NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate

Quality standards

Briefing paper

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| Quality standard topic: Heavy menstrual bleeding Output: Prioritised quality improvement areas for development. Date of Quality Standards Advisory Committee meeting: 18 September 2019 |

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1. Introduction

This briefing paper presents a structured overview of potential quality improvement areas for heavy menstrual bleeding. It provides the committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

* 1. Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the committee in considering potential statements and measures.

* 1. Development source

The key development source referenced in this briefing paper is:

[Heavy menstrual bleeding: assessment and management](https://www.nice.org.uk/guidance/ng88) (2018) NICE guideline NG88.

1. Overview
	1. Focus of quality standard

This quality standard will cover the assessment and management of heavy menstrual bleeding (menorrhagia), including suspected or confirmed fibroids or adenomyosis in women of reproductive age. It will replace the existing NICE quality standard for [heavy menstrual bleeding](https://www.nice.org.uk/guidance/qs47) (QS47).

* 1. Definition

Heavy menstrual bleeding (HMB) is excessive (heavy) menstrual blood loss that interferes with a woman’s physical, social and emotional quality of life. Excessive menstrual blood loss is classified as 80 mL or more and/or a duration of more than 7 days; however, direct measurement is complex to undertake in clinical practice[[1]](#footnote-1).

* 1. Incidence and prevalence

HMB is one of the most common reasons for gynaecological consultations in both primary and secondary care. Approximately 1 in 20 women aged between 30 and 49 years consult their GP each year because of heavy periods or menstrual problems, and menstrual disorders. These comprise of 12% of all gynaecological service referrals. Approximately 30,000 women in England and Wales undergo surgical treatment for HMB each year[[2]](#footnote-2).

* 1. Current service delivery and management

Since the publication of the original [heavy menstrual bleeding guideline (CG44)](http://guidance.nice.org.uk/CG44/Guidance/pdf/English) in 2007, there have been some significant changes in service delivery and management. For example, equipment and software for transvaginal ultrasound have improved and outpatient hysteroscopy has become more widely available and is more acceptable to women with the implementation of equipment such as miniature hysteroscopes. The relative clinical and cost effectiveness of diagnostic strategies have therefore changed. Improvements in diagnostic imaging in recent years have also resulted in an increase in the reported prevalence of adenomyosis. Adenomyosis, which is associated with abnormal uterine bleeding, pelvic pain and infertility, was not included in the previous version of the guideline.

There are a range of pharmacological and surgical treatment options for HMB. Outpatient management comprising insertion of a levonorgestrel-releasing intrauterine system (LNG-IUS) has increased in popularity in recent years with a reduction in surgical procedures. However, some endometrial ablation techniques (such as microwave endometrial ablation) are no longer available in the UK.

Please see appendices 2–3 for the HMB diagnostic and management care pathways from NICE guideline NG88.

* 1. Resource impact

We do not expect this quality standard to have a significant impact on resources. When the heavy menstrual bleeding: assessment and management guideline was developed, a resource impact statement was produced which noted that:

the resource impact of implementing any single guideline recommendation will be less than £1 million per year in England (or £1,800 per 100,000 population) **and**

the resource impact of implementing the whole guideline in England will be less than £5 million per year (or £9,100 per 100,000 population).

This is because it is considered that where clinical practice changes as a result of this guidance, there will not be a significant impact on resources. The 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.

Heavy menstrual bleeding services are commissioned by clinical commissioning groups (CCGs) and NHS England. Providers are NHS hospital trusts and primary care.

1. Summary of suggestions
	1. Responses

In total 15 registered stakeholders responded to the 2-week engagement exercise 17 July - 31 July 2019. 13 of these registered stakeholders provided areas for quality improvement and 2 advised they had no comment to make. We also received comments from 5 specialist committee members. The responses have been merged and summarised in table 1 for further consideration by the Committee.

Full details of all the suggestions provided are given in appendix 4 for information.

**Table 1 Summary of suggested quality improvement areas**

| **Suggested area for improvement** | **Stakeholders**  |
| --- | --- |
| **History, physical examination and laboratory tests*** Impact of HMB on women
* History
* Physical examination
* Laboratory tests
 | BAYER, PCWHF, RCGP, RCOG, RCPCH, SCM3, SCM4 |
| **Investigations for the cause of HMB*** Investigations
* Women with suspected submucosal fibroids, polyps or endometrial pathology
* Women with suspected adenomyosis
 | BSGE, HOL, NHSE, RCGP, RCOG, RCPCH, SCM1, SCM2, SCM3, SCM4, SCM5 |
| **Information for women about HMB and treatments*** Information about HMB management and all treatment options
* Hysterectomy
 | BAYER, BSGE, HOL, NHSE, RCGP, RCOG, SCM3, SCM4 |
| **Management of HMB*** Management of HMB
* Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis
* Treatments for women with fibroids of 3 cm or more in

diameter * Route and method of hysterectomy
 | BAYER, BCT, BSGE, BSIR, PCWHF, RCGP, RCOG, SCM3, SCM4, SCM5 |
| **Additional areas*** Commissioning and funding
* Data collection of LARC prescriptions
* Equalities
* Review of NICE guideline NG88
* Service provision
* Training
 | FEM, FRSH, HOL, NHSE, RCGP, RCOG,RCPCH, SCM1, SCM2, SCR |
| Abbreviations:BAYER, Bayer BCT, Birmingham Clinical Trials Unit, Birmingham Women's and Children's Hospital BSGE, British Society for Gynaecological EndoscopyBSIR, British Society of Interventional RadiologyFEM, FEmISA: Fibroid Embolisation, Information, Support and AdviceFRSH, Faculty of Sexual and Reproductive HealthHOL, HologicNHSE, National Clinical Director of women’s and maternal healthNHSE & NHS Improvement (Patient safety)PCWHF, Primary Care Women’s Health ForumRCGP, Royal College of General PractitionersRCN, Royal College of NursingRCOG, Royal College of Obstetricians and GynaecologistsRCPCH, Royal College of Paediatrics and Child HealthSCM 1-5, Specialist Committee MemberSCR, The Society and College of Radiographers |

* 1. Identification of current practice evidence

Bibliographic databases were searched to identify examples of current practice in UK health and social care settings; 700 papers were identified for heavy menstrual bleeding. In addition, 20 papers were suggested by stakeholders at topic engagement and 15 papers internally at project scoping.

Of these papers, 9 have been included in this report and are included in the current practice sections where relevant. Appendix 1 outlines the search process.

1. Suggested improvement areas
	1. History, physical examination and laboratory tests
		1. Summary of suggestions

Impact of HMB on women

Stakeholders highlighted how HMB has a major impact on women’s quality of life. This is however not always recognised which can lead to women being under treated.

History

Stakeholders highlighted the importance of documenting a detailed history for women presenting with HMB to determine whether and which examination and investigations are required. This history should include related symptoms, co-morbidities and the impact of HMB on quality of life. A detailed history may reduce unnecessary costs and time for both the woman and healthcare services by ensuring women only access appropriate effective treatment without delay and unnecessary referrals to secondary care are minimised.

Physical examination

Stakeholders suggested offering a physical examination in primary care is important as this could determine the HMB care pathway.

Laboratory tests

Stakeholders supported performing appropriate blood tests including a full blood count (FBC) if HMB is suggested by the woman’s history. FBC will determine if further investigations and treatment for iron deficiency anaemia is needed. This will reduce intraoperative complications and improve post-op recovery time for surgically managed cases.

* + 1. Selected recommendations from development source

Table 2 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 2 to help inform the committee’s discussion.

### Table 2 Specific areas for quality improvement

|  |  |
| --- | --- |
| Suggested quality improvement area | Suggested source guidance recommendations |
| Impact of HMB on women | NICE NG88 Recommendation 1.1.1 |
| History  | NICE NG88 Recommendations 1.2.1 - 1.2.3 |
| Physical examination | NICE NG88 Recommendation 1.2.4  |
| Laboratory tests | NICE NG88 Recommendation 1.2.6 |

### Impact of HMB on women

NICE NG88 Recommendation 1.1.1

Recognise that heavy menstrual bleeding (HMB) has a major impact on a woman's quality of life, and ensure that any intervention aims to improve this rather than focusing on blood loss. **[2007]**

### History

NICE NG88 Recommendation 1.2.1

Take a history from the woman that covers:

* the nature of the bleeding
* related symptoms, such as persistent intermenstrual bleeding, pelvic pain and/or pressure symptoms, that might suggest uterine cavity abnormality, histological abnormality, adenomyosis or fibroids
* impact on her quality of life
* other factors that may affect treatment options (such as comorbidities or previous treatment for HMB). **[2007, amended 2018]**

NICE NG88 Recommendation 1.2.2

Take into account the range and natural variability in menstrual cycles and blood loss when diagnosing HMB, and discuss this variation with the woman. If the woman feels that she does not fall within the normal ranges, discuss care options. **[2007]**

NICE NG88 Recommendation 1.2.3

If the woman has a history of HMB without other related symptoms (see recommendation 1.2.1), consider pharmacological treatment without carrying out a physical examination (unless the treatment chosen is levonorgestrel-releasing intrauterine system [LNG IUS][[3]](#footnote-3)). **[2007, amended 2018]**

### Physical examination

NICE NG88 Recommendation 1.2.4

If the woman has a history of HMB with other related symptoms (see recommendation 1.2.1) offer a physical examination. **[2007, amended 2018]**

### Laboratory tests

NICE NG88 Recommendation 1.2.6

Carry out a full blood count test for all women with HMB, in parallel with any HMB treatment offered.**[2007]**

* + 1. Current UK practice

### Impact of HMB on women

An online survey[[4]](#footnote-4) on women’s HMB experiences concluded:

* 74% experienced anxiety due to HMB
* 69% experienced depression due to HMB
* 62% reported an impact on physical wellbeing
* 43% had taken time off work.

### History, physical examination and laboratory tests

The All-Party Parliamentary Group on Women’s Health survey[[5]](#footnote-5) on endometriosis or fibroids found that 40% of the women surveyed needed 10 GP appointments or more before being referred to the specialist.

* 1. Investigations for the cause of HMB
		1. Summary of suggestions

Investigations

A stakeholder highlighted that HMB can be due to a variety of causes such as uterine, ovarian, systemic and iatrogenic causes or a hormonal imbalance. There are many conditions that can cause a hormonal imbalance such as polycystic ovary syndrome, insulin resistance, thyroid gland disorders anovulation cycle, insulin resistance and obesity.

A stakeholder highlighted that hysteroscopy or ultrasound should be used appropriately as first-line investigations when diagnosing HMB as this can lead to more effective, tailored treatments.

Women with suspected submucosal fibroids, polyps or endometrial pathology

Stakeholders supported the change in practice to provide outpatient hysteroscopy services for symptoms such as persistent intermenstrual bleeding and risk factors for endometrial pathology. Stakeholders also supported endometrial biopsy as being a less invasive procedure than hysteroscopy.

The need for best outpatient practice standards for hysteroscopy services and the procedures performed was supported which include offering ‘see-and-treat’ treatment in a single setting when appropriate, advising women about oral analgesia before the procedure and offering vaginoscopy with 3.5mm or smaller hysteroscopes.

Overall it was felt that best practice standards would positively reduce NHS costs and improve patient experience by alleviating significant distress with less invasive interventions and empowering women about their options and future treatment choices. It was however acknowledged that a move to outpatient hysteroscopy would happen at different rates between centres with a resource impact on service organisation and training.

Women with suspected adenomyosis

A stakeholder supported offering transvaginal ultrasound to women with suspected adenomyosis as this is a less invasive procedure compared to transabdominal ultrasound or MRI.

* + 1. Selected recommendations from development source

Table 3 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 3 to help inform the committee’s discussion.

### Table 3 Specific areas for quality improvement

|  |  |
| --- | --- |
| Suggested quality improvement area  | Selected source guidance recommendations |
| **Investigations**  | NICE NG88 Recommendation 1.3.3 |
| **Women with suspected submucosal fibroids, polyps or endometrial pathology** | NICE NG88 Recommendations 1.3.4, 1.3.5, 1.3.6, 1.3.7, 1.3.10 and 1.3.11 |
| **Women with suspected adenomyosis** | NICE NG88 Recommendation 1.3.13  |

### Investigations

NICE NG88 Recommendation 1.3.3

Take into account the woman's history and examination when deciding whether to offer hysteroscopy or ultrasound as the first-line investigation. **[2018]**

### Women with suspected submucosal fibroids, polyps or endometrial pathology

NICE NG88 Recommendation 1.3.4

Offer outpatient hysteroscopy to women with HMB if their history suggests submucosal fibroids, polyps or endometrial pathology because:

* they have symptoms such as persistent intermenstrual bleeding **or**
* they have risk factors for endometrial pathology (see recommendation 1.3.10). **[2018]**

NICE NG88 Recommendation 1.3.5

Ensure that outpatient hysteroscopy services are organised and the procedure is performed according to best practice, including:

* advising women to take oral analgesia before the procedure
* vaginoscopy as the standard diagnostic technique, using miniature hysteroscopes (3.5 mm or smaller). **[2018]**

NICE NG88 Recommendation 1.3.6

Ensure that hysteroscopy services are organised to enable progression to 'see-and-treat' hysteroscopy in a single setting if feasible. **[2018]**

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]**

NICE NG88 Recommendation 1.3.10

Consider endometrial biopsy at the time of hysteroscopy for women who are at high risk of endometrial pathology, such as:

* women with persistent intermenstrual or persistent irregular bleeding, and women with infrequent heavy bleeding who are obese or have polycystic ovary syndrome
* women taking tamoxifen
* women for whom treatment for HMB has been unsuccessful. **[2007, amended 2018]**

NICE NG88 Recommendation 1.3.11

Obtain an endometrial sample only in the context of diagnostic hysteroscopy. Do not offer 'blind' endometrial biopsy to women with HMB. **[2018]**

### Women with suspected adenomyosis

NICE NG88 Recommendation 1.3.13

Offer transvaginal ultrasound (in preference to transabdominal ultrasound or MRI) to women with HMB who have:

* significant dysmenorrhoea (period pain) **or**
* a bulky, tender uterus on examination that suggests adenomyosis. **[2018]**
	+ 1. Current UK practice

### Investigations

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder’s knowledge and experience.

### Women with suspected submucosal fibroids, polyps or endometrial pathology

The Royal College of Obstetricians and Gynaecologists’ National Heavy Menstrual Bleeding Audit[[6]](#footnote-6) examined the organisational structure of gynaecology outpatient clinics. It was reported that 80% of hospitals had access to ultrasound, hysteroscopy and endometrial biopsy but only 38% of hospitals had a dedicated menstrual bleeding clinic with approximately 90% of these being one-stop clinics.

A study at NHS Lothian[[7]](#footnote-7) reviewed outpatient hysteroscopies across two clinical sites- a central tertiary referral centre (site A) and a district general hospital (site B). A total of 420 outpatient hysteroscopies were performed across both sites; 299 (71.2%) at site A and 121 (28.8%) at site B. Overall, outpatient hysteroscopy was reported as highly successful these sites with low immediate complication rates. There was however a significant difference in the success rates between site A to site B with recommendations suggested for site A to address the availability of cervical dilators in clinics.

### Women with suspected adenomyosis

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder’s knowledge and experience.

* 1. Information for women about HMB and treatments
		1. Summary of suggestions

Information for women about HMB and all treatment options

Providing information about all HMB treatment options was highlighted as important as there is variation in access to treatment. Discussing all options with explanation of benefits and risks with the woman was supported by stakeholders for increasing informed choice. This informed choice will enable decision making in partnership with the clinician and allow the woman to maximise the benefit of available treatment. Involving patients in treatment decisions was felt to be key in ensuring treatment adherence and patient satisfaction.

Hysterectomy

A stakeholder highlighted that as hysterectomy is major surgery it is not always appropriate for the woman with HMB and should only be offered at the far end of the treatment pathway after other methods have been tried or offered.

* + 1. Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 4 to help inform the committee’s discussion.

### Table 4 Specific areas for quality improvement

|  |  |
| --- | --- |
| Suggested quality improvement area  | Selected source guidance recommendations |
| **Information for women about HMB and all treatment options**  | NICE NG88 Recommendations 1.4.1 and 1.4.2 |
| **Hysterectomy** | NICE NG88 Recommendation 1.4.7  |

**Information for women about HMB and treatments**

NICE NG88 Recommendation 1.4.1

Provide women with information about HMB and its management. Follow the principles in the NICE guideline on [patient experience in adult NHS services](https://www.nice.org.uk/guidance/cg138%22%20%5Ct%20%22_top) in relation to communication, information and shared decision-making. **[2018]**

[Patient experience in adult NHS services](https://www.nice.org.uk/guidance/qs15) (QS15) [statement 4](https://www.nice.org.uk/guidance/qs15/chapter/quality-statement-4-individualised-care#quality-statement-4-individualised-care)

People using adult NHS services experience care and treatment that is tailored to their needs and preferences. **[2012, updated 2019]**

[Patient experience in adult NHS services (QS15) statement 6](https://www.nice.org.uk/guidance/qs15%22%20%5Ct%20%22_top)

People using adult NHS services are supported in shared decision making. **[2012, updated 2019]**

NICE NG88 Recommendation 1.4.2

Provide information about all possible treatment options for HMB and discuss these with the woman (see section 1.5). Discussions should cover:

* the benefits and risks of the various options
* suitable treatments if she is trying to conceive
* whether she wants to retain her fertility and/or her uterus. **[2018]**

**Hysterectomy**

NICE NG88 Recommendation 1.4.7

Have a full discussion with all women who are considering hysterectomy about the implications of surgery before a decision is made. The discussion should include:

* sexual feelings
* impact on fertility
* bladder function
* need for further treatment
* treatment complications
* her expectations
* alternative surgery
* psychological impact. **[2007]**
	+ 1. Current UK practice

**Information for women about HMB and treatments**

The All-Party Parliamentary Group on Women’s Health survey[[8]](#footnote-8) on endometriosis and fibroids concluded:

* 62% of women were not satisfied with the information that they received about treatment options
* Nearly 50% of women were not told about the short-term or long-term complications from the treatment options provided to them.
* 67% of women said they got most of their information from the internet.
* 16% of NHS Trusts provide women with written information about HMB and pelvic pain.
* 86% of NHS Trusts could not provide information as to how many diagnostic tests were needed.

**Hysterectomy**

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder’s knowledge and experience.

* 1. Management of HMB
		1. Summary of suggestions

Management of HMB

When deciding on the best treatment option for HMB, a stakeholder highlighted the importance of patient-centred, individualised treatment. Patient involvement in treatment decisions is key in ensuring patient satisfaction and allows choice of appropriate treatment.

Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis

LNG-IUS as the first primary care treatment was supported by a stakeholder as it could empower GPs and community treatment settings and also help reduce inappropriate secondary care referrals. Current provision in primary care was reported by stakeholders as variable based on unequal access.

Secondary care referral was supported by stakeholders if treatment is unsuccessful, the woman declines pharmaceutical treatment or where symptoms are severe. It was emphasised that women with distressing HMB symptoms need to access specialist investigations and treatment quickly.

Treatments for women with fibroids of 3 cm or more in diameter

A stakeholder highlighted that women have a long time to wait before LNG-IUS insertion or ultrasound scan or hysteroscopies are performed. This delay can impact on the health and the quality of life of the woman. Starting treatment early benefits the woman and their future treatment outcomes. Offering interim drug treatment including tranexamic acid and/or non-steroidal anti-inflammatory drugs at the initial assessment was therefore supported for women who are waiting for definitive treatment or further investigations.

A stakeholder also supported considering performing uterine artery embolisation for women with fibroids of 3 cm or more in diameter with patient information offered on this procedure prior to hysterectomy.

Ulipristal was also supported by a stakeholder as a cost-effective treatment option which avoids major surgery for women with fibroids of 3 cm or more in diameter.

Route and method of hysterectomy

Discussing all possible hysterectomy methods (vaginal, laparoscopic and abdominal) with their advantages and disadvantages was supported by a stakeholder. Where appropriate, minimally invasive, vaginal or laparoscopic methods were supported by a stakeholder.

* + 1. Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 5 to help inform the committee’s discussion.

### Table 5 Specific areas for quality improvement

|  |  |
| --- | --- |
| Suggested quality improvement area  | Selected source guidance recommendations |
| **Management of HMB** | NICE NG88 Recommendation 1.5.1  |
| **Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis** | NICE NG88 Recommendations 1.5.2, 1.5.3 and 1.5.5  |
| **Treatments for women with fibroids of 3 cm or more in diameter**  | NICE NG88 Recommendations 1.5.8, 1.5.10 and 1.5.12  |
| **Route and method of hysterectomy** | NICE NG88 Recommendation 1.5.18  |

**Management of HMB**

NICE NG88 Recommendation 1.5.1

When agreeing treatment options for HMB with women, take into account:

* the woman's preferences
* any comorbidities
* the presence or absence of fibroids (including size, number and location), polyps, endometrial pathology or adenomyosis
* other symptoms such as pressure and pain.**[2018]**

**Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis**

NICE NG88 Recommendation 1.5.2

Consider an LNG-IUS[[9]](#footnote-9) as the first treatment for HMB in women with:

* no identified pathology **or**
* fibroids less than 3 cm in diameter, which are not causing distortion of the uterine cavity **or**
* suspected or diagnosed adenomyosis.**[2018]**

NICE NG88 Recommendation 1.5.3

If a woman with HMB declines an LNG-IUS or it is not suitable, consider the following pharmacological treatments:

* non-hormonal:
* tranexamic acid
* NSAIDs (non-steroidal anti-inflammatory drugs)[[10]](#footnote-10)
* hormonal:
* combined hormonal contraception[[11]](#footnote-11)
* cyclical oral progestogens. **[2018]**

NICE NG88 Recommendation 1.5.5

If treatment is unsuccessful, the woman declines pharmacological treatment, or symptoms are severe, consider referral to specialist care for:

* investigations to diagnose the cause of HMB, if needed (see [section 1.3](https://www.nice.org.uk/guidance/ng88/chapter/recommendations#women-with-suspected-submucosal-fibroids-polyps-or-endometrial-pathology)) taking into account any investigations the woman has already had **and**
* alternative treatment choices, including:
* pharmacological options not already tried (see recommendations 1.5.2 and 1.5.3)
* surgical options:
* second-generation endometrial ablation
* hysterectomy. **[2018]**

**Treatments for women with fibroids of 3 cm or more in diameter**

NICE NG88 Recommendation 1.5.8

If pharmacological treatment is needed while investigations and definitive treatment are being organised, offer tranexamic acid and/or NSAIDs[[12]](#footnote-12) **[2007]**

NICE NG88 Recommendation 1.5.10

For women with fibroids of 3 cm or more in diameter, take into account the size, location and number of fibroids, and the severity of the symptoms and consider the following treatments:

* pharmacological:
* non-hormonal:
* tranexamic acid
* NSAIDs11
* hormonal:
* ulipristal acetate (see recommendations 1.5.11 and 1.5.12)
* LNG-IUS[[13]](#footnote-13)
* combined hormonal contraception[[14]](#footnote-14)
* cyclical oral progestogens
* uterine artery embolisation
* surgical:
* myomectomy
* hysterectomy. **[2018, amended Nov 2018]**

NICE NG88 Recommendation 1.5.12

When ulipristal is used for intermittent treatment in women who are not eligible for surgery, for example where the risks of surgery outweigh the benefits or where the woman declines surgical treatment:

* Offer ulipristal acetate 5 mg (up to 4 courses) to women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level of 102 g per litre or below.
* Consider ulipristal acetate 5 mg (up to 4 courses) for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level above 102g per litre. **[Nov 2018]**

**Route and method of hysterectomy**

NICE NG88 Recommendation 1.5.18

When discussing the route of hysterectomy (laparoscopy, laparotomy or vaginal) with the woman, carry out an individual assessment and take her preferences into account. **[2007, amended 2018]**

* + 1. Current UK practice

**Management of HMB**

A survey on patient choice of fibroid treatment[[15]](#footnote-15) concluded that 67% of NHS Trusts take no measures to ensure women with fibroids are aware of their treatment options and are offered choice.

**Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis**

A cohort study[[16]](#footnote-16) also reported that 74% of the women had experienced HMB symptoms for more than 1 year with 30% of these having no prior primary care treatment. One year later, 43% had received surgery and of these, 58% had endometrial ablation and 37% had a hysterectomy.

**Treatments for women with fibroids of 3 cm or more in diameter**

The All-Party Parliamentary Group on Women’s Health survey[[17]](#footnote-17) on endometriosis and fibroids highlighted the range of treatment options women were informed about, offered and received. Please see Graph 1 below.

**Graph 1**



**Route and method of hysterectomy**

During 2017-18 NHS England[[18]](#footnote-18) reported there were 27,660 hysterectomies performed for HMB nationally.

The Royal College of Obstetricians and Gynaecologists’ report[[19]](#footnote-19) highlighted significant variation in hysterectomy rates across hospitals. Abdominal hysterectomy rates ranged between 17% to 66% of all hysterectomies performed. One third of all abdominal hysterectomies were performed laparoscopically with variation of 1% to 72%. Vaginal hysterectomy was performed in 37% of prolapse cases.

* 1. Additional areas

### Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise. However, they were felt to be either unsuitable for development as quality statements, outside the remit of this particular quality standard referral or need further discussion by the committee to establish potential for statement development.

There will be an opportunity for the committee to discuss these areas at the end of the session on 18 September 2019.

### Commissioning and funding

The NHS Long Term Plan and the future of sexual and reproductive healthcare commissioning was highlighted by stakeholders. A stakeholder also recommended that NICE guidance should include the need for consistent commissioning of Intrauterine System (IUS) devices to treat HMB in community and primary services with clear roles of accountability. Another stakeholder recommended that ulipristal acetate should be funded by the NHS. Recommendations about commissioning and funding are both beyond the remit of the development of NICE quality standards.

**Data collection of LARC prescriptions to treat HMB**

A stakeholder highlighted the need for better data collection of long-acting reversible contraception (LARC) prescriptions to treat HMB to identify if an IUS has been fitted for contraception or for HMB or for both. This suggestion has not been progressed. Participation in audit is a method by which quality improvement can be evidenced. Quality statements focus on actions that demonstrate high quality care or support, not the methods by which evidence is collated. However, audits and suggested methods of data collection may be referred to in the data sources for quality measures.

**Equality and diversity issues**

A stakeholder highlighted that inequalities particularly relating to the woman’s ethnicity, deprivation and mental health need to be addressed.

Equality and diversity issues will be considered for each quality statement in the quality standard, including the issues which have been raised by these stakeholders. In addition, an equality impact analysis is updated at different stages throughout quality standard development.

**Review of NICE guideline NG88**

A stakeholder highlighted the need for a review of the NICE guideline NG88 (2018) [Heavy menstrual bleeding: assessment and management](https://www.nice.org.uk/guidance/ng88) in terms of expert involvement, patient safety, efficacy, costing, indicators, the evidence of ulipristal acetate and current practice of endometrial ablation techniques.

**Service provision**

Stakeholders highlighted current unequal service provision such as the time taken from symptom presentation to symptom relief, the availability of updated technology and multidisciplinary teams to work together. It was also suggested there should be access to a choice of out-patient or in-patient procedures at every secondary care hospital, using cross hospital referral if required to ensure all women are offered equal choices of treatment options. These suggestions have not been progressed as there are no recommendations on these areas.

**Training**

Training of healthcare professionals was highlighted by stakeholders in areas such general HMB awareness, outpatient hysteroscopy and the differentiation between fibroids and adenomyosis.

These suggestions have not been progressed. Quality statements focus on actions that demonstrate high quality care or support, not the training that enables the actions to take place. The committee is therefore asked to consider which components of care and support would be improved by increased training. However, training may be referred to in the audience descriptors.

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# Appendix 1: Review flowchart

Records identified through topic engagement
[n =20]

Records identified through IS scoping search
[n = 15]

Records identified through ViP searching
[n = 700]

Records excluded
[n = 720]

Records screened
[n = 735]

Citation searching or snowballing

[n= 20]

Full-text papers excluded
[n = 26]

Full-text papers assessed
[n = 35]

Current practice examples included in the briefing paper
[n = 9]

# Appendix 2 details the HMB diagnostic care pathway from NICE guideline NG88. Appendix 2

# Appendix 3


# Appendix 4: Suggestions from stakeholder engagement exercise – registered stakeholders

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
| --- | --- | --- | --- | --- | --- |
| History, physical examination and laboratory tests |
| 1 | Bayer | Key area for quality improvement 3Management of HMB for women with no identified pathologyProposed Quality Statement:Recognise that heavy menstrual bleeding (HMB) has a major impact on a woman's quality of life, and ensure that any intervention aims to improve this rather than focusing on blood loss (based on recommendation 1.1.1 NICE Clinical Guideline on Heavy Menstrual Bleeding 2018). | As described in the NICE guideline on HMB, “evidence shows that HMB has a measurable effect on quality of life”.1 However, evidence suggests that the impact of HMB on women’s HRQoL is not always being recognised, and women are undertreated for this condition.  | In an internet survey conducted by the All-Party Parliamentary Group on Women's Health (WHAPPG) of over 2,600 women who had suffered from fibroids or endometriosis, 42% of women said that they were not treated with dignity and respect.2 Recent patient data from IQVIA Solutions UK Ltd (MAT Nov 2018), also showed that of 213,000 women aged 18-50 who were diagnosed with HMB, only 138,000 (65%) were treated.3Women also face significant delays from diagnosis to treatment. The National HMB audit revealed that almost three-quarters of women reported HMB symptoms for more than 1 year and nearly a third (30.4%) reported that they had not received medical treatment for their HMB in primary care before referral.4 This is further supported by evidence reported in the WHAPPG report which showed that for women with fibroids, the time to treatment from diagnosis was:- 1-3 months for 23%- 3-6 months for 20%- 6-9 months for 11%- 9-12 months for 7%- 1-2 years for 12%The report states that “given that fibroids can increase in size dramatically some of these waiting times are alarming.” | National Collaborating Centre for Women's and Children's Health. Heavy menstrual bleeding: full guideline. 2007. Available from: https://www.nice.org.uk/guidance/ng88/evidence/full-guideline-pdf-4782291810..2. All-Party Parliamentary Group on Women's Health. Informed Choice? Giving women control of their healthcare. March 2017.3. LPD, IQVIA Solutions UK Ltd, incorporating data derived from THIN, A Cegedim Database, Nov 2018.4. Geary RS, Gurol-Urganci I, Kiran A, Cromwell DA, Bansi-Matharu L, Shakespeare J, et al. Factors associated with receiving surgical treatment for menorrhagia in England and Wales: findings from a cohort study of the National Heavy Menstrual Bleeding Audit. BMJ Open. 2019;9(2):e024260. |
| 2 | RCOG | Additional developmental areas of emergent practice: QOL pre and post ablationQOL pre and post hysterectomyQOL in women diagnosed with adenomyosis and HMB |   |   |   |
| 3 | RCPCH | Key area for quality improvement 1: Definition | There can be an overlap in medical terms | Heavy menstrual bleeding is a common concern, although most women don't experience blood loss severe enough to be menorrhagia. Even so, some women cannot maintain their usual activities during their period because of blood loss and cramping. |   |
| 4 | SCM3 | Women should be offered treatment in primary care (including LNG-IUS or other pharmaceutical option), often without the necessity of further examination or investigation | Most women who present with HMB to primary care can be managed without the need for delay from further investigation or referral | To ensure most women can access effective treatment without delay or the need for unnecessary vaginal examination, and to minimise unnecessary referrals to secondary care | NICE HMB guidelines (key recommendations 1.2.3 & 1.3.1)Key national audits are listed in the Quality Standard Topic Overview for this committee.  |
| 5 | RCGP | Key area for quality improvement 2Document a clear history to determine if examination and further investigation recommended.  | Women do not always need investigation if there are no history or examination findings suggestive of adenomyosis, uterine enlargement or endometrial pathology.Cervical smear must be up to date but in low risk women with no concerning features treatment can be recommended without further intervention.In women requiring further investigation, the history and examination will help determine whether there is likely to be fibroids +/- adenomyosis (in which case ultrasound scanning is recommended), or whether there is likely to be uterine cavity abnormality (in which case hysteroscopy is the first recommended investigation). | The history can help identify whether the concern is likely to be due to a uterine cavity abnormality, including in women with co-morbidities, then examination and consideration of referral for hysteroscopy is the recommended investigation. | Heavy Menstrual Bleeding: assessment and management. NICE guideline NG88https://www.nice.org.uk/guidance/ng88 |
| 6 | SCM4 | Physical examination in primary care |  | Important not to offer medical management in primary care without a physical examination to at least assess the abdomen.It might be that medical management is appropriate and the patient’s wish, but palpation of a bulky uterus might mean more could be offered to the patient. Physical examination is left optional and down to clinical judgment as part of the management pathway for HMB. But palpating an abdominal mass could lead to a different pathway so is important.  | Heavy menstrual bleeding: assessment and managementNICE guideline [NG88]. |
| 7 | RCGP | Key area for quality improvement 1Women presenting with HMB have detailed history documented, including related symptoms, co-morbidities and impact on her quality of life. Appropriate examination and appropriate blood tests including a full blood count should be performed if the history suggests HMB. Other investigations such as TFTs or hormonal analysis are now not recommended first line. | NICE guidance recommends that the history should help determine whether and which examination and investigations are required.The impact of HMB on the quality of life is underestimated and undervalued.The most frequent cause of iron deficient anaemia in women of reproductive age is due to HMB and as the onset is insidious this is often not identified. A FBC will determine if further investigations and treatment of anaemia is indicated.  | Many women have unnecessary investigations performed which are inconvenient, unnecessary and costly. A detailed history and examination may reduce unnecessary cost and time for the woman and the health service. The impact of HMB on quality of life is underestimated and undervalued according to the APPG women’s health report and is a key aspect of the NICE HMB guideline. | Heavy Menstrual Bleeding: assessment and management. NICE guideline NG88www.nice.org.uk/guidance/ng88APPG on women’s health; Informed Choice Inquiry 2017www.appgwomenshealth.org/inquiry2017National HMB Auditwww.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/completed-projects/national-hmb-audit |
| 8 | RCPCH | Key area for quality improvement 2: History and Physical Exam | More than 70% of medical complaints and diseases can be diagnosed from a thorough history check and physical exam | A history check for confirming or refuting diagnosis could include asking for the number of soaked pads per hour for several consecutive hours, the occurrence of waking during the night for changing sanitary protection, the incidence of bleeding for more than a week, checking for the passing of blood clots larger than a quarter, and seeing how often daily activities are restricted due to tiredness. |   |
| 9 | PCWHF | All women presenting with symptoms on HMB should have a Full Blood Count blood test.This is a NICE recommendation. | Iron deficiency anaemia (IDA) is a common sequale of HMB. It comes on gradually and often unrecognised. HMB is the most common cause of IDA in women still menstruating and is easily treated. | Many women end up having lots of other blood tests that are not necessary, this is wasteful to scarce NHS resources. Correction of IDA improves quality of live. |  |
| 10 | PCWHF | Clinical history should record the impact HMB has on QoL | HMB affects women of working age. It has an impact on productivity, sickness, etc which limits promotion and progression at work. | It is commonly recorded that women are not taken seriously when reporting HMB. HMB is subjective diagnosis and the impact on a woman’s life has more significance that the volume of blood loss. |  |
| 11 | PCWHF | Women are offered treatment options at the first consultation | Treatment options at initial presentation are widely available over the counter or via a prescription from primary care. | By offering treatment from the initial consultation a woman will know she is being taken seriously. She can also start an initial treatment regime with her next bleed. She can also reflect on alternative options available |  |
| 12 | RCOG | Key area for quality improvement 2:Investigation of HMB. All women should have an FBC done. | Proper investigation leads to correct diagnosis. For example timely identification and treatment of iron deficiency anaemia minimises the need for unnecessary blood transfusion. It also reduces intraoperative complications and aids quicker post-op recovery for surgically managed cases.  | FBC is not always performed in women presenting with HMB. | National HMB audit |
| **Investigations for the cause of HMB** |
| 13 | SCM2 | Optimal diagnosis:Hysteroscopy and ultrasound scan should be used appropriately in diagnostic work of heavy menstrual bleeding (HMB). | Accurate diagnosis of pathologies causing HMB can lead to tailored, more effective treatments | Inequitable service provision currently | <https://reader.elsevier.com/reader/sd/pii/S0015028211005097?token=B051245577836906DD3BFDB154519A67D87782C3B5606CFEEB4F7F0CB85B4B90B12F4A42D4E5651D029CE426C3AB3959>https://www.ncbi.nlm.nih.gov/books/NBK261900/?report=reader |
| 14 | RCPCH | Key area for quality improvement 3: Causes | This is very important because there are specific treatments for each cause | Various causes can include uterine causes, a hormonal imbalance, ovarian causes or systemic and iatrogenic causes. In a normal cycle there is balance between oestrogen and progesterone that regulates the build-up of uterine lining (endometrium) which sheds during menstruation, if there is a hormonal imbalance the endometrium will develop in excess causing more bleeding during menstruation. There are many conditions that can cause a hormonal imbalance such as polycystic ovary syndrome, insulin resistance, thyroid gland disorders anovulation cycle, insulin resistance and obesity. |   |
| 15 | BSGE | Hysteroscopy |   | Hysteroscopy performed according to best practice including by vaginoscopy & with <3.5mm hysteroscopes (including techniques and equipment to minimise discomfort and pain in women; biopsy only in context of hysteroscopy; adequately sized, equipped, and staffed facilities; staff with necessary training, skills and expertise; and the need for audit and benchmarking of outcomes). |   |
| 16 | BSGE | Referral for hysteroscopy persistent intermenstrual bleeding or persistent irregular bleeding |   | Referring for hysteroscopy persistent intermenstrual bleeding or persistent irregular bleeding, and women with infrequent heavy bleeding who are obese or have polycystic ovary syndrome or failed treatment. |   |
| 17 | Hologic | Key area for quality improvement 4Move to outpatient based treatment where possible and see and treat | This is better for patients and better for the NHS cost wise, many procedures can be done in the outpatient dept.Hospitals should be supported in this area to develop and tariffs reflect this | Moving procedures out of the operating theatre were possible to free up that OR for more operations and move suited procedures for HMB to outpatients  | Tariff data for NHS, audit data BSGE & RCOG |
| 18 | SCM3 | Outpatient hysteroscopy is performed to best practice standards | Current variation in practice with reports of women experiencing marked distress. Units that follow best-practice guidelines report excellent patient acceptability, but other units appear to have introduced outpatient hysteroscopy without having invested in suitable equipment, training or staff | Patient campaign groups frequently publish reports of poor practice, and this has led to questions and even debate in Parliament (most recently in March 2019). Not only are women having distressing experiences which should be avoidable, but it is also likely that fewer women are being offered, or willing to consider, the gold standard procedure owing to concern that the process is distressing. Where best practice is followed, outpatient hysteroscopy should be equivalent or less painful than normal menstruation, or other procedures routinely delivered in clinic & primary care such as endometrial biopsy or fitting of an intrauterine contraceptive device.  | Best practice standards taken from NICE HMB guidelines recommendation 1.3.5, rationale (para 2 p23) and evidence review A p39-40: • vaginoscopy as the standard diagnostic technique• using miniature hysteroscopes (3.5 mm or smaller) for diagnosis• routine collection of patient-reported outcomes, benchmarked against national standards\*• avoid unnecessary biopsy (“Do not offer 'blind' endometrial biopsy to women with HMB”)• service organisation to enable ‘see-and-treat’ in a single setting where feasible• advise women to take oral analgesia prior to their procedure.• staff have necessary training, skills and expertise to perform outpatient hysteroscopy• facilities are appropriately sized, equipped and staffed with a toilet and private changing facilities• a nurse is available to act as the woman’s advocate and empowered to stop procedure if there is significant distress\* = This is a repeated request from patient groups – specifically that pain scores are sought from all women and benchmarked using a national database such as that being established by the BSGE. Personally I think a better measure of “distress” is “would you choose the same way of having this procedure if you had to undergo it again?”, though pain scores have a good evidence base and lend well to benchmarking. Other evidence: • RCOG guideline “Best Practice in Outpatient Hysteroscopy”, 2011• Vaginoscopy Against Standard Treatment (VAST): a randomised controlled trial. Smith et al, BJOG 2019 |
| 19 | SCM2 | Equity and access:Units should be able to offer all treatments for HMB and provide them or have pathways to refer into tertiary centres (e.g. hysteroscopic / laparoscopic myomectomy; abdominal v laparoscopic v vaginal hysterectomy; uterine artery embolisation) | Service provision needs to be compliant with the NICE HMB Update Guidelines | Inequitable service provision currently | https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/clinical-indicators-programme/benign-gynaecological-care/benign-gynaecology-report-2015-16/ |
| 20 | SCM2 | Management setting:There should be a choice of setting (ambulatory v operating theatre) where appropriate for diagnostic and therapeutic interventions for HMB | Compliant with the NICE HMB Update Guidelines and the soon to be updated BSGE / RCOG Green Top Guideline (CG59) in “Best Practice in Outpatient Hysteroscopy” | Inequitable service provision currently |   |
| 21 | SCM2 | Funding and recovery:Less invasive interventions (that allow more rapid return to usual activities in the community or hospital setting) should be prioritised.  | Compliant with current evidence base for ambulatory interventions and minimal access surgery  | Data regarding personalised recovery are not collected so hospitals failing to provide minimally invasive settings / techniques are non-identifiable | <https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/clinical-indicators-programme/benign-gynaecological-care/benign-gynaecology-report-2015-16/> |
| 22 | RCGP | Key area for quality improvement 5Women should be offered appropriate information prior to hysteroscopy including advice about analgesia, procedure and options. | As diagnostic services improve, women may be referred into an out-patient hysteroscopy clinic without a prior gynaecology clinic appointment and may not have the opportunity to discuss what the procedure involves or which analgesia to take prior to attendance. Good information prior to the procedure (via patient information leaflet if a prior gynaecology appointment is not given) allows better uptake of pre-procedure analgesia which reduces post-procedure pain and empowers women about their options and future treatment choices. | Recent reports suggest that women are not being provided with sufficient evidence to be able to make informed choices. | APPG on women’s health; Informed Choice Inquiry 2017www.appgwomenshealth.org/inquiry2017National HMB Auditwww.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/completed-projects/national-hmb-auditRCOG patient information leaflet; outpatient hysteroscopy.www.rcog.org.uk/en/patients/patient-leaflets/outpatient-hysteroscopy/ |
| 23 | RCOG | Key area for quality improvement 3: Outpatient hysteroscopy performed according to best practice including by vaginoscopy & with <3.5mm hysteroscopes (including techniques and equipment to minimise discomfort and pain in women; adequately sized, equipped, and staffed facilities; staff with necessary training, skills and expertise; and the need for audit and benchmarking of outcomes) |   |   |   |
| 24 | SCM4 | Investigating the causes of heavy menstrual bleeding |  | Since the update of the Guidance for Heavy Menstrual Bleeding (NG88), outpatient hysteroscopy has been recommended as a first line investigation as well as ultrasound. Furthermore, suggestions were made that centres should organise their hysteroscopy services so that they could offer a ‘see and treat’ service in a single setting where possible.It’s inevitable that this change to service provision will happen at different rates and there may be differences in what is offered at centres.  | 1.3.3 to 1.3.11 of Heavy menstrual bleeding: assessment and managementNICE guideline [NG88].  |
| 25 | SCM1 | First line Transavaginal/Transabdominal USS in the diagnosis of HMB |   | Less invasive first-line than Hysteroscopy | In the absence of clinical trials, decision analytical economic models evaluating all possible outpatient testing algorithms have indicated that using ultrasound or hysteroscopy for initial diagnostic testing for women with HMB are the most effective diagnostic strategies. Pelvic ultrasound has been most commonly used because it has been more widely available and is considered less intrusive than hysteroscopyHysteroscopy, in preference to pelvic ultrasound, is recommended for women with HMB who are suspected of having submucosal fibroids, polyps or endometrial pathology based on their history and examination. This change in practice will have a resource impact on service organisation and training.  |
| 26 | SCM1 | Endometrial Pipelle biopsy Versus Outpatient hysteroscopy.  |   | Less invasive than Hysteroscopy |   |
| 27 | SCM 5 | Hysteroscopy numbers OPH/GA | The 2018 guideline suggested biopsy of the endometrium for women for whom treatment of HMB has been unsuccessful. |   |   |
| 28 | SCM1 | Women with suspected adenomyosis |   | Agreement that Transvaginal is the most sensitive modality (in preference to transabdominal ultrasound or MRI) to women with HMB who have:significant dysmenorrhoea (period pain) ora bulky, tender uterus on examination that suggests adenomyosis |   |
| 29 | NHSE (NCD for maternity and women’s health) | Focus on preventative health eg. role of obesity in heavy menstrual periods |   |   | NHS Long term plan priorities |
| **Information for women about HMB and treatments** |
| 30 | BSGE | Information provision |   | Provide information about all possible treatment options for HMB (including as appropriate Mirena, pharmaceutical, ablation & hysterectomy) and discuss these with the woman. |   |
| 31 | Bayer  | Information for women about HMB and treatmentsProposed Quality Statement:Women with heavy menstrual bleeding have a documented discussion about all recommended treatment options (based on recommendation 1.4.2 NICE Clinical Guideline on Heavy Menstrual Bleeding 2018). | As described in the NICE guideline on Heavy Menstrual Bleeding (HMB), education and information provision, patient choice and patient empowerment are important, as among other things, they enable decision making in partnership with the clinician based on informed choice, allow a woman with HMB to maximise the benefit of available treatment and may improve satisfaction and adherence to treatment.1 | However, a survey conducted by the All-Party Parliamentary Group on Women's Health of over 2,600 women who had suffered from fibroids or endometriosis shows that “…women are rarely told about the full variety of treatment options, and are often pushed towards a treatment choice that they might not want, based on their clinician’s recommendation.”2The survey revealed that “62% of women were not satisfied with the information that they received about treatment options.” These findings are supported by a FEmISA survey which reported that “67% of Trusts take no measures to ensure women are aware of their treatment options and offered choice.”3 In women with fibroids, 70% of women were told about hysterectomy, whereas only 47% of women were told about myomectomy, 54% were told about Uterine Fibroid Embolisation, and ‘few’ were told about pharmaceutical options. The report also found that “only 16% of NHS Trusts provide women with written information about Heavy Menstrual Bleeding and pelvic pain.”2This indicates that there may be room for improvement in the provision of patient information with regards to their treatment options. | 1. National Collaborating Centre for Women's and Children's Health. Heavy menstrual bleeding: full guideline. 2007. Available from: https://www.nice.org.uk/guidance/ng88/evidence/full-guideline-pdf-4782291810.2. All-Party Parliamentary Group on Women's Health. Informed Choice? Giving women control of their healthcare. March 2017.3. 3. Fibroid Embolisation: Information, Support and Advice (FEmISA). Patient Choice and NICE Compliance Survey on Fibroid Treatment. Acute NHS Trusts in England. Conducted in 2016. 2017. Available from: http://www.femisa.org.uk/images/femisa%20report%20on%20patient%20choice%20and%20nice%20compliance%209.17%20-%20final.pdf  |
| 32 | SCM3 | Provide information about all possible treatment options for HMB (including as appropriate LNG-IUS, pharmaceutical, ablation & hysterectomy) | There is variation in access to treatment. National audits have shown regional variations in conservative treatment measures (like LNG-IUS or ablation) with higher hysterectomy rates in some areas. At the same time some areas restrict access to hysterectomy as a “low priority procedure” despite NICE guidelines stating it should be offered as a first line treatment where symptoms are severe or where the woman declines pharmaceutical treatment. The key issue is that the full range of treatment options should be discussed and offered as appropriate | To reduce variation in access to effective treatment at all levels – primary care, secondary care and in commissioning. In particular, the majority of women who are suitable for simple treatments (such as LNG-IUS or ablation) should be offered those choices, but commissioners should not restrict access to those in whom hysterectomy is appropriate as a first line treatment.  | NICE HMB guideline (key recommendations are 1.4.2 & 1.5.5)Key national audits are listed in the Quality Standard Topic Overview for this committee. One quality measure should be that hysterectomy is not listed by commissioners as a low priority treatment (given that it is both clinically and cost effective).  |
| 33 | RCGP | Key area for quality improvement 4Women with HMB have a documented discussion about all recommended treatment options. | Women make decisions based on the information provided to them. Decision aids are helpful for women to be able to make informed treatment choices by assessing the side effect profile, outcomes, effect on future fertility, time away from the workplace and home. | Recent reports suggest that women are not being provided with sufficient evidence to be able to make informed choices. | Ref statement 5 NICE HMB QS47www.nice.org.uk/guidance/qs47APPG on women’s health; Informed Choice Inquiry 2017www.appgwomenshealth.org/inquiry2017RCOG patient information leafletswww.rcog.org.uk/en/patients/patient-leafletsNICE HMB ng88 shared decision aidwww.nice.org.uk/guidance/ng88/resources/endorsed-resource-decision-making-aid-for-heavy-menstrual-bleeding-6540669613 |
| 34 | RCOG | Key area for quality improvement 4: Information provision | Appropriate information provision on available treatment options allows informed decision to be made by the patient. | All women must have the opportunity to discuss details of treatment (e.g hysteroscopy) with a specialist, including associated risks, in order to be able to make an informed decision about their treatment | National HMB audit |
| 35 | SCM4 | Key area for quality improvement 3 | Discussing treatment options | To ensure that women are at the centre of the decision-making process. Discussions should explore all options with an explanation of benefits and risks so that women are aware of the impact to their fertility and how treatments may affect their quality of life (e.g. bleeding changes after IUS or possible outcomes after a hysterectomy). |   |
| 36 | NHSE (NCD for maternity and women’s health) | Personalised care which may be highly pertinent to women’s preferences to the treatment of HMB |   |   | NHS Long term plan priorities |
| 37 | BSGE | Hysterectomy |   | \* Discuss all possible methods (vaginal, laparoscopic and abdominal) including the advantages and disadvantages of each.\* Audit practice and performance of hysterectomy using outcome measures assessed in the RCOG clinical indicators project – Patterns of Benign Gynaecology Care, 2016] |   |
| 38 | Hologic | Key area for quality improvement 5Hysterectomy and D&C for HMB were declared procedures of low clinical value for treatment of HMB yet Hysterectomies are still being performed for HMB and some HCPs arguing that laparoscopic hysterectomy is towards minimally invasive | Hysterectomy is major surgery and should as identified in the NICE\_HMB guidelines be at the far end of the treatment pathway after other methods have been tried or offered to the patient. More data is needed on the different types of hysterectomy and the risk benefits associated with each | Hysterectomy is major surgery and not suitable for all patients with HMB, we have seen studies comparing hysterectomy to other treatments in HMB which may not be appropriate as they are part of a work up and not equal risk-benefit wise etc  | NICE\_HMB needed more data for the guidelines hopefully more research will be done and the rates of hysterectomy in UK and reason for the operation looked into. |
| **Management of HMB** |
| 39 | RCOG | Key area for quality improvement 5Management options | Patient-centred, individualised treatment is key when deciding on the best treatment option for HMB. | Involving patients in treatment decisions is key in ensuring patient satisfaction and allows choice of appropriate treatment. There is variation in the availability of recommended treatment options across the country (e.g. availability of interventional radiology/uterine artery embolization). | National HMB audit |
| 40 | BSGE | Empowering GP and community treatment |   | Empowering GP and community treatment without examination or investigation (offer Mirena). |   |
| 41 | PCWHF | Women with HMB who are suitable are all offered an LNG-IUS (levonorgestrel-intrauterine system) | There is lots of clinical evidence that LNG-IUS is highly effective in treating HMB. The major problem is in women accessing this treatment. Many primary care services are no longer commissioned to deliver this service. This means women have to be referred to alternative services, causing timely delays and adding barriers in accessing then best treatment.Some practices have opted out of offering this service due to competing demands on their scarce resources or funding on offer not covering the cost of providing this service. A national survey ran by the PCWHF showed a significant reduction in IUS service provision across primary care. | As it is getting harder for women to access the fitting of IUS they are choosing other less effective treatments. This is likely to be less cost effective in the long run as they give up and are referred to secondary care. This pathway is very costly, often fails to follow the NICE guidelines and women end up with significant surgical interventions. There are agreed pathways of care based on NICE guidelines set up across the country. They are designed to avoid any delays to care but when there is no access due to lack of local provision this is causing huge delays in treatmentCommissioners and PHE need to look again at the provision of IUS and work collaboratively drawing together this fragmented service. The decision to move contraception and sexual health services over the public health/local authority has resulted in a divergent service that has added huge confusion and reduced access to IUS fitting. |  |
| 42 | Bayer  | Key area for quality improvement 2Management of HMB for women with no identified pathologyProposed Quality Statement:Women with heavy menstrual bleeding with no identified pathology are offered an LNG-IUS as the first treatment (based on recommendation 1.5.2 NICE Clinical Guideline on Heavy Menstrual Bleeding 2018). | The NICE guideline has recommended an LNG-IUS as the first treatment for women with no identified pathology since publication of the original guideline in 2007.1 However, there is evidence that implementation of this recommendation is lower than expected and that current provision is variable, raising concerns about inequality of access.  | According to patient data from IQVIA Solutions UK Ltd (MAT Nov 2018), 213,000 women aged 18-50 were diagnosed with HMB, of these 138,000 (65%) were treated. Of the treated women, only 11,000 (8%) were prescribed an LNG-IUS, whereas 64,000 (46%) were prescribed oral contraception.2In terms of availability, the first annual report of the Royal College of Obstetricians and Gynaecologists (RCOG) National Heavy Menstrual Bleeding Audit (2011)3 reports that “the option of inserting a LNG-IUS varied significantly by region”. “In Wales and the North East of England, the majority of hospitals reported this was an option for 50% or more of women, conversely, most hospitals in South Central England and the West Midlands said this was an option for only 0-20% of women.” The RCOG report hypothesised that this was one potential explanation for the variation in surgical procedures across English regions which was revealed in their organisational audit.3Improving implementation of this recommendation in primary care should also help to reduce inappropriate referrals, however according to the Faculty of Sexual and Reproductive Healthcare (FSRH) when discussing ‘contraception for gynaecological purposes’: “A combination of system fracture, reduced funding, and a lack of financial incentives for GPs to provide LARC has led to a reduction in the availability of LARCs in general practice. This has raised concerns regarding the deskilling of SRH clinicians across primary care. As most women choose to access contraception in primary care, it is paramount that women are able to access LARCs and that clinicians working in primary care have adequate opportunity to gain competencies in delivering LARCs. Women used to be treated cheaply and effectively in the community and are now being sent to gynaecologists in hospitals despite the much higher cost of this and inconvenience to the patient”.4According to patient data from IQVIA Solutions UK Ltd (MAT Nov 2018), 213,000 women aged 18-50 were diagnosed with HMB, of these 138,000 (65%) were treated. Of the treated women, only 11,000 (8%) were prescribed an LNG-IUS, whereas 64,000 (46%) were prescribed oral contraception.2In terms of availability, the first annual report of the Royal College of Obstetricians and Gynaecologists (RCOG) National Heavy Menstrual Bleeding Audit (2011)3 reports that “the option of inserting a LNG-IUS varied significantly by region”. “In Wales and the North East of England, the majority of hospitals reported this was an option for 50% or more of women, conversely, most hospitals in South Central England and the West Midlands said this was an option for only 0-20% of women.” The RCOG report hypothesised that this was one potential explanation for the variation in surgical procedures across English regions which was revealed in their organisational audit.3Improving implementation of this recommendation in primary care should also help to reduce inappropriate referrals, however according to the Faculty of Sexual and Reproductive Healthcare (FSRH) when discussing ‘contraception for gynaecological purposes’: “A combination of system fracture, reduced funding, and a lack of financial incentives for GPs to provide LARC has led to a reduction in the availability of LARCs in general practice. This has raised concerns regarding the deskilling of SRH clinicians across primary care. As most women choose to access contraception in primary care, it is paramount that women are able to access LARCs and that clinicians working in primary care have adequate opportunity to gain competencies in delivering LARCs. Women used to be treated cheaply and effectively in the community and are now being sent to gynaecologists in hospitals despite the much higher cost of this and inconvenience to the patient”.4The Academy of Medical Royal Colleges (AoMRC), Royal College of Obstetricians and Gynaecologists (RCOG), Faculty of Sexual and Reproductive Healthcare (FSRH), Royal College of General Practitioners (RCGP), Royal College of Pathologists (RCPath) and Royal College of Paediatrics and Child Health (RCPCH) would like to see “holistic integrated commissioning of sexual and reproductive healthcare because of the negative impact of the current situation for women”.5 | 1. National Collaborating Centre for Women's and Children's Health. Heavy menstrual bleeding: full guideline. 2007. Available from: https://www.nice.org.uk/guidance/ng88/evidence/full-guideline-pdf-4782291810.2. LPD, IQVIA Solutions UK Ltd, incorporating data derived from THIN, A Cegedim Database, Nov 2018.3. The Royal College of Obstetricians and Gynaecologists. National Heavy Menstrual Bleeding Audit. First Annual Report. A national audit to assess patient outcomes and experiances of care for women with heavy menstrual bleeding in England and Wales. 2011. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/nationalhmbaudit\_1stannualreport\_may2011.pdf 4. The Faculty of Sexual and Reproductive Healthcare (FSRH). Consultation Response - Rebuilding a Public NHS: Health and Social Care Policy Commission of the Labour Party. Jul 2019. Available from: https://www.fsrh.org/documents/fsrh-consultation-response-rebuilding-a-public-nhs-health-and/?preview=true 5. Holistic Integrated Commissioning of Sexual & Reproductive Healthcare - AoMRC, RCOG, FSRH, RCGP, RCPath and RCPCH Position. Apr 2019. Available from: https://www.fsrh.org/documents/fsrh-rcog-rcgp-position-holistic-integrated-srh-commissioning/  |
| 43 | Birmingham Clinical Trials Unit | Implementing the increased use of pharmaceutical therapy e.g. LNG-IUS (as first line), tranexamic acid in primary care before the woman is referred to secondary care | Heavy menstrual bleeding (HMB) is a prevalent condition that affects 20–30% of women of a reproductive age. New developments in the management of women with HMB, namely the levonorgestrel releasing intrauterine system (IUS) (a cost-effective first-line treatment especially when fertility preservation is desirable) | The RCOG, on behalf of HQIP, conducted a four-year national audit from 2010 to 2013 to examine the care received by women with HMB and to assess patient outcomes and experience of care. The existing local referral pathways between primary and secondary care show that nearly a third of women reported that they had not received any treatment for their HMB in primary care. | There is RCT data published in NEJM that supports the use of pharmaceutical therapy in primary care: Gupta, J., et al., Levonorgestrel intrauterine system versus medical therapy for menorrhagia. New England Journal of Medicine, 2013. 368(2): p. 128-137. https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/advice-for-hmb-services-booklet.pdf |
| 44 | SCM 5 | IUS use in primary care  | The 2018 guideline state that an IUS can be used as a first line treatment if there are no other symptoms. Provision of IUS services in the Uk is variable and may not be able to meet the needs of the UK population. |   | National data not available to me but now funding is via public health only pay for IUS fitted for contraceptive reasons there is complexity regarding funding steam in primary care. |
| 45 | BSGE | Referral to secondary care |   | Referral to secondary care if treatment unsuccessful, woman declines pharmaceutical treatment or where symptoms are severe |   |
| 46 | SCM3 | Women referred to specialist care (where treatment in primary care is unsuccessful, the woman declines pharmacological treatment, or symptoms are severe) should be offered: • investigations to diagnose the cause of HMB• alternative treatment choices including: o pharmacological options not already triedo second-generation endometrial ablationhysterectomy | Women with distressing symptoms need to access investigation and treatment quickly. Secondary care needs to offer a range of appropriate treatment options that includes both conservative measures and effective treatments including ablation and hysterectomy | There is evidence of marked variation in hysterectomy rates. This is because access to conservative treatments such as LNG-IUS or ablation is variable, but also access to hysterectomy (which is both clinically and cost effective) is restricted in some areas | NICE HMB guidelines 1.5.5Key national audits are listed in the Quality Standard Topic Overview for this committee.  |
| 47 | SCM4 | Key area for quality improvement 4 | Access to specialist care when needed for prompt treatment or investigation | Whilst HMB can be managed in primary care, women who were previously satisfied with this management should be promptly referred on when they experience changes to their symptoms, quality of life or wish to conceive. Three-quarters of women have symptoms for over a year when presenting at secondary care. Women from deprived areas also tend to have worse symptoms and worse condition-specific quality of life at their first outpatient appointment. It’s not clear if the differences between women are from how they present in primary care or if there are delays to referral.  | Kiran A, Geary RS, Gurol-Urganci I, et al Sociodemographic differences in symptom severity and duration among women referred to secondary care for menorrhagia in England and Wales: a cohort study from the National Heavy Menstrual Bleeding Audit BMJ Open 2018;8:e018444. doi: 10.1136/bmjopen-2017-018444 |
| 48 | BSGE | Ulipristal  |   | Offer ulipristal where fibroids are >3cm |   |
| 49 | SCM3 | Additional developmental areas of emergent practice – Offer treatment with ulipristal where fibroids are >3cm | Although this is an “offer” recommendation in the NICE guidelines, few areas are commissioned to do so | Access to ulipristal has been variable, and this provision has become worse since restrictions were introduced by the European Medicines Agency. Ulipristal is a valid and cost-effective treatment choice which avoids major surgery | NICE HMB guidelines 1.5.12 |
| 50 | RCGP | Key area for quality improvement 3Interim drug treatment should be offered | If women are waiting for definitive treatment or further investigations interim drug treatment should be offered, including tranexamic acid and/or non-steroidal anti-inflammatory drugs at the initial assessment. | Many women have to wait long times before LNG-IUS insertion or ultrasound scan or hysteroscopy. This may mean several more months of ongoing problems and concern impacting on their health and social wellbeing. Starting treatment early will not only benefit the woman but provide some recommendation to the healthcare provider about future treatment outcomes.  | Ref statement 4 NICE HMB QS47www.nice.org.uk/guidance/qs47APPG on women’s health; Informed Choice Inquiry 2017www.appgwomenshealth.org/inquiry2017National HMB Auditwww.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/completed-projects/national-hmb-audit |
| 51 | BSIR | Considering uterine artery embolization Prior to hysterectomy in section 1.5.5 | If possible Uterine preservation must be considered .Uterine artery embolization can be performed in :- Patients with uterine enlargement ( multiple small fibroids <3cm)Patients with adenomyosis | Uterine preservation in women of child-bearing age must be considered prior to considertion for hysterectomy. | UAE is NICE approved for fibroids and adenomyosis. The dissconnet betweenthose guidelines and this is noticeable .https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5779563/https://www.nice.org.uk/guidance/ipg473 |
| 52 | BSIR | Women who are at risk of prothrobosis need a special mention as this is increasing in women of child bearing age | TXA can be a pro thrombotic.Uterine artery embolization should be considered for these subet of patients ( again it should ber offered post medial therapy trial and prior to hysterecotmy) | Uterine preservation and reduction in risk of DVT/PE and recurrent miscarriage | UAE should be offered to women who cannot tolerate medical therapy. |
| 53 | BSIR | Patient information for UAE should be offered prior to hysterectomy | Patients have the right to choose UAE prior to be considered for hysterecotmy fo heavy bleeding. | Uterine preservation in presence of failed medical and ablative therapy |   |
| 54 | SCM3 | For hysterectomy, use minimal access route (vaginal or laparoscopic) where technically feasible | There is variation in rates of hysterectomy by laparotomy vs minimal access (vaginal or laparoscopic routes). The RCOG Patterns of Benign Gynaecology Care report 2015-16 stated: “More than 40% of hysterectomies for benign conditions were performed abdominally, with substantial variation (mean proportion conducted abdominally: 17-67% (lowest vs. highest decile)).“Where technically feasible hysterectomy should be performed using a minimally invasive or vaginal route“Trusts should review whether they provide the full range of hysterectomy types so treatment decisions are not restricted by hospital factors” | Minimal access routes are better for women, the NHS and wider society (e.g. owing to quicker return to normal activities). The RCOG clinical indicators project found that outcome measures of route of hysterectomy were some of the only ones that were valid in benign gynaecology, but that they also showed the most variation. The report listed a number of valid indicators, the simplest of which is “Proportion of all hysterectomies performed abdominally” with denominator, numerator, mean and deciles for all NHS Trusts defined.  | NICE HMB guidelines 1.5.18. Key national audits are listed in the Quality Standard Topic Overview for this committee. Patterns of Benign Gynaecology Care in English NHS Hospital Trusts. RCOG, London School of Hygiene & Tropical Medicine, 2016 |
| **Additional areas** |
| 55 | SCM2 | **Ulipristal acetate:**Ulipristal acetate should be funded by the NHS to allow prescription by Hospitals / GPs for women with HMB and fibroids who are refractory to medical therapies or high risk for surgery. | Compliant with the NICE HMB Update Guidelines and strong evidence base (and European Medical Agency post-investigation recommendations) | Inequitable service provision currently. I would go so far as to say that ulipristal acetate is unavailable to most women and where it is prescribed it is restricted to one, 3 month course prior to surgical intervention |   |
| 56 | The Faculty of Sexual and Reproductive Healthcare (FSRH) | Commissioning of IUS devices (LARC) to treat Heavy Menstrual Bleeding (HMB) in community and primary services. | Heavy Menstrual Bleeding (HMB) has a major impact on a woman's quality of life.IUS (a form of Long Acting Reversible Contraception – LARC) is used to treat HMB but this is poorly commissioned and/or not commissioned. This results in a lack of clarity around issues of commissioning meaning our healthcare system is not responding efficiently to HMB issues, as well as a lack of standardisation in commissioning and budgeting practices.In particular, it is unclear to commissioners and providers of services whether LARC is being used for gynaecological or contraceptive purposes. As a result, it is difficult to budget for LARC provision and GPs encounter difficulties in achieving reimbursement. FSRH recommends the NICE guidance recommends consistent commissioning of IUS devices (LARC) to treat Heavy Menstrual Bleeding in community and primary services, with clear lines of accountability.  | Contraception for gynaecological purposes (to treat HMB, for instance) is in some cases commissioned by CCGs in primary care. However, LARC in primary care is also commissioned by Local Authorities if the GP prescribes it as contraception to avoid pregnancy.Thus, the same procedure may be commissioned from a different source, depending on its purpose. This is despite both FSRH and RCGP pointing out that the distinction between contraceptive and gynaecological purposes is often in clinical terms meaningless. Where there is a dual purpose for a treatment, the incentive is created to claim back costs from the commissioner who will pay more. Reference: RCGP, 2017, Sexual and Reproductive Health, Time to Act. Accessible here: https://www.rcgp.org.uk/-/media/Files/Policy/Media/8895-RCGP-Sexual-Health-online.ashx?la=en | In PHE’s latest review on commissioning of SH, RH & HIV services commissioners commented on a lack of clarity and the existence within the system of different views regarding who should be responsible for commissioning elements of specific services.In this context, the review specifically names LARC prescribed for Menorrhagia/Heavy Menstrual Bleeding (HMB) in GP settings, highlighting the following comments from commissioners: “Ongoing efforts to clarify GMS/PMS contract baselines for contraception in order to budget for IUD provision.” “Complications in differentiating HMB/Contraception with regards to Identifying, monitoring and responsibility for payment.”In a joint position statement, endorsed by the Academy of Royal Medical Colleges (AoMRC), FSRH, RCOG and RCGP along with many other medical bodies, have evidenced that holistic integrated commissioning of sexual and reproductive healthcare would act as a significant longer-term step in counteracting challenges such as these. References: PHE, 2017, Sexual health, reproductive health and HIV: commissioning review. Accessible here: https://www.gov.uk/government/publications/sexual-health-reproductive-health-and-hiv-commissioning-review.Multiple medical bodies,2019, Holistic Integrated Commissioning of Sexual & Reproductive Healthcare - AoMRC, RCOG, FSRH, RCGP, RCPath and RCPCH Position. Accessible here: https://www.fsrh.org/documents/fsrh-rcog-rcgp-position-holistic-integrated-srh-commissioning/ |
| 57 | The Faculty of Sexual and Reproductive Healthcare (FSRH) | Allocated funding for IUS devices (LARC) to treat Heavy Menstrual Bleeding in primary (HMB) and community services. | Consistent commissioning of LARC, requires adequate funding. As indicated above, due to a lack of clarity in responsibility, from a GP perspective, reimbursement for contraception provision from primary care is complicated. No patient should have difficulty in accessing treatment as a result of contractual arrangements.FSRH recommends the NICE guidance makes clear the need to allocate funding for IUS devices to treat Heavy Menstrual Bleeding in primary and community services. | It is clear that at a local level issues of commissioning and funding are important ongoing issues. | Evidence highlights that there will have been a £700m real-terms reduction in the public health grant between 2014/15 and 2019/2020. Furthermore, the Kings Fund estimates that between 2014/15 and 2018/19 there was an 18 per cent real-terms reduction in spending on sexual health services.Adding weight to this evidence, in a recent survey, out of 86% of GPs in England who provide LARC in their practice, 39% said they have experienced cuts to the funding for this service. ReferenceMultiple medical bodies,2019, Holistic Integrated Commissioning of Sexual & Reproductive Healthcare - AoMRC, RCOG, FSRH, RCGP, RCPath and RCPCH Position. Accessible here: https://www.fsrh.org/documents/fsrh-rcog-rcgp-position-holistic-integrated-srh-commissioning/ |
| 58 | The Faculty of Sexual and Reproductive Healthcare (FSRH) | Data collection of IUS devices (LARC) prescriptions to treat Heavy Menstrual Bleeding (HMB). | There is a need for better data collection of LARC prescriptions to treat Heavy Menstrual Bleeding (HMB).FSRH recommends the NICE guidance recommends services report the reason an IUS device has been fitted i.e. for contraception, for Heavy Menstrual Bleeding or for both. | The prescriptions of LARC devices by GPs are collected and reported regularly by the NHS Business Authority (NHSBA). This data will not include any devices purchased directly by practices and will include some devices that are not successfully fitted. NHSBA data does not allow any identification of demographics. It is not possible to identify if an IUS has been fitted for contraception or for HMB or for both. | Information accessible via information services portal, NHS Business Services Authority. Reference: NHS Business Services Authority, n.d, Accessible here: https://www.nhsbsa.nhs.uk/prescription-data |
| 59 | NHSE (NCD for maternity and women’s health) | Addressing inequalities particularly relating to race, deprivation and mental health  |   |   | NHS Long term plan priorities |
| 60 | FEMISA | Key area for quality improvement 1 – Before releasing any guidance it must be ensured by a separate body within NICE that the recommendations improve the quality of treatment and outcomes for the patient populations involved. There must not be a repeat of the recommendations in 2018 Clinical Guidelines Review of Heavy Menstrual Bleeding [HMB] where taxpayers paid for part of RCOG – the National Guidelines Alliance [NGA] that reports to the Board of RCOG with RCOG members to benefit RCOG members but increase morbidity, mortality, severe complication of patients, reduce lack of choice for patients. | “NICE's role is to improve outcomes for people using the NHS and other public health and social care services.”The recommendation in the 2018 guidelines review increased mortality and morbidity for women with HMB considerably by recommending hysteroscopy as a first line diagnostic tool for HMB; allowing hysterectomy to be a first line treatment for HMB when in the previous guidelines this had specifically been disallowed ; promoting extension of endometrial ablation for fibroids >3cm when there is no evidence of safety or efficacy for this; did not address the complete lack of safety and efficacy evidence particularly mortality and morbidity and severe complication rates for myomectomy and in particular made access more difficult for women with fibroids to much safer less invasive treatments not carried out by gynaecologists, but interventional radiologists. | NICE guidance is supposed to improve diagnosis, treatment and outcomes and be patient-centred. The 2018 HMB recommendation did precisely the opposite.Comparative morbidity and mortality rates were not considered at all. | **Comparative mortality rates were not considered – HES ONS hospital mortality data by procedure shows** Diagnosis of HMB and fibroids – the mortality rate for ultrasound and MRI approaches zero – i.e. is as safe as it can be. The mortality rate for self-referrals by gynaecologists for hysteroscopy as a first line diagnosis is 0.3% i.e. 180 women a year in the NHS in England alone die within 90 days of this procedure.Similarly, the comparative morbidity and serious complication rates of the diagnostic modalities were not considered – again ultrasound and MRI very small – hysteroscopy – serious complication rate 3.14% - nearly 3,000 women in the NHS in England each year – see tables in next section for more details and clinical and statistical references.**No diagnostic or therapeutic procedure should be recommended that has not been formally reviewed for safety and efficacy by a reputable external body such as NICE.**• Hysteroscopy has never been formally reviewed for safety and efficacy and has a very high mortality and morbidity rate.• Hysterectomy has never been formally reviewed for safety and efficacy and it is questionable that it would be found safe enough for such wide-spread use, particularly as it was recommended as a first line therapy in the 2018 HMB review when previously it was specifically excluded. • Myomectomy has never been formally reviewed for safety and efficacy and the morbidity and mortality rate and severe complication rates are unknow. • Endometrial ablation to treat fibroids >3cm was recommended even though this has never been reviewed for safety and efficacy. Only treatment for fibroids <3cm has been reviewed for safety and efficacy. • **Uterine artery/fibroid embolisation is the only treatment for symptomatic fibroids that has been formally reviewed by NICE and its safety and efficacy found to be good enough for general use.** (Unlike hysterectomy and other treatments there have been no deaths from UAE in recent years.)**Acceptability to women** – Hysteroscopy has been recommended as a first line diagnosis for HMB/fibroids. The acceptability and cost to women has not been considered at all. Hysteroscopy is painful and can be exceedingly pain, yet no analgesia is offered nor has it ever been established that the procedure can be used without pain control. This is another example of discrimination against women. There is in fact considerable evidence, including parliamentary questions that hysteroscopy is extremely painful. It should only be considered with appropriate analgesia, yet gynaecologists do so regularly without reference to the detrimental effects on their women patients. https://www.hysteroscopyaction.org.uk/ Furthermore, alternative less expensive imaging e.g. ultrasound or MRI have significantly less cost not only to the NHS but to the women themselves and their employers and society. Ultrasound and MRI are non-invasive, much safer and only require a few hours off work with no side effects. Hysteroscopy is invasive relatively much less safe (see morbidity and mortality stats) and requires a woman to take at least a day off work or longer, depending on the side effects experienced. |
| 61 | FEMISA | Key area for quality improvement 2 – The Objective of the quality standard should be to ensure that clinical and other guidelines for the diagnosis, treatment and management of women with heavy menstrual bleeding, fibroids and adenomyosis is patient-centred, improves safety, morbidity and mortality and outcomes and promotes patient access to less invasive treatments that can maintain fertility and gives all women a choice in the treatment and access to a treatment that suits them, particular access to alternatives to hysterectomy and less invasive types of hysterectomy and myomectomy. | “NICE's role is to improve outcomes for people using the NHS and other public health and social care services.”In the revised Heavy Menstrual Bleeding Clinical Guidelines (HMB) guidelines 2018 the recommendations did exactly the opposite – increased mortality, morbidity and reduced safety for women patients. They also reduced treatment choice and deliberately did not include some treatments provided by other clinical specialities than gynaecology particularly Interventional Radiology. The previous NICE Clinical Guidelines on Heavy Menstrual Bleeding developed in 2007 made significant advances in giving women access to safer, less invasive treatment that enabled women to retain their fertility with alternatives to hysterectomy as a first line treatment for heavy menstrual bleeding and fibroids >3cm.  As FEmISA commented in their press release at the time – “The new recommendations contained in this review are not patient centred, promote old, less safe, very invasive procedures, particularly hysterectomy, which have never been reviewed for safety or efficacy, have a higher complication and death rate and are more expensive to the women, their families, their employers and the NHS. This is a very regressive step for women and the NHS.” | It does not meet the ‘raison d’etre’ for NICE – improving outcomes - more women will die and suffer severe complications; healthy ovaries can be more easily removed – this is sexual discrimination – men do not have healthy prostates removed. Fewer women have informed choice of the treatment that suits them and more feel bullied into unwanted hysterectomies. It is excessively expensive to women with HMB, fibroids and adenomyosis, their employers, society and the NHS.Costs to patients, their families, their employers and wider society need to be included. | Hysteroscopy – promoted by RCOG as a self-referral first line diagnostic investigation instead of much safer and more cost-effective ultrasound and MRI-

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| --- | --- | --- | --- | --- |
| Hysteroscopy | No. Procedures p.a. [HES 14-15] | Mortality @ 90 days | Mortality Rate | No. Serious Complications - rate 3.14% |
| Current |   |   |   |   |   |
| Diagnostic |   | 55,377 | 148 | 0.3% |  1,739  |
| Therapeutic | 31,573 | 32 | 0.1% |  991  |
| Total |   | 86,950 | **180** |   |  **2,956**  |
| Projected x 2 |   |   |   |   |
| Diagnostic |   | 110,754 | 296 | 0.3% |  3,478  |
| Therapeutic | 63,146 | 64 | 0.1% |  2,147  |
| Total |   | 173,900 | **360** |   |  **5,913**  |
| Projected x 3 |   |   |   |   |
| Diagnostic |   | 166,131 | 444 | 0.3% |  5,648  |
| Therapeutic | 94,719 | 128 | 0.1% |  3,220  |
| Total |   | 260,850 | **572** |   |  **8,869**  |
|  |  |  |  |  |  |
|  *i NHS – HES ONS hospital mortality data ii The incidence of fluid overload - 1.6% and 2.5% (Agostini A 2002a; Overton 1997), uterine perforation is 0.014%, and infectious complications account for 0.3% to 1.6% of cases (Bradley 2002) average 3.14% iii**The incidence of uterine perforation is 0.014%, and infectious complications account for 0.3% to 1.6% of cases (Bradley 2002)* |
|  |  |  |  |  |  |
| *The incidence of fluid overload is between 1.6% and 2.5% (Agostini A 2002a; Overton 1997).* |
|  |  |  |  |  |  |
| Overall rate  | 3.14 |  |  |  |

Hysterectomy promoted by RCOG as a first line treatment for HMB, when in the previous guidelines it was specifically excluded this –

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| --- | --- | --- | --- | --- | --- |
| Hysterectomy | No. Procedures p.a. [HES 14-15] | Mortality @ 90 days | Mortality Rate | No. Serious Complications - | Serious Complication Rate Maresh |
| Current |   |   |   |   |   |   |
| Abdominal |   | 31,086 | **176** | 0.6% |  **1,430**  | 4.6% |
| Vaginal |   | 7,236 | **6** | 0.10% |  **514**  | 7.10% |
| Projected +20% |   |   |   |   |   |
| Abdominal |   | 37,303 | **211** | 0.6% |  **1,716**  | 4.6% |
| Vaginal |   | 8,683 | **7** | 0.10% |  **617**  | 7.10% |
| Projected +30% |   |   |   |   |   |
| Abdominal |   | 40,412 | 229 | 0.6% |  **1,859**  | 4.6% |
| Vaginal |   | 9,407 | 8 | 0.10% |  **668**  | 7.10% |

\*Maresh et AL –The VALUE national hysterectomy study: description of the patients and their surgery 202  HES-ONS hospital mortality data**COST TO THE NHS COST** – HYSTEROSCOPY IS NOT COST EFFECTIVE  The NHS Tariff for an abdominal ultrasound is £40 for hysteroscopy is £340. This ‘excruciatingly painful and ‘barbaric’ procedure as well as being very expensive to women also costs the NHS and taxpayer is 850% more expensive. There are currently 55,377 diagnostic hysteroscopy procedures and 31,573 therapeutic ones pa. with a total cost of £29.5 million. If all women with suspected structural abnormalities were given hysteroscopy instead of ultrasound this figure is likely to double or triple as per model in comment 3. 64,500 women are diagnosed each year with fibroids and structural abnormalities of the cervix and other parts of the reproductive tract.  It would also be expensive for women, their families and employers, as ultrasound is a quick non-invasive procedure taking a few minutes, while hysteroscopy even in outpatients is likely to require a whole day off work and require a family member too escort them. **COST** – HYSTERECTOMY VS UFE (UTERINE ARTERY/FIBROID EMBOLISATIONEach year the NHS introduces new NHS Tariffs, which are the average cost of a procedure across the NHS in England. The Tariff costs below are for financial year 17/18 The Department of Health wants to encourage less hysterectomies and more less invasive treatments such as UFE.

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| --- |
| Cost Comparisons |
| Procedure | Hysterectomy | Myomectomy | Embolisation |
| NHS Tariff 17-18 | £3,275 | £2,609 | £2,400 |
| Cost Saving Comparison with UAE/UFE per procedure | £875 | £209 |   |

In the table below we show how much the NHS could save if all the 60% of hysterectomies performed for fibroids in England each year were converted to UFE. FEmISA does not advocate this as all women should have a choice in treatment, but most do not as they are not told of alternatives to hysterectomy. Here is an analysis for England as a whole, on the savings that could be made if women had fully informed choice of their treatment options from a multi-disciplinary fibroid outpatients’ clinic run by interventional radiologists and gynaecologist working together for the benefit of women with fibroids. There are few of these clinics in the country, but one is at Heartlands Hospital in Birmingham. Here 60% of women with fibroids opt for UFE. This is a benchmark for the rest of the UK. Potential Saving on In-Patient Costs from Treatments with Embolisation instead of Hysterectomy

|  |  |  |
| --- | --- | --- |
| **Savings Under Current 17-18 NHS Tariff** |  |  |
| Total number of Hysterectomies in England in the NHS |                31,624 |  |
| 60% for fibroids |                18.974 |  |
| In-patient cost of Hysterectomy (MA07E-F £3,275- 4,259) using lower tariff | £     103,568,600 |  |
| If 60% of hysterectomies for fibroids were treated by UFE - costs | £       27,323,136 |  |
| (60% e.g.   Heart of England)(YR54Z UFE £2,400) |  |  |
| **Potential   Cost saving by treating 60% with embolisation**  | **£       51,389,000** |  |
| **Number   of potential bed days saved** | **139,145** |  |
|  |  |  |

Further potential cost savings* Reduction in HRT usage from early menopause associated with hysterectomy
* Reduction in short and longer term readmissions and morbidity

**It is also important to look at some of the costs to patients and their families and employers**.Reduction in cost of patients and their families* Less need for care at home from family member
* Return to work/normal life 1-2 weeks with embolisation c.f. Hysterectomy 10 weeks
* Early HRT use much less likely - prescription charges per hormone so at least double normal charge
* Reduction in cost to the economy, employers, society

 **Reduction in Cost to the Economy, Employers and Society**

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| --- |
| Return to work/normal life 1-2   weeks with embolisation c.f. Hysterectomy 10 weeks |
| 2 weeks off work versus 10 weeks - working days saved | **151,795** |
| Average weekly earnings May '17[Office for National Statistics]  | £       503.00 |
| **Potential   economic saving from earlier return to work from UFE - £76,352,986** |  |

 |
| 62 | FEMISA | Key area for quality improvement 3 – Active involvement in developing guidelines and reviews of all clinical specialities involved in the care, diagnosis and treatment of heavy menstrual bleeding and patients, patient groups and carers | The previous guidelines 2018 for HMB were dominated by gynaecologists with little or no involvement from all other important specialities and were run by part of RCOG.- NGA  | The outcome and revised HMB Clinical Guidelines were greatly inferior to the previous one, which gave women more choice and had safety and optimal outcomes as their priority. The last revised HMB guidelines were paid for by the taxpayer and carried out by part RCOG for the benefit of RCOG members, not women with HMB or fibroids.  | All other clinical specialities involved in the diagnosis, treatment and management of HMB, fibroids and adenomyosis need to be involved and their evidence included –Primary Care –• GPs – RCGP• Nurse practitioners specialising in women’s health• Pathologists for advice on appropriate blood tests – counts, hormones, histology, cytology etc• Endocrinologists – hormone etc• Radiologists – Royal College of Radiologists – appropriate diagnosis – ultrasound – enhanced or not, MRI – enhanced or not • Pharmacists – drug treatments• Patient groups – Fibroid Network, FEmISA, Hysterectomy Assoc, British Fibroid Trust, All Party Parliamentary Group on Women’s Health, Hysteroscopy action. TOHETI• High Risk Demographic Groups e.g. Afro-Caribbean Women’s GroupsSecondary Care – As for primary care plus• Interventional Radiologists – British Society of Interventional Radiologists – provides uterine artery/fibroid embolisation [UFE/UAE] treatment, Magnetic resonance guided focused ultra-sound [MRgFUS] – gynaecologists have no training or education in these treatments and view them as competition. Many deny information or access to their women patients to interventional radiology treatments.• X-ray nurses and radiographers involved in diagnosis and treatment• Hysteroscopy nurses – this diagnostic procedure is offered without pain control, although it is exceedingly painful for women.• Gynaecology nurses• Independent health economists not employed by RCOG directly or indirectly who are familiar with NHS statistics and data on procedures and outcomes should be employed.In addition to RCOG |
| 63 | FEMISA | Key area for quality improvement 4 Key development sources (NICE and NICE-accredited sources) | As previously stated the current HMB Guidelines (revised 2018) excluded clinical and economic evidence on alternative diagnostic and treatment pathways and did not include any NHS statistics on diagnoses, treatments, outcomes and morbidity and mortality | The recommendations from the 2018 HMB guidelines were not properly evidence based and would result in higher death and complication rates, more pain and less choice for women and hugely greater expense for the NHS, women, their families and the economy. | The current quality standards only include evidence sources from RCOG and no NHS statistics or evidence on alternative safer and less invasive treatments provided by other specialities e.g. UAE, MRgFUS etcNHS statistics that need to be included –• Primary care - Practice Level Prescribing – NHS Digital• Diagnoses of HMB, fibroids in primary care • Diagnoses of HMB, fibroids and adenomyosis• CCG Outcomes Indicator Set - by hospital by diagnosis• NHS/ONS mortality data by diagnosis and treatment – hysterectomy by type - abdominal; vaginal etc, myomectomy – by type, UAE, MRgFUS, endometrial ablation etc• NHS emergency admission data by diagnosis• NHS readmission data by diagnosis and procedure For diagnosis – • Royal College of Pathology and subspecialties involved in diagnosis• Royal College of Radiology – particularly ultrasound and MRI clinical informationGIRFT Gynaecology – statistics and information on adverse events in gynaecology and how to improve outcomes - http://gettingitrightfirsttime.co.uk/surgical-specialty/obstetrics-and-gynaecology/For UAE and MRgFUS – British Society of Interventional Radiology –• Registry and Audit on UAE and surveys on UAE and MRgFUS• Key policy documents, reports and national audits• UAE/UFE Registry • Society of Interventional Radiology registry, audits and surveys of UAE/UFE via BSIR**And full clinical evidence searches on all treatments, not just hysterectomy and myomectomyThis guidance should be patient-centred but is not and no patient research was included. It is very important to know how those involved feel, what they want, the shortcomings and what needs to change as they have to live with the consequences. This was ignored in the 2018 HMB Review****Women’s Health organisations surveys and reports on HMB, choice etc**• Women’s Health APPG Report – Informed Choice? Giving women control of their healthcare - http://www.appgwomenshealth.org/inquiry2017• Medical Technology Group Survey - A review of the provision of and access to Uterine Artery / Fibroid Embolisation, a treatment for Fibroids for women in England – December 2011 - https://mtg.org.uk/wp-content/uploads/2016/07/UFEResearchReport.pdf• FEmISA Reports – Patient Choice and NICE Compliance Survey on Fibroid Treatment Acute NHS Trusts In England Conducted In 2016 - http://www.femisa.org.uk/images/femisa%20report%20on%20patient%20choice%20and%20nice%20compliance%209.17%20-%20final.pdf • YouUr First ChoicE Patient Information and Choice – UFE Patient Survey - http://www.femisa.org.uk/images/stories/downloads/patient\_information\_\_%20choice\_survey\_report.pdf • TOHETI – Report on Uterine Fibroids - www.toheti.org• Fibroid Network - Summary of Fibroid Research findings for Women with Fibroids and Black Women related Health Issues - http://www.fibroid.network/category/news/  |
| 64 | FEMISA | Key area for quality improvement 5 –Existing indicators and ensuring informed choice for woman  | The current indicators are totally inadequate and do not cover alternatives to hysterectomy or address the very significant issue that many women feel bullied by gynaecologists into hysterectomies they don’t want or need and are not given informed choice contrary to the NHS Constitution | There is no point in recommending guidelines of supposedly best clinical practice unless you introduce metrics to ensure they are implemented and to monitor outcomes. | **Hospital Episode Statistics- Activity Data**Number of diagnoses of HMB, fibroids, adenomyosis etc and comparison with previous yearsHow these were diagnosed – procedure data linking radiology imaging and hysteroscopy procedures with the initial diagnosisHospital activity data – numbers of procedures for treatment of HMB, fibroids and adenomyosis – hysterectomy, myomectomy UAE/UFE, endometrial ablation MRgFUS etcRemoval of healthy ovariesHospital Mortality data HES/ONS – morbidity at 90 days from each of these proceduresHospital readmission data – readmission from complications for up to 20 years e.g. prolapse from an earlier hysterectomyIn addition, GIRFT gynaecology data on safety and quality.NHS Litigation Statistics (now know as NHS Resolution) on litigation on all procedures involved in the diagnosis and treatment or HMB, fibroids and adenomyosis – gynaecology is only second to obstetrics as the highest speciality for litigation, so there is a lot to be learned from studying the information on how this could be improved. https://resolution.nhs.uk/wp-content/uploads/2019/07/NHS-Resolution-Annual-Report-2018-19.pdf Specific reports on gynaecology and all procedures for HMB, fibroids and adenomyosis need to be requested.Audits with all clinical specialities on outcomes of all proceduresThis will determine the uptake of each of the diagnoses and treatments, their outcomes and safety.An audit of all NHS hospitals on how they ensure compliance e.g. FEmISA report**Ensuring Informed Choice for Women** – comprehensive patient information for women scrutinised by all the clinical specialities involved (not just gynaecologists) and patient groups to replace the limited and inaccurate information available to the NHS web site and give information on the risks – morbidity and mortality as there is plenty of evidence that women are not fully informed about these. As in the 2007 HMB guidelines all women should be sent all the patients information booklets about every possible procedure before their outpatients appointment and these should also be available to their GP surgery. Many women are not informed about any treatment other than hysterectomy. This is absolutely unacceptable. |
| 65 | FEMISA | Additional developmental areas of emergent practiceThat all diagnostic and therapeutic procedure recommended in guidelines has been externally formally reviewed for safety and efficacy  | All recommendations should be evidence based and should ensure that they are safe and efficacious, not just the new ones  |   | Formal reviews by recognised external bodies such as NICE should be carried out on all the diagnostic and treatment procedures recommended and the risks to women – morbidity, mortality severe complication rate time to feeling completely well, time to getting back to work/normal life, time off work should be included for –• Hysterectomy – all approached abdominal, vaginal, hysteroscopic etc• Myomectomy – as for hysterectomy• Endometrial ablation for fibroids >3cm• Hysteroscopy – outpatient and in-patient and the requirement for pain control |
| 66 | SCM1 | Ulipristal acetate (ESMYA) |   | To review evidence on ulipristal acetate as an option for these women. However, ulipristal acetate was removed from the recommendations because the European Medicines Agency was reviewing its use for uterine fibroids and introduced temporary safety measures. This was due to concerns about serious liver injury.Is there further evidence to suggest that this has now been restored as a viable recommendation? |   |
| 67 | SCM1 | Endometrial ablation techniques |   | Explore current practices nationally and variance |   |
| 68 | RCGP | Additional developmental areas of emergent practice | There should be access to a choice of out-patient or in-patient procedures at every secondary care hospital, using cross hospital referral if required to ensure all women are offered equal choices of treatment options including endometrial ablation and polyp/fibroid morcellation. | As treatment options develop using smaller diameter equipment women should have access to a choice of whether they require general anaesthetic or local anaesthetic out-patient, preferably one-stop procedure. |   |
| 69 | RCOG | Key area for quality improvement 1:Time taken from symptom presentation to symptom relief |   | This is the key as often there is delay in diagnosis and appropriate management |   |
| 70 | RCPCH | Key area for quality improvement 4: Investigation and medical imaging | This is a paramount step for reaching a proper diagnosis | Reaching a definite diagnosis will be assisted by the availability of updated technology and well skilled personnel. |   |
| 71 | RCPCH | Key area for quality improvement 5: Therapy | This the most important step in management and must be as specific as possible | Therapy should be directed according to the condition that is diagnosed and must be treated according to current, updated guidelines. In some conditions this will necessitate a multidisciplinary team to work together. |   |
| 72 | Hologic | Key area for quality improvement 1HMB awareness and education to patients, nurses and GPs | HMB awareness and education is not currently aligned with the NICE-HMB guidelines, they cannot be fully leveraged without this education at a primary care and patient level.  | HMB is poorly recognised and understood as a treatable medical condition by patients and in some cases HCPs for instance in Primary Care. To improve the patient pathway especially the delays and recognition and treatment of HMB | RCOG audit report, data from RCOG and RCGP work in Women’s Healthcare task force and data collected in the Wear White Again patient awareness survey. As used by RCOG president in recent address. |
| 73 | Hologic | Key area for quality improvement 2Hysteroscopy increase especially in diagnostic hysteroscopy to increase as suggested in the NICE HMB guidelines | Currently the training for hysteroscopy especially at the nurse level is in flux and more training is required if more diagnostic hysteroscopy is to be performed to move more patients through according to the NICE-HMB guidelines | More diagnostic hysteroscopy was identified in the diagnosis pathway for NICE-HMB work up and an increase of 5,000 to 15,000 for England alone | Audit data used in NICE-HMB and NHS information for tariffs |
| 74 | Hologic | Key area for quality improvement 3Standards for office based hysteroscopy training and service for diagnostic and treatment | There needs to be a standard for outpatient abased hysteroscopy to ensure patients are well treated in all hospitals or community  | Hysteroscopy needs to be increased in UK and to do this standards should be important both for training, provision and ongoing quality | Current data on units offering outpatient hysteroscopy, RCOG/BSGE data and the newly formed BSGE ACN databases. Registry data would be really helpful for RWE ongoing |
| 75 | The Society and College of Radiographers | Additional developmental areas of emergent practice | There would be value in determining the number of ultrasound practitioners who are trained to differentiate fibroids and adenomyosis. Also audit results of ultrasound diagnosis v MRI or other investigations, in patients that have both, as this is one of the most underdiagnosed pathologies that cause patients a great deal of anxiety & delays to treatment.  |   |   |
| **Additional evidence sources for consideration** |
| 76 | SCM3 |  | Patterns of Benign Gynaecology Care in English NHS Hospital Trusts. RCOG, London School of Hygiene & Tropical Medicine, 2016 – https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/clinical-indicators-programme/benign-gynaecological-care/benign-gynaecology-report-2015-16/ |   |   |
| 77 | NHSE (NCD for maternity and women’s health) |  |   |   | NHS England Evidence-Based InterventionsIntervention J: Hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding.https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf |
| 78 | NHSE (NCD for maternity and women’s health) |  |   |   | NHS England Evidence-Based InterventionsIntervention B: Dilatation and curettage (D&C) should not be used as a diagnostic intervention for heavy menstrual bleeding in womenhttps://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf |
| 79 | NHSE (NCD for maternity and women’s health) |  |   |   | NICE Quality Standard Heavy Menstrual Bleeding (QS47)Quality standard 2: Women with heavy menstrual bleeding who have a suspected uterine cavity abnormality, histological abnormality, adenomyosis or fibroids have a physical examination before referral for further investigations.https://www.nice.org.uk/guidance/qs47/chapter/Quality-statement-2-Diagnosis-physical-examination |
| 80 | NHSE (NCD for maternity and women’s health) |  |  |  | NICE Quality Standard Heavy Menstrual Bleeding (QS47)Quality standard 4: Women with heavy menstrual bleeding who are undergoing further investigations or awaiting definitive treatment are offered tranexamic acid and/or non-steroidal anti-inflammatory drugs at the initial assessment.https://www.nice.org.uk/guidance/qs47/chapter/Quality-statement-4-Interim-drug-treatment |
| 81 | NHSE (NCD for maternity and women’s health) |   |   |   | NICE Quality Standard Heavy Menstrual Bleeding (QS47)Quality standard 5: Women with heavy menstrual bleeding have a documented discussion about all recommended treatment options.https://www.nice.org.uk/guidance/qs47/chapter/Quality-statement-5-Discussing-treatment-options |
| 82 | NHSE (NCD for maternity and women’s health) |   |   |   | National HMB Audit, RCOGhttps://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/completed-projects/national-hmb-audit/ |
| 83 | NHSE (NCD for maternity and women’s health) |  |   |   | Period Povertyhttps://uk.lunette.com/blogs/news/period-poverty-what-is-it-and-what-can-we-doGet Lippy, Eve Appealhttps://eveappeal.org.uk/getting-involved/take-part-in-an-event/get-lippy/top-tips-for-talking-gynae/ |
| **General**  |
| 84 | NHSE & NHS Improvement (Patient safety) | No comments |
| 85 | RCN | No comments |

1. Menorrhagia (2018) [NICE Clinical Knowledge Summaries](https://cks.nice.org.uk/menorrhagia) [↑](#footnote-ref-1)
2. Royal College of Obstetricians and Gynaecologists (2014) [National Heavy Menstrual Bleeding Audit Final Report](https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/completed-projects/national-hmb-audit/) [↑](#footnote-ref-2)
3. At the time of publication (March 2018), not all LNG-IUSs have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp) for further information. [↑](#footnote-ref-3)
4. Opinium Research (2017) [Women aged 18+ years who currently experience menorrhagia/heavy periods or have experienced them within the last 3 years](https://www.opinium.co.uk/). [↑](#footnote-ref-4)
5. All-Party Parliamentary Group on Women’s Health (2017) [Informed Choice? Giving women control of their healthcare](http://www.appgwomenshealth.org/inquiry2017) [↑](#footnote-ref-5)
6. Royal College of Obstetricians and Gynaecologists (2014) [National Heavy Menstrual Bleeding Audit Final Report](https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/completed-projects/national-hmb-audit/) [↑](#footnote-ref-6)
7. Main, A; Rose, K (2019) [Outpatient hysteroscopy: Scope for improvement?](https://www.ejog.org/article/S0301-2115%2818%2930796-6/abstract) [↑](#footnote-ref-7)
8. All-Party Parliamentary Group on Women’s Health (2017) [Informed Choice? Giving women control of their healthcare](http://www.appgwomenshealth.org/inquiry2017) [↑](#footnote-ref-8)
9. At the time of publication (March 2018), not all LNG-IUSs have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp) for further information. [↑](#footnote-ref-9)
10. At the time of publication (March 2018), NSAIDs do not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp) for further information. [↑](#footnote-ref-10)
11. At the time of publication (March 2018), not all combined hormonal contraceptives have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp) for further information. [↑](#footnote-ref-11)
12. At the time of publication (March 2018), NSAIDs do not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp) for further information. [↑](#footnote-ref-12)
13. At the time of publication (March 2018), not all LNG-IUSs have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp) for further information. [↑](#footnote-ref-13)
14. At the time of publication (March 2018), not all combined hormonal contraceptives have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp) for further information. [↑](#footnote-ref-14)
15. FEmISA (2016) [Patient choice and NICE compliance survey on fibroid treatment](http://www.femisa.org.uk/) [↑](#footnote-ref-15)
16. Geary RS et al. (2019) [Factors associated with receiving surgical treatment for menorrhagia in England and Wales: findings from a cohort study of the National Heavy Menstrual Bleeding Audit.](https://bmjopen.bmj.com/content/9/2/e024260) [↑](#footnote-ref-16)
17. All-Party Parliamentary Group on Women’s Health (2017) [Informed Choice? Giving women control of their healthcare](http://www.appgwomenshealth.org/inquiry2017) [↑](#footnote-ref-17)
18. NHS England (2019) [Evidence-based interventions: Guidance for CCGs](https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf) [↑](#footnote-ref-18)
19. Royal College of Obstetricians and Gynaecologists (2015-16) [Patterns of Benign Gynaecology Care report](https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/clinical-indicators-programme/benign-gynaecological-care/benign-gynaecology-report-2015-16/) [↑](#footnote-ref-19)