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Heavy menstrual bleeding management during the Covid pandemic

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Abstract
Heavy Menstrual Bleeding (HMB) is a common gynaecological presentation, which can affect girls and women throughout their reproductive years and cause significant health issues. This review discusses the most recent evidence-based management of HMB and strategies for providing safe and effective care during the Covid 19 pandemic. Thus protocols and recommendations for HMB, developed to tackle the Covid 19, could become the ‘new normal’ for both primary and secondary care. There is a need for administrative changes, improved technology and effective communication to adapt these new recommendations.

Keywords heavy menstrual bleeding; NHS E-referral; PALM-COEIN; SARS-CoV-2

Introduction
Heavy menstrual bleeding (HMB) is one of the most common gynaecological problems which presents to both primary and secondary care. Occurring anytime from the onset of menarche, throughout the reproductive period and up until menopause it can have a significant impact on the mental health, wellbeing and quality of life of adolescent girls and women including loss of time in education or work. The National Institute for Health and Care Excellence (NICE) defines HMB as ‘excessive menstrual blood loss, which interferes with a woman’s physical, social, emotional and/or material quality of life.’ It is a symptom of excessive menstrual loss as perceived by the woman, rather than meeting an objective diagnostic criterion. NICE published comprehensive management guidance in 2018.

The challenges of living with Covid 19 and the backlogs created in the health care system by the lockdown in response to the Coronavirus pandemic have increased the need for efficient pathways to manage women presenting with heavy menstrual bleeding. Most women will be effectively managed in primary care. In secondary care appropriate triage of referrals and the use of virtual and telephone consultations in patient pathways can be employed to move women efficiently through the treatment ladder whilst reducing unnecessary face to face consultations and follow up. This is intertwined with the need to accommodate social distancing in clinics and separate patients who are known to be Covid-positive from other groups within hospitals.

Classification
According to FIGO system 2(2011) HMB is classified under Abnormal Uterine Bleeding (AUB) which is described as any variation from normal pattern of bleeding in non-pregnant, reproductive age woman lasting for at least 6 months. AUB also encompasses other menstrual irregularities like inter-menstrual bleeding, post coital bleeding and post-menopausal bleeding but these are outside the scope of this article.

Classification of AUB is based on pathology, using the acronym PALM-COEIN–P(polyps), A(Adenomyosis), LM(Leiomyoma), C(coagulopathy), O(Ovulatory Dysfunction), E(Endometrial pathology), I(Iatrogenic) and N(nonspecific causes). In adolescents, anovulation (AUB-O) and underlying bleeding disorders (AUB-C) are the most common and second most common cause for HMB respectively. Approximately 20% of all adolescent girls with heavy menstrual bleeding and 33% of adolescent girls hospitalized for heavy menstrual bleeding have an underlying bleeding disorder. The most common bleeding disorders are von Willebrand disease, platelet function defects, thrombocytopenia, and clotting factor deficiencies.

Investigations
An initial history should ascertain the severity and nature of bleeding and associated symptoms including pelvic pain and discharge, as well as persistent intermenstrual bleeding (IMB) or irregular bleeding which may be suggestive of endometrial hyperplasia (EH). The impact on quality of life is important to elicit. Co-morbidities which increase a woman’s risk of endometrial hyperplasia should be determined, including obesity, presence of diabetes and polycystic ovarian syndrome (PCOS), as well as a history of tamoxifen use and history of Lynch Syndrome.

A Full Blood Count (FBC) should be carried out as an initial investigation for all women presenting with HMB. A coagulation screen, for example for von Willebrand disease, should be considered only if the woman has a positive family history of a coagulation disorder, or there are salient features in her history suggestive of one. These include HMB since menarche or excessive bleeding during routine procedures such as teeth extractions. Thyroid function tests are only required if a thyroid disorder is suggested.

According to the NICE 2018 guidelines, if no other associated symptoms are ascertained from the initial history, management can be commenced without a physical examination, unless the patient opts for a levonorgestrel-releasing intrauterine system (LNG IUS) (Mirena®, Bayer Healthcare Pharmaceuticals, Pittsburgh, PA, USA). A pelvic ultrasound should be offered if the woman has a palpable uterus or pelvic mass as suggested by history or examination, or if information from examination is limited, for example in obese women. A transvaginal ultrasound scan (TVUS) will yield the most information particularly if
adenoamyosis is suspected, for example if the woman suffers from dysmenorrhea. However, a transabdominal ultrasound scan (TAS) or MRI pelvis should be offered if a TVUS is not acceptable to the woman.

Outpatient hysteroscopy should be offered if a diagnosis of endometrial polyp, submucosal fibroid or endometrial pathology is suggested, either by features in the history such as intermenstrual bleeding particularly not responding to treatment, or by a woman’s risk factors/co-morbidities indicating endometrial sampling is required. If an outpatient hysterectomy is declined, a hysterectomy under general or regional anaesthesia should be offered. If this too is declined, a pelvic ultrasound scan or MRI pelvis along with the limitations of this route should be discussed.

Management

An informed discussion regarding the risks and benefits of each treatment option should take place considering the underlying pathology causing HMB. Treatment needs to follow an individualized approach taking into account the woman’s preferences, fertility considerations, whether she is actively trying to conceive and whether she wishes to keep her uterus.

If after taking an initial history, with or without a physical examination, there is a low risk of fibroids, uterine cavity abnormality, histological abnormality or adenomyosis, pharmacological treatment may be started without further investigations. Fibroid features including size, number and location of fibroids, the presence of polyps or adenomyosis and endometrial pathology, are all important when considering treatment options.

An LNG-IUS is the first-line treatment for HMB according to NICE if any fibroids are less than 3 cm and the uterine cavity is not distorted, and there is an absence of other uterine pathology (including adenomyosis). The woman must be counselled regarding the rare risk of uterine perforation during LNG-IUS insertion (2 in 1000; however, this is higher in breastfeeding women) and risk of expulsion (1 in 20, most common in the first year post-insertion, particularly the first 3 months). Unscheduled vaginal bleeding, particularly for the first 6 months post-insertion, is common and can be managed with a 3-month trial of the combined oral contraceptive pill, if medically eligible. Other treatments to be considered if an LNG-IUS is declined or is not appropriate are non-hormonal pharmacological treatments including tranexamic acid (personal high risk of venous thromboembolism should be excluded prior to use) or NSAIDs (non-steroidal anti-inflammatory drugs), specifically mefenamic acid. Hormonal pharmacological treatments to be considered include combined hormonal contraception and cyclical oral progestogens.

A referral to secondary care for further investigations and alternative treatment options are required if treatment fails, pharmacological treatment is declined or symptoms are severe. Secondary care should also be considered for fibroids 3 cm or more in diameter; the pharmacological treatments discussed already may still be considered. The LNG-IUS may not be appropriate if the fibroid distorts the uterine cavity making correct site insertion difficult and the risk of expulsion more likely. Alternative treatment options are uterine artery embolisation (UAE), endometrial ablation, and surgical options, including myomectomy and hysterectomy.

Endometrial ablation is an important surgical technique, which has helped to reduce the incidence of hysterectomy for HMB. Its aim is to permanently destroy active endometrium; therefore, it is important to counsel the woman that this is an option for women who have completed their family and do not wish to conceive in the future. Endometrial ablation includes first-generation (hysteroscopic) and second-generation (non-hysteroscopic) techniques. First-generation endometrial ablation are ablation techniques using hysteroscopy to remove endometrium and some of the superficial myometrium under direct vision using a resectoscope. This includes the following techniques: transcervical resection of endometrium (TCRE), using an electrosurgical loop and either normal saline or glycine, which is associated with the risk of glycine overload and transurethral resection syndrome, roller ball endometrial ablation, and endometrial laser ablation. The use of laser carries risks and added costs.

Second-generation techniques are generally considered to be easier to learn, quicker and safer to use. Mostly, they are not performed under direct vision. Thermal balloon ablation was the most commonly used second-generation techniques in the UK until GYNECARE THERMACHOICE® III Uterine Balloon Therapy System (Ethicon Inc., Johnson and Johnson, New Brunswick, NJ, USA) was withdrawn by the manufacturers due to issues with shelf life. Other second-generation techniques include bipolar radiofrequency endometrial ablation such as Novasure® (Hologic Inc, Bedford, MA, USA) which requires some cervical dilatation, and hydrothermal ablation which has a lack of long-term evidence associated with it and needs pre-treatment with gonadotrophin-releasing hormone (GnRH) analogues. Endometrial atypia should be excluded prior to ablation as it will be difficult to obtain a biopsy post-ablation if later required. Risks of ablation techniques include infection, pregnancy-related complications should conception occur post-ablation, including ectopic pregnancy, intrauterine growth restriction and abnormal placentation, and post-ablation syndrome which describes dysmenorrhea, synoecia and possibly haematometra. The satisfaction rate at 12-months post-ablation ranges from 68% to 92%. The cost-efficiency of ablation in comparison to a hysterectomy is not as great in the long-term as in the short term, due to the possible need for retreatment with ablation or further surgery, including hysterectomy which ranges from 10% to 20% at 5 years post-ablation.

Uterine assessment by ultrasound, and by MRI in addition if further information regarding fibroid position, number and vascularity is required, should be carried out prior to UAE or myomectomy. Myomectomy can be performed at hysteroscopy if the fibroid position is submucosal. Myomectomy can also be undertaken by laparoscopy if feasible, and finally by laparotomy which may be required depending on fibroid specifics, however is associated with greater morbidity and a longer post-operative recovery. Risks of myomectomy include post-operative adhesions and intra-operative bleeding. There is the potential risk of inadvertent dissemination of an undiagnosed malignancy in a presumed benign fibroid when using a morcellator. Pre-operative GnRH analogue therapy before myomectomy or hysterectomy may aid surgery, however it may also blur the boundary between fibroid and non-fibroid tissue making fibroid enucleation more challenging. Esmya® (ulipristal acetate) is a progestosterone
receptor modulator with a partial progesterone antagonist effect, which was licenced for the pre-operative treatment of fibroids. The licence for Esmya® was suspended by MHRA/CHM in March 2020 due to the risk of serious liver injury.

A hysterectomy is the surgical removal of the uterus and is major surgery with associated morbidity. It can be performed by the abdominal, vaginal or laparoscopic route. The decision regarding route of surgery depends on numerous factors including previous abdominal surgery, degree of uterine descent and presence of possible malignancy. Risks of a hysterectomy include infection, bleeding, venous thromboembolism, injury to bladder, bowel and ureters, neuropathy and vaginal cuff dehiscence. When discussing a hysterectomy, conservation or removal of ovaries should be discussed; if ovaries are conserved there may be a risk of future surgery for oophorectomy should this procedure become necessary. If ovaries are removed, immediate menopause will ensue. The decision regarding total versus subtotal hysterectomy should be part of the discussion with the patient. In a total hysterectomy, the cervix is removed and no further cervical smears are required. In a subtotal hysterectomy a cervical stump remains. This may be a technically less challenging operation, but risks persistence of cyclical bleeding (Figure 1).

Managing HMB during Covid-19

During the Covid-19 pandemic, there should be agreed pathways of providing care to patients should be established, without compromising resources for the pandemic or increasing risk of dissemination of coronavirus. Joint RCOG, BSGE and BGCS guidance on management of abnormal uterine bleeding was issued during the acute phase of the pandemic in May 2020. Some of the guidance developed during the covid-19 era could continue to be implemented in the form of a “new normal” if that proves to be an efficient use of resources without compromising care.

Women should be reassured that SARS-CoV-2 has no impact on abnormal uterine bleeding (AUB) of any type including the symptoms of heavy and/or irregular menstrual bleeding. All women, especially those with the symptom of heavy menstrual bleeding (HMB) are at risk for iron deficiency anaemia and should ensure adequate dietary iron intake and supplement with oral iron if appropriate. According to FIGO (MDC SARS-CoV-2 Response), to reduce nausea and perhaps increase absorption alternate day dosing of 60–130 mg of elemental iron may be useful.

Women with HMB with passage of clots should contact, preferably remotely, an appropriate Health Care Professional (HCP) urgently for advice. Based on relevant history, patients should be appropriately triaged based on whether they need immediate referral to hospital or could be treated with medicines remotely. They should be reassured that the risk of malignancy is negligible.

Those with the recurrent symptom of cyclic (q 24–38 days) HMB attributed to adenomyosis, fibroids, coagulopathy or endometrial pathology, could potentially be treated (unless there are contraindications) by the use of appropriate doses of
analogue treatment is to be continued beyond 3 months (nafarelin acetate spray). Addback hormone replacement therapy of significant uterine fibroids. Moving to a 3-month duration recommended NICE medical treatments and/or in the presence of severe and/or prolonged such that severe anaemia or haemodynamic compromise is suspected. Women should be referred to secondary care for further management, and seen within 30 days, if ongoing HMB has been resistant to NICE-recommended oral treatments and is considered unmanageable by the woman.

In adolescent girls, similar medical treatment, assurance and prompt referral to haematology if there is a suspicion of bleeding disorder can avert development of anaemia and hospital admission for blood transfusion. Women should be referred as an emergency to secondary care for further management if HMB is severe and/or prolonged such that severe anaemia or haemodynamic compromise is suspected. Women should be referred to secondary care for further management, and seen within 30 days, if ongoing HMB has been resistant to NICE-recommended oral treatments and is considered unmanageable by the woman.

Individuals with irregular HMB bleeding likely have AUB-O due to declining ovarian function, but, especially in the later reproductive years (age >45 years), with obesity (BMI ≥ 35), type 2 diabetes or Lynch syndrome there is an increased chance of endometrial cancer. Such individuals should be triaged for further referral to secondary care and investigation like USS and subsequent hysteroscopy if required. When access to outpatient testing modalities like pelvic ultrasound is limited, then a pelvic examination should be offered to all, rather than in selected women to identify rectifiable causes (e.g. prolapsed cervical fibroid) and detect significant uterine fibroids.

Individuals with above risk factors for endometrial pathology, should also be offered endometrial sampling to rule out pathology. This can reduce referrals and subsequent waiting time for hysterectomy and facilitate early diagnosis of endometrial hyperplasia and cancer.

Women referred to secondary care should be managed according to the NICE HMB assessment and management guideline, with exceptions where access to surgical and/or radiological treatments are restricted due to covid-19 pandemic. In such circumstances, Gonadotrophin releasing hormone (GnRH) analogues can be used for refractory bleeding despite use of recommended NICE medical treatments and/or in the presence of significant uterine fibroids. Moving to a 3-month duration injection can be considered, once patient tolerance of GnRH analogues has been established or delivery via the nasal route (nafarelin acetate spray). Addback hormone replacement therapy (HRT) should be considered, once HMB is controlled, if GnRH analogue treatment is to be continued beyond 3–6 months.

Organisational aspects of managing heavy menstrual bleeding pre- and post-Covid-19

The initial investigation and most management of HMB takes place in primary care and the development of primary care pathways in collaboration with GPs and commissioners can ensure that women are treated in a timely way and, where possible, without the need for referral to secondary care. Following preliminary investigations, and when initial management fails, appropriate referral criteria to secondary care should be agreed between primary and secondary care providers to minimize unnecessary referrals, allow rapid decision making and avoid duplication of investigations. This also frees up capacity within secondary care for women who need surgical management.

The NICE Heavy menstrual bleeding: diagnosis care pathway provides a useful framework for investigation of the condition (Figure 2). The vast majority of women will have these investigations initiated by their general practitioner.

NICE diagnosis care pathway

The NICE guideline recommends referral directly for hysterectomy (without pelvic ultrasound) for women with persistent intermenstrual bleeding and women at high risk of endometrial pathology; defined as women with persistent intermenstrual or persistent irregular bleeding and women with infrequent bleeding who are obese or have polycystic ovary syndrome, women taking tamoxifen and women for whom treatment for HMB has been unsuccessful. The NICE evaluation of cost effectiveness recommends this strategy because, although pelvic ultrasound is less expensive, outpatient hysterectomy allows the opportunity for a ‘see and treat’ approach to endometrial pathology such as endometrial polyps.

In practice, many women who fit the criteria for direct referral will also have a pelvic USS because this is a more readily available investigation with direct access from general practice. The NICE guidance also recognizes the resource implication of their recommendations in terms of provision of facilities and staffing for hysterectomy services in line with best practice guidelines.

When considering an effective ‘see and treat’ strategy within the outpatient setting the woman needs to be informed in advance of what is involved with the investigations and which treatments she may be offered. The provision of clear and comprehensive information in advance of the outpatient appointment is therefore essential. The RCOG website has a patient information leaflet on outpatient hysterectomy (https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/gynaecology/pi-outpatient-hysterectomy.pdf). This can be incorporated into a locally developed information pack which includes clinic contact numbers and emergency arrangements should a woman have concerns following a procedure.

In addition, as part of the NICE guidance there is a shared decision making tool that patients may also be signposted to (https://www.nice.org.uk/guidance/ng88/informationforpublic). This sets out clearly the treatments available and the benefits, risks and side effects of each.

The NHS E-referral system Advice and guidance feature can be used to support the management of women with HMB in primary care. This is an IT system whereby GPs instead of referring to secondary care can ask for advice, and their queries are answered directly by a secondary care gynaecologist.
The response to Covid-19 has seen a huge increase in the use of telephone and virtual consultations in managing patient care in many specialties including gynaecology. The initial step in the secondary care pathway could be a virtual consultation with an advanced nurse practitioner in which a detailed history is obtained along with a discussion of the patient’s aims for treatment and wishes regarding future fertility which will determine the nature of subsequent treatments offered. This virtual appointment can be used to provide information on outpatient hysteroscopy so that a patient is fully prepared for ‘see and treat’ when they attend the clinic. A virtual appointment can also be used to take verbal consent, which can be confirmed on the day although electronic virtual solutions with the ability to sign digitally are becoming more available.

Evidence-Based Interventions Guidance for CCGs was published by NHS England in partnership with NHS Clinical Commissioners, the Academy of Medical Royal Colleges, NHS Improvement and the National Institute for Health and Care Excellence in 2018 with the aim of reducing the number of inappropriate interventions provided on the NHS. Of the 17 interventions listed, 2 are relevant to investigation and treatment of HMB. These are dilatation and curettage for HMB and Hysterectomy as a first line treatment for HMB. Dilatation and curettage for HMB is designated a category 1 intervention, that is an intervention which should not be routinely commissioned or performed. Hysterectomy for HMB is designated a category 2 intervention which should only be routinely commissioned or performed when specific criteria are met.
The stated primary goals of the Evidence-Based Interventions programme are to:
- Reduce avoidable harm to patients. With surgical interventions, there is always a risk of complications. Weighing the risks and benefits of appropriate treatments should be co-produced with patients.
- Save precious professional time
- Help clinicians maintain their professional practice and keep up to date with the changing evidence base and best practice.
- Create headroom for innovation.
- Maximize value and avoid waste.

In addition to publishing statutory guidance NHS England mandates compliance to the Evidence-Based Interventions programme through the NHS Standard Contract. For Category 2 interventions including hysterectomy for HMB, clinicians will need to demonstrate that the patient meets the criteria set out in the guidance and CCGs will need to ensure compliance. These criteria are based on the 2018 NICE guidelines and state that hysterectomy should be considered only when: other treatment options have failed, are contradicted; there is a wish for amenorrhoea (no periods); the woman (who has been fully informed) requests it; the woman no longer wishes to retain her uterus and fertility. CCGs may, where there are concerns about achieving the desired clinical change and proposed activity reduction goals, introduce measures such as a prior approval process. A prior approval process for category 2 interventions could include monitoring through regular audits and engagement with clinicians and, if needed, be reinforced through financial levers.

**Conclusion**

Heavy menstrual bleeding is a significant clinical problem the UK and globally. Pathways have been created and updated to provide optimum, efficient and evidence-based treatment. The nationally agreed guidelines provide information and guidance which should facilitate the shift of care towards primary rather than secondary care. Changes in care delivery adopted during the Covid pandemic demonstrate how patients’ complaints can be addressed even without physical attendance. Local pathways should agree to help general practitioners commence medical management early, seek advice if required, and refer appropriately. This would allow more opportunity for efficient management in one-stop clinics, avoid long waiting time and repeated attendance.

**FURTHER READING**

Evidence-based interventions: guidance for CCGs published by NHS England in partnership with NHS clinical commissioners, the academy of medical royal colleges, NHS improvement and the national institute for health and care excellence, Nov 2018.

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**Practice points**

- HMB should be aimed to be managed medically promptly and effectively in Primary healthcare to avoid anaemia.
- Referral to secondary healthcare should be only for suspected cancers and where surgical management is essential.
- There is a shift towards virtual consultation in the era of covid-19, where medical management with oral progestogens would be preferred to Mirena to avoid delay in treatment.
- Effective triaging based on local guidelines should be available and encouraged to avoid long waiting time for HMB management.
- Minimal invasive surgery and one stop hysteroscopy should be the mainstay of surgical management.