

# Evidence Review for the use of Hysteroscopy as a First Line Investigation

## Question to be addressed

1. In female adults, are there clinical circumstances where the use of hysteroscopy would be clinically more effective than ultrasound as a first line investigation?

## Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of the use of hysteroscopy as a first line investigation and identification of the clinical circumstances in which use as a first line investigative tool this intervention would be most clinically effective to inform their decisions on commissioning policy development.

## Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use hysteroscopy as a first line intervention, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness in all clinical circumstances, the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.
3. The Committee considers that there is sufficient evidence to suggest that the use of hysteroscopy as a first line treatment is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

## Summary:

### Background

- Heavy periods are common, but they can have a big effect on a woman's everyday life. HMB does not always have an underlying cause but can result from problems such as fibroids or endometriosis.
- Heavy menstrual bleeding is defined as losing 80ml or more in each period, having periods that last longer than 7 days, or both.
- A hysteroscopy is a procedure used to examine the inside of the womb (uterus).

### Clinical effectiveness

- Evidence including the NICE review 2018 demonstrated clinically robust evidence to support the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial

pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

- Evidence including the NICE evidence review 2018 enabled a review of the diagnostic tests to be used to direct treatment according to the woman's underlying pathology. In the NICE 2018 model, diagnostic test accuracy was used to estimate the proportion of women who would be correctly identified and receive the appropriate first line treatment.

### **Safety**

- NICE supports the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology in NG 88.

### **Cost effectiveness**

- A high quality economic evaluation from the UK (Cooper 2014) concluded that either outpatient hysteroscopy or outpatient hysteroscopy in combination with endometrial biopsy represented cost-effective strategies for HMB.
- NICE NG 88 established that whilst outpatient hysteroscopy was the most expensive diagnostic test but the least expensive diagnostic strategy. An important contributing factor to this is that hysteroscopy can facilitate a one stop 'see-and-treat' approach which reduces treatment cost.

### **Equity issues**

NICE identified the following groups of women whom may require special consideration, but equity issues were not identified:

- women who have difficulties communicating in English
- women with learning difficulties
- women from some minority ethnic groups (because women from some minority ethnic group might find it difficult to talk about HMB with health care professionals)
- women from disadvantaged socio-economic groups.

### **Context**

#### **1.1 Introduction**

In about half of women with heavy menstrual bleeding, no underlying reason is found. But there are several conditions and some treatments that can cause heavy menstrual bleeding.

Some conditions of the womb and ovaries can cause heavy bleeding, including:

- fibroids – non-cancerous growths that develop in or around the womb and can cause heavy or painful periods

- endometriosis – where the tissue that lines the womb (endometrium) is found outside the womb, such as in the ovaries and fallopian tubes (although this is more likely to cause painful periods)
- adenomyosis – when tissue from the womb lining becomes embedded in the wall of the womb; this can also cause painful periods
- pelvic inflammatory disease (PID) – an infection in the upper genital tract (the womb, fallopian tubes or ovaries) that can cause symptoms like pelvic or abdominal pain, bleeding after sex or between periods, vaginal discharge and fever
- endometrial polyps – non-cancerous growths in the lining of the womb or cervix (neck of the womb)
- cancer of the womb – the most common symptom is abnormal bleeding, especially after the menopause
- polycystic ovary syndrome (PCOS) – a common condition that affects how the ovaries work; it causes irregular periods, and periods can be heavy when they start again

Other conditions that can cause heavy periods include:

- blood clotting disorders, such as Von Willebrand disease
- an underactive thyroid gland (hypothyroidism) – where the thyroid gland does not produce enough hormones, causing tiredness, weight gain and feelings of depression
- diabetes

Medical treatments that can sometimes cause heavy periods include:

- an IUD (intrauterine contraceptive device, or "the coil") – this can make your periods heavier for the first 3 to 6 months after insertion
- anticoagulant medication – taken to prevent blood clots
- some medicines used for chemotherapy
- some herbal supplements, which can affect your hormones and may affect your periods – such as ginseng, ginkgo and soya

## 1.2 Management

A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so the doctor or specialist nurse can see inside the womb. The hysteroscope is passed into the womb through the vagina and cervix.

NICE Guideline 88 states:

In Women with suspected submucosal fibroids, polyps or endometrial pathology

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

Women with possible larger fibroids

1.3.12 Offer pelvic ultrasound to women with HMB if any of the following apply:

- their uterus is palpable abdominally
- history or examination suggests a pelvic mass
- examination is inconclusive or difficult, for example in women who are obese.

Women with suspected adenomyosis

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.

1.3.14 If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques.

1.3.15 Be aware that pain associated with HMB may be caused by endometriosis rather than adenomyosis (see NICE's guideline on endometriosis).

### **Other diagnostic tools**

1.3.16 Do not use saline infusion sonography as a first-line diagnostic tool for HMB.

1.3.17 Do not use MRI as a first-line diagnostic tool for HMB.

1.3.18 Do not use dilatation and curettage alone as a diagnostic tool for HMB

## **1.3 Existing national policies and guidance**

- National Institute for Health and Care Excellence (NICE) Guidance

Guidance was published in 2018 on the use of hysteroscopy as a first line treatment, which states that a hysteroscopy should be used as a first line treatment in women who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

## **2 Epidemiology**

HMB is one of the most common reasons for gynaecological consultations in both primary and secondary care. About 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 comprise 12% of all referrals to gynaecology services.

The focus of this review is on women of reproductive age (after puberty and before the menopause) with HMB, including women with suspected or confirmed fibroids, and women with suspected or confirmed adenomyosis. The guideline does not primarily cover women with gynaecological bleeding other than HMB (for example, intermenstrual bleeding or postcoital bleeding) or with gynaecological conditions in which HMB is not the main symptom (such as endometriosis).

Since 2007, equipment and software for transvaginal ultrasound have improved. Outpatient hysteroscopy has become more widely available, and is more acceptable to women with the advent of modern equipment such as miniature hysteroscopes.

Therefore, the relative clinical and cost effectiveness of diagnostic strategies have changed. Improvements in diagnostic imaging in recent years have resulted in an increase in the reported prevalence of certain conditions, e.g. adenomyosis.

### **3 The interventions**

#### **3.1 Ultrasound scan**

##### **3.1.1 Abdominal**

Ultrasound imaging involves sending high-frequency sound waves into the body. These waves reflect off of organs and other structures inside the body. A receiver then picks up these response signals.

It is possible to create images by analyzing the data that these signals create.

The abdominal ultrasound scan is undertaken with a probe moving over the stomach to identify structures within the abdominal and pelvic areas.

##### **3.1.2 Transvaginal**

The transvaginal (internal) ultrasound scan does not require a full bladder as the scan probe is placed inside the vagina and is closer to the pelvic organs being examined.

This type of scan is used to help provide clearer pictures of the womb, ovaries and surrounding structures.

#### **3.2 Hysteroscopy**

A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It's carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so that the inside the womb may be examined. The hysteroscope is passed into the womb through the vagina and cervix.

### **4 Findings**

#### **4.1 Evidence of effectiveness**

In reviewing the evidence NICE 2018 considered the following requirements:

- that the correct identification of the cause of HMB is important as this can impact the treatment options offered to women.
- If a test is sensitive, it may help the clinicians to choose the right initial treatment to be offered to women.
- It is important to avoid false positives because unnecessary treatment, especially surgical treatment, can cause harm.
- The evidence on diagnostic accuracy was assessed using adapted GRADE methodology.
- The evidence on patient satisfaction or acceptability was assessed using Cochrane Collaboration's tool for assessing risk of bias.

NICE in their evidence review accepted that the quality of evidence in these reviews ranged from very low to moderate with most evidence being of very low quality. The NICE committee recognised that the evidence was fragmented and with several limitations. The NICE committee agreed that the quality of evidence was most often downgraded because of unclear sampling, unclear inclusion and exclusion criteria, unclear diagnostic criteria, and at times, considerable number of drop-outs.

#### **4.1.1 Clinical effectiveness**

It was noted that there was a lack of robust evidence to support the intervention.

The NICE committee agreed that many women presenting to primary care with symptoms of HMB can be offered treatment without the need for further examination or investigation. However, investigation via a diagnostic technique might be warranted for women for whom history or examination suggests a structural or endometrial pathology or for whom the initial treatment has failed.

The NICE committee considered outpatient hysteroscopy to be an efficient and safe technique with a low risk of complications, and acceptable to most women if done according to best practice guidance. It would also allow for services to be developed to offer women the option of see-and-treat by having submucosal fibroids or polyps identified and removed in one process when appropriate.

#### **4.1.2 Trials in progress**

Review of *clinicaltrials.gov* provided no current trials being undertaken to evaluate the use of hysteroscopy and the clinical circumstances in which hysteroscopy would be a first line treatment.

### **4.1.3 Cost-effectiveness**

A high quality economic evaluation from the UK (Cooper 2014) compared a number of diagnostic strategies for HMB. This analysis took an NHS perspective and the setting was a 'one-stop' secondary care clinical setting. The study concluded that either outpatient hysteroscopy or outpatient hysteroscopy in combination with endometrial biopsy represented cost-effective strategies for HMB. Treatment effectiveness was estimated through patient satisfaction although the authors also derived a cost per QALY estimate based on this.

Outpatient hysteroscopy is a more expensive investigation than pelvic ultrasound but there are potential off-setting savings to treatment costs as the technique can allow a 'see and treat' approach.

### **4.2 Safety**

National Institute for Health and Care Excellence (NICE) Guidance 88 supports the use of hysteroscopy as a first line investigation to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

### **4.3 Summary of findings**

The evidence identified in the NICE review and the paucity of reliable evidence which was found within this evidence review, appears to be a result of a lack of quality/ strong evidence, not evidence which does not support hysteroscopy as a first line intervention.

The safety and cost effectiveness of hysteroscopy as a first line treatment, particularly in a see and treat scenario are documented by NICE (2018).

### **5 Equity issues**

This issue solely relates to women. However, further equity issues have not been identified.

### **6 Discussion and conclusions**

A paucity of robust, current evidence, has meant that NICE Guidance 88 has been heavily relied on in reviewing this intervention. The guidance has identified that the most appropriate clinical circumstances in which hysteroscopy should be used is as a first line investigation. NICE recognise the limited evidence available and have used clinical experts to guide the development of this guidance.

Further research in this area, would be welcomed.

## 7 Search Strategy

- PubMed

("hysteroscopy"[MeSH Terms] OR "hysteroscopy"[All Fields]) AND first[All Fields] AND ("long interspersed nucleotide elements"[MeSH Terms] OR ("long"[All Fields] AND "interspersed"[All Fields] AND "nucleotide"[All Fields] AND "elements"[All Fields]) OR "long interspersed nucleotide elements"[All Fields] OR "line"[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) AND ("menorrhagia"[MeSH Terms] OR "menorrhagia"[All Fields] OR ("heavy"[All Fields] AND "menstrual"[All Fields] AND "bleeding"[All Fields]) OR "heavy menstrual bleeding"[All Fields])

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