 | Hysteroscopy Action | 2 | Data Source to include “Outpatient hysteroscopy patient survey” is erroneous.  The current administration of the BSGE survey is flawed. The survey asks good questions but • BSGE members’ patients are likely to have received hysteroscopy from better trained teams than non-BSGE hysteroscopists. Our CAPH survey shows that some Trusts supply far fewer horror stories than others. • Not all women undergoing Outpatient Hysteroscopy in November and December 2019 have been GIVEN a survey to complete.  • The survey has to be completed in the department. One patient has complained to us that she felt obliged to give positive feedback, as she was being watched by health professionals when completing the form.  Those who are in most pain and/or most traumatised will be unable to complete the survey. The Care Opinion website includes harrowing accounts from women during the survey period who have experienced severe pain and use words such as “horrific”, “traumatising”, “utterly barbaric”, “agony”, “unbearable”. |
| 81 | Hysteroscopy Action | 2 | Numerator – Who will collect and how will data be collected? Needs to be done independently of the clinic.  Data source: “The BSGE OPH survey includes national data on patient satisfaction.” Patients are being asked to complete the BSGE survey immediately after the procedure when some patients will not be well enough to answer questions, or will feel obliged to give falsely appreciative replies because the nurses are standing over them, or because they don’t want to hurt the feelings of the ‘nice people’ whose managers asked them to inflict pain. The data will be flawed. |
| 82 | Hysteroscopy Action | 2 | “Outpatient hysteroscopy... is carried out without the use of general or regional anaesthesia”. This statement as a definition of a Quality Standard is shocking in its disregard of any mention of  • the benefits of local anaesthetic • the risks of local anaesthetic • the medically established risk of severe pain, shock, trauma, sense of violation • the need for a medical history • the need for a pre-op assessment of suitability • the need for informed choice of OPH, GA, IV sedation with analgesia • the need for a non-anxious patient • the need for a fully trained hysteroscopy team  The definition here of outpatient hysteroscopy reads as if this is something that can be tried on any patient without any analgesia or anaesthesia providing no speculum (‘vaginoscopy’) and a 3.5mm scope is used. Hundreds of replies to the Campaign Against Painful Hysteroscopy’s survey of painful OPH shows that this is not the case. Our survey to date shows a high % of women who had painful hysteroscopies reported no pain or minimal pain during introduction of the speculum.   The Briefing Paper comments that Outpatient Hysteroscopy “should be equivalent or less painful than normal menstruation”. For some women “normal menstruation” is excruciatingly painful, causing vomiting, fainting, etc. It is not acceptable to expect women to endure that level of pain.   The fact that women are already burdened with pain cannot be a valid reason for inflicting more of it upon them. How can this comply with “First do no harm”? There are no situations in which men are asked, “Have you experienced pain in your life? If yes, then you won’t need an anaesthetic”. Also some women suffer horribly during OPH, far exceeding their “normal menstrual” pain. In the words of one gynaecologist, “some women we’re scraping off the ceiling.” Some practitioners suggest that the rapid carrying out OPH causes less pain. This has not been quantified and, should women who have suffered be asked, many would confirm that the pain lasted longer than was acceptable / bearable. Using the length of the procedure to justify not having pain control is unacceptable. The trauma lasts for years.  It is not acceptable that procedures are carried out that knowingly have the potential to cause the following (as listed in the RCOG/BSGE Green Top Guidance 59): Feeling sick, vomiting, fainting, hypotension, bradycardia, pallor, sweating and reduced conscious state.   For testicular biopsy, where it would be possible to have a local, it is recommended by BAUS that a GA or spinal is used. This is sex discrimination. PLEASE WHY IS THIS NOT MENTIONED IN THE EQUALITY IMPACT ASSESSMENT?    Men being investigated for possible prostate cancer often have an MRI first, then only a biopsy if needed. Cystoscopy guidelines recommend GA when using ridged scopes, outpatient for flexible scopes for both sexes.  Best practice standards - routine collection of patient-reported outcomes. These must be collected and analysed BEFORE any ramp-up in OPH, to understand patient experience before increasing the number of women exposed to it. If you are unable to guarantee pain free procedures you should not be performing them, and certainly not ramping up the numbers, until suitable pain control is available.  The Briefing Paper refers to a “…rapid return to usual activities”. Is there any quantifiable evidence? How is activity after appointment measured, as women have left the unit by then? |
| 83 | Hysteroscopy Action | 2 | [“Adapted from the RCOG OPH PIL”] The leaflet also says that women should be advised of the alternatives available to them in terms of anaesthesia, sedation etc. and that some people experience severe pain with this procedure.   There are also groups of women (as previously stated) who should not be considered for hysteroscopy without GA or other sedation. There must be a caveat stating that women have the right to choose the option of hysteroscopy performed under GA or with safely monitored procedural IV sedation with analgesia. It is vital that patients and HCPs are aware that the alternatives of GA and IV sedation exist. Evidence from the Campaign Against Painful Hysteroscopy’s survey of painful OP hysteroscopy shows that 75% patients who had a painful OPH had not been informed that they had the option of having a GA. |
| 84 | RCGP | 2 | Can the committee consider altering the statement to specify ‘endometrial’ polyps rather than simply ‘polyps’. |
| 85 | RCGP | 2 | Under section “People with heavy periods that may be related to other problems”, can the committee consider changing nurse is also available to act as the persons advocate if necessary to “health care professional is also available to act as the persons advocate if necessary. Not all services use nurses in these roles and with the increasing number of advanced clinical practitioners from all backgrounds and physician assistants it may not always be a nurse available to help therefore healthcare professional is more appropriate, |
| 86 | RCGP | 2 | Increasing the number of one-stop therapeutic procedures, reduces the number of repeat appointments, procedures and time required for people with HMB to be absent from work, social and family commitments thus impacting on financial savings for the NHS |
| 87 | FEmISA | 2 | Should state ‘Women’ rather than people. How many men have heavy menstrual bleeding? |
| 88 | FEmISA | 2 | Should state ‘Women’ rather than people |
| 89 | FEmISA | 2 | Women with suspected fibroids should first be given outpatient ultrasound or preferably an MRI scan to determine, the type and size of the fibroid. The mortality rate for ultrasound and MRI approaches zero. Hysteroscopy has a very high mortality rate - 0.3% i.e. 180 women a year in the NHS in England alone die within 90 days of this procedure, and the morbidity rate is very high too – the serious complication rate 3.14% - nearly 3,000 women in the NHS in England each year. As a considerable increase in outpatient hysteroscopy is being recommended without proper evidence the numbers of women experiencing serious morbidity and death will increase if this first line diagnosis is used. This is completely unacceptable and NHS HES and ONS figures have been ignored. There is also likely to be a considerable increase in litigation. |
| 90 | FEmISA | 2 | There should also be a check to ensure that women have access to choose an alternative safer diagnostic procedures such as ultrasound and MRI, as hysteroscopy is not sufficiently safe and has never been formally reviewed for safety and efficacy. Sufficient analgesia must be available for women undergoing this procedure before the procedure at the outpatient’s department to ensure they do not suffer. Women who are offered this procedure should be fully informed of all the risks and pain, including mortality and morbidity. “Healthcare professionals They advise people to take oral analgesia before the procedure and perform vaginoscopy as the standard diagnostic technique, using miniature hysteroscopes (3.5 mm or smaller)”  This advice has been proved inadequate and is not evidence based. Adequate analgesia should be provided in the outpatient’s clinic before the procedure. Ibuprofen should not be taken on an empty stomach, which would be necessary if the women were to take it at home before the procedure and is likely to have worn off.  Women should be given the opportunity to take part in an anonymous questionnaire of their experience, pain experienced any side effects, morbidity and time off work/away from normal responsibilities as a consequence of this procedure, since safer/ non-invasive alternatives are available which require no convalescence.   A nurse is available to act as the person’s advocate if required.  The patient should be asked anonymously if a nurse was available and if she felt the nurse acted as an advocate for her in any way and was supportive to her needs and fears. |
| 91 | FEmISA | 2 | Need to monitor patient safety which is not included  • Mortality actual deaths and rate  • Morbidity actual and rate – short, medium and long-term • Pain experienced • Cost to patient – accompanied travel, time off work, pain and duration • Cost to patient’s family and employer – accompanied travel, care at home, time off work • Time to complete recovery – patient returns to normal health and can completely resume normal activities • What was the women told and did she feel she was fully informed - if not why not, how could it be improved? • Were the women offered alternatives and fully informed of these? • Would the women be prepared to have the same procedure again and what would need to improve if she did? • Could communication be improved with medical and nursing staff? If so how? • How would she rate patient care 1-10 • How would she rate clinical care 1-10 – asked at least 2 weeks after the procedure confidentially in an anonymous survey at home – via PC or paper survey Need to monitor HES and ONS data for morbidity, readmission rates, mortality |
| 92 | FEmISA | 2 | Commissioners need to monitor and measure carefully the cost effectiveness of outpatient hysteroscopy compare with ultrasound and MRI – • NHS Tarif for each procedure • Number of procedures • Total cost • Cost of alternatives – ultrasound and MRI • Readmission rates and costs • Total costs procedure and readmission • Costs of litigation • Deaths |
| 93 | FEmISA | 2 | Hysteroscopy cannot diagnose the different types of fibroids, particularly subserosal or intermural and as well as being too risky it is also unacceptably painful, if women were properly informed and given a choice. The background paper states – “outpatient hysteroscopy has become more widely available and is more acceptable to women with the implementation of equipment such as miniature hysteroscopes” this is completely untrue and is not evidence based. |
| 94 | FEmISA | 2 | Ultrasound and MRI are non-invasive and a woman can travel unaided to outpatients and return. The scan will take probably less than an hour and she can return to work/normal life unaided. Hysteroscopy is painful, the women will be unable to travel to and from the hospital unaided and will also require recuperation at home, possibly extending to several days. This standard should be patient-centred but is not and is extremely costly to the women involved, their families and the NHS. |
| 95 | NHSE&I | 2 | ‘Statement 2 People with heavy menstrual bleeding and suspected submucosal fibroids, polyps or endometrial pathology have outpatient hysteroscopy’ seems to imply hysteroscopy is mandated and therefore appears to conflict with NICE NG88 Recommendation 1.3.7 Explain to women with HMB who are offered outpatient hysteroscopy what the procedure involves and discuss the possible alternatives. [2018].  The text relating to statement 2 does address the issues of choice and pain relief at hysteroscopy which are important issues and has been raised in recent parliamentary questions. I suggest the statement is modified to include the importance of informed consent, choice and respecting autonomy.  For example:  Either  Statement 2 People with heavy menstrual bleeding and suspected submucosal fibroids, polyps or endometrial pathology are offered outpatient hysteroscopy.  Or  Statement 2 People with heavy menstrual bleeding and suspected submucosal fibroids, polyps or endometrial pathology are offered outpatient hysteroscopy with an explanation of the benefits, risks, what the procedure involves and the possible alternatives. |
| 96 | Hologic | 2 | This statement refers to Outpatient Hysteroscopy as a diagnostic tool for HMB referring to audit figures this provision would need to be significantly scaled up in England as well as the rest of the UK. Some provision is given by the UK Gyne Societies and organisations to train registrars and some nurses in outpatient hysteroscopy but it is on a low level in regards to numbers as far as we see it.  Education is also needed on what hysteroscopy is for appropriate referral by primary care physicians since NICE-HMB came out we have not seen such an increase in training or education and wonder how this is to be done as it will restrict this standard and statement if it is not scaled up to meet the demand and move treatment on to effectively implement NICE-HMB ng88 |
| 97 | Hologic | 2 | More figures are needed to estimate the level of outpatient hysteroscopy needed and resources required for this to be planned if the NICE-HMB guidelines are to be implemented. Numbers of HMB patients, Number of outpatient hysteroscopy units currently in England/UK and numbers of patients they screen etc |
| 98 | BSGE | 2 | Where there is a recommendation for outpatient hysteroscopy for women with HMB and suspected submucosal fibroids, polyps or endometrial pathology then it must be recognised that not all centres across the United Kingdom have access to outpatient hysteroscopy. Clearly this is the preferred option with suspected submucosal fibroids and polyps but I think there needs to be clarification where it is important to exclude endometrial pathology, such as, endometrial carcinoma or forms of hyperplasia ---- that suction endometrial biopsy may have a place.  This is a question that is certainly raised by clinicians where access to outpatient hysteroscopy has to be more selective. It would also be important to consider that if outpatient hysteroscopy is not available whether some form of enhanced imaging with ultrasound (with saline infusion) may have a place. It is not clear whether the evidence base in these areas was considered. |
| 99 | RCOG | 3 | All their investigation and treatment options (including no investigations?) |
| 100 | Menstrual Health Coalition | 3 | Quality statements 2 and 3 relate to access to treatment. The Coalition welcomes the renewed focus on ensuring that information about appropriate treatment is shared with patients, as we believe that choice for women should be at the centre of any treatment pathway. The fact that the statements emphasise the need for healthcare professionals to discuss all treatment options rather than taking a prescriptive approach will ensure that women can access the treatment that is right for them. This entails healthcare professionals providing information about all treatments options for heavy menstrual bleeding and discussing this with women, as well as following NICE guidance on heavy menstrual bleeding, whenever possible. |
| 101 | FTWW | 3 | Would add ‘and / or symptomatology potentially indicative of menopause’ |
| 102 | FTWW | 3 | Make reference to equivalent bodies in devolved nations |
| 103 | FTWW | 3 | Add bullet point to incorporate an up-to-date and accurate discussion of benefits / risks of HRT |
| 104 | FTWW | 3 | Make reference to equivalent bodies within the devolved nations whose work / outcomes would be supported by the Quality Standard. |
| 105 | Hysteroscopy Action | 3 | “have a documented discussion with their HCP” – When will this take place? At the GP’s? At a pre-op assessment appointment? It cannot take place on the same day as ‘See & Treat’ as does this does not allow time for the patient to make an informed choice |
| 106 | Hysteroscopy Action | 3 | **For service providers.**  Women need to have written information about the full range of treatment options, which must include GA (and IV sedation if available). Information about the full range of treatment options must be available to women at least 2 days before an outpatient hysteroscopy so that women are not ‘tricked’ into a procedure they might regret.   **For commissioners**  The full range of treatment options for HMB must include general anaesthetic so that the patient is not forced to undergo endoscopy of the womb while awake if this is not acceptable to her. |
| 107 | Hysteroscopy Action | 3 | Discussion “where” > whether they want to retain their fertility and/or uterus |
| 108 | The National Institute of Medical Herbalists (NIMH) | 3 | **NIMH accredited practitioner experience** Local practice case studies - treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis.  Medical Herbalists have traditionally used herbal medicines to support people with heavy menstrual bleeding. The treatment provided by a medical herbalist varies with each individual. A combination of herbs will be selected depending on the symptoms and the cause. Two common causes of heavy bleeding are the result of uterine pathology such as fibroids or the hormonal imbalance that occurs during the perimenopause.  The initial aim of herbal treatment is to reduce the heavy bleeding with astringent and anti-haemorrhagic herbs. Those used in chronic and acute menorrhagia include: Yarrow (Achillea millefolium) Ladies’ mantle (Alchemilla vulgaris) Cranesbill (Geranium maculatum) Beth root (Trillium erectum) Greater periwinkle (Vinca major) Horsetail (Equisetum arvense) Goldenseal (Hydrastis canadensis) Shepherd’s purse (Capsella bursa-pastoris) (Pizzorna et al, 2016).  A clinical study has shown that Shepherd’s purse is effective in reducing post-partum haemorrhage (Ghalandari et al, 2017). If heavy bleeding is the result of fibroids, then the herbs selected for treatment are exemplified in the following case: A 49-year-old patient suffering from heavy bleeding and painful periods She had a history of fibroids with myomectomy performed 7 years previously. The fibroids have since regrown as shown by ultrasound. The aim of the herbal treatment was to reduce bleeding, prevent an increase in fibroid size, improve liver function, balance ovarian hormone levels, and reduce fatigue. She was also prescribed multivitamin containing iron. The woman reported a reduction in menstrual bleeding and fatigue over a 4-month period. Herbal prescription (herb, strength and dose per week) Capsella bursa-pastoris 1:3 30ml Alchemilla vulgaris 1:1 20ml Eleutherococcus sentocosus 1:1 15ml Phytolacca americana 1:5 8ml Equisetum arvense 1:1 10ml Thuja occidentalis 1:3 10ml Vitex agnus castus 1:1 10 ml Silybum marianum 1:1 30 ml   Total = 133ml  Ghalandari, S., Kariman, N., Sheikhan, Z., Mojab, F., Mirzaei, M., Shahrahmani, H., 2017. Effect of Hydroalcoholic Extract of Capsella bursa pastoris on Early Postpartum Hemorrhage: A Clinical Trial Study. The Journal of Alternative and Complementary Medicine, 23 (10). https://doi.org/10.1089/acm.2017.0095 |
| 109 | The National Institute of Medical Herbalists (NIMH) | 3 | **NIMH accredited practitioner experience**  Local practice case studies - treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis. Hormone imbalance can result in heavy bleeding. This is particularly evident in the perimenopause period when fewer ovulations can lead to oestrogen excess in comparison to progesterone, causing endometrial thickening and increase in blood loss. Vitex agnus castus is an important component of herbal treatment helping to improve luteal function and progesterone release via a dopaminergic action (van Die et al, 2009). Medical herbalists offer effective treatment of menopausal symptoms (Ralph & Webley, 2019). Altered endometrial prostaglandin synthesis with an increase in PGE2 production and uterine binding sites occurs with heavy menstrual bleeding. A recent clinical trial has demonstrated that ginger (Zingiber officinale) and frankincense (Boswellia serrata) provided a complementary therapy enhancing the therapeutic action of NSAID and reducing menstrual blood loss (Eshaghian et al, 2019). A previous study had shown that ginger reduced heavy menstrual bleeding in teenage girls (Kashefi et al, 2015).  The following case demonstrates the benefit of herbal medicine treatment for heavy menstrual bleeding associated with hormonal imbalance during the perimenopause.  A 48-year-old patient had experienced heavy menstrual bleeding over the last 2 years. Her menstrual cycles were regular but for 2 to 3 days bleeding was very heavy requiring changing sanitary protection every hour. She was taking tranexamic acid during the first four days of her period which had increased the formation of clots but not decreased the amount of bleeding. The aims of the herbal treatment were to reduce bleeding, balance hormone levels, improve liver function and manage stress as she was coping with a full-time job and three children. She was also prescribed a multivitamin with iron. The woman reported a reduction in bleeding (as assessed by the frequency of changing tampons) compared to taking tranexamic acid alone after two months of treatment.  Herbal prescription (herb, strength and dose per week) Achillea millefolium 1:1 15ml Alchemilla vulgaris 1:2 30ml Schisandra sinensis 1:3 30ml Capsella bursa-pastoris 1:3 30 ml Vitex agnus castus 1:1 15 ml Zingiber officinale 1:2 10 ml  Total 130 ml Eshaghian, R., Mazaheri, M., Ghanadian, M., Rouholamin,S., Feiza, A., Babaeian, M. 2019. The effect of frankincense (Boswellia serrata, oleoresin) and ginger (Zingiber officinale, rhizoma) on heavy menstrual bleeding: A randomized, placebo-controlled, clinical trial. Complementary Therapies in Medicine, 42: 42-47. https://doi.org/10.1016/j.ctim.2018.09.022 Kashefi, F., Khajehei, M., Alavinia, M., Golmakani, E., Asili, J. 2015 Effect of Ginger (Zingiber officinale) on Heavy Menstrual Bleeding: A Placebo‐Controlled, Randomized Clinical Trial. Phytotherapy Research 29 (1): 114-119. https://doi.org/10.1002/ptr.5235  Pizzorno, J.E., Murray, M.T., Joiner-Bey, H., 2016. Menhorragia in The Clinician's Handbook of Natural Medicine (Third Edition): 648-657. Churchill Livingstone.  Ralph, A., Webley, G. 2019. A prospective audit of pragmatic herbal treatment of women experiencing menopausal symptoms using measure yourself medical outcome profile (MYMOP2) questionnaires. Journal of Herbal Medicine in press https://doi.org/10.1016/j.hermed.2019.100286  Van Die, M.D., Burger, H.G. Teede, H.J., Bone, K.M. 2009. Vitex agnus-castus (Chaste-tree/Berry) in the treatment of menopause-related complaints. Journal of Alternative and Complementary Medicine, 15 (8): 853-862. https://doi.org/10.1089/acm.2008.0447. |
| 110 | The National Institute of Medical Herbalists (NIMH) | 3 | **NIMH accredited practitioner experience** Local practice case studies - treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis.  I have found that young patients in their teens, 20’s and 30’s often respond to a broad hormone balancing approach. In other words, by treating such patients with herbs such as Vitex agnus-castus alongside any co-factors such as IBS, or recurrent infections - these individuals often report improvement to PMS and heavy menstrual bleeding all together.  If heavy menstrual bleeding is a feature for these patients with other menstrual symptoms of disorder, I will usually consider uterine tissue tonics and blood tonics alongside hormone balancing herbs such as Vitex agnus castus. This means a typical prescription may include Urtica dioica, Achillea millefoilium, Alchemilla vulgaris, and Lamium album. If there is period pain (dysmennorhoea) as well, I will almost certainly include Zingiber officinale, Viburnum opulus or prunifolium and perhaps Aesculus hippocastanum.  Results are often very quick to observe - within 2 cycles changes are apparent, and by 4-6 cycles things are often on track. Treatment will often cease after 4-8 months, and patients remain symptom free for many years or indefinitely. |
| 111 | The National Institute of Medical Herbalists (NIMH) | 3 | **NIMH accredited practitioner experience** Local practice case studies - treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis  People approaching menopause are much more liable to experience persistent or extreme flooding with heavy menstrual bleeding. In this instance, I have found that mixtures of herbs such as Achillea millefolium, Alchemilla vulgaris and Hamamelis virginiana (cortex) have remarkably swift and helpful effects when used at the time and as often as required.  Many people also respond to preventative treatment taken for 4-8 months aimed at improving ovarian function – in many cases this can prevent the heavy bleeding from becoming persistent. In these cases, herbs such as Vitex agnus-castus are complemented by ovarian tonics such as Paeonia lactiflora and Dioscorea villosa, whilst addressing blood flow (Achillea millefolim) and uterine tissue integrity (Rubus idaeus, Alchemilla vulgaris, Capsella bursa-pastoris, Lamium album).  Treatment is often required through the duration of perimenopause, but many patients are often very happy to do this due to the many other beneficial effects they notice - such as relief from other perimenopausal symptoms |
| 112 | FEmISA | 3 | It is a requirement in the NHS Constitution that patients should be fully informed of all their treatment options and be able to make an informed decision of what they want. FEmISA and others have already submitted numerous surveys and evidence that women are not properly or fully informed and many are pushed into unwanted hysterectomies. FEmISA and many others have suggested that there needs to be patient information leaflet written with and approved by patient groups involved in HMB and fibroids setting out all the possible treatments with the risks, benefits and time getting back to normal life sent to all women before their outpatients’ appointment. This was removed from the latest HMB guidelines at great detriment to women and they remain uninformed experiencing unwanted hysterectomies and long-term morbidity associated with it.  Gynaecologists still pressurise women into having healthy ovaries and cervices removed, although this was outlawed in the previous, superior version of HMB guidelines it was put into the latest version to the great detriment of women. The risks of having healthy ovaries and cervices removed need to be explained as well as the dubious benefits if any.   Sending out patient information leaflets to women before their outpatients appointment needs to be reinstated and audited to ensure women receive objective information on all their treatment options. It will also ensure that they know what questions to ask at their outpatients’ appointment and communications will be more effective, There also needs to be multi-disciplinary fibroid clinics with interventional radiologists and gynaecologists working together in outpatients so a woman can be properly informed. This needs to be audited. Women need to be asked in a formal anonymous patient survey if they felt they were fully informed and asked specifically what they were informed about. Were they given sufficient information? Where they able to make an informed choice? Auditing patient notes, which patients do not see and cannot verify is inadequate. |
| 113 | Hologic | 3 | This statement assumes good knowledge of all HMB treatment options at the level of patient and all Health Care professionals but this is not the case. Knowledge on HMB is not good at a patient or primary care physician level so this required informed discussion on HMB and all treatment options taking place during that initial or subsequent consultations in primary care is unlikely and difficult to measure. In secondary care one would hope the situation would be improved but in some cases they will be starting a referral again at zero if the referring primary care physician has not taken a good history nor started or discussed any treatment options and this is not what the NICE-HMB work up implies. I do not know if there are plans to develop education on the patient or primary care level but this statement and the implementation of NICE-HMB ng88 will be restricted in implementation unless this changes. |
| 114 | Hologic | 3 | I do not know how far NICE would take this QS as there is a lot to do at a patient and primary care level and I am not sure if there is a plan for collaboration with key societies such as RCGP, RCG, BSGE etc |

## Registered stakeholders who submitted comments at consultation

* Bayer PLC
* British Society for Gynaecological Endoscopy (BSGE)
* Fair Treatment for the Women of Wales (FTWW)
* Fibroid Embolisation, Information, Support and Advice (FEmISA)
* Hologic
* Hysteroscopy Action
* Menstrual Health Coalition
* National Institute of Medical Herbalists
* NHS England and Improvement
* Royal College of General Practitioners (RCGP)
* Royal College of Nursing (RCN)
* Royal College of Obstetricians and Gynaecologists (RCOG)
* Royal College of Paediatrics and Child Health (RCPCH)

# Appendix 2: Quality standard consultation comments table – respondents with links to the tobacco industry

| **ID** | **Stakeholder** | **Statement number** | **Comments[[2]](#footnote-2)** |
| --- | --- | --- | --- |
| 1 | Bayer plc | General | We are disappointed to see that a quality statement has not been included in the area of ‘management of HMB’ despite reported feedback that it is a ‘key priority for implementation’ from 7 of the 13 responding stakeholders who provided areas for quality improvement, and 3 of 5 specialist committee members. The quality standard briefing document also outlines the evidence of the issues with current clinical practice.  We understand that the intention of the quality standard is to set out the priority areas for quality improvement in health and social care, and it seems to be a missed opportunity to omit evidence based recommendations from the NICE guideline that could help address issues around inequality of access and variability in service provision for LNG-IUS which is the first line treatment option for women with no identified pathology, and to drive improvements in quality of care for women with HMB. |

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1. PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees. [↑](#footnote-ref-1)
2. PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees. [↑](#footnote-ref-2)