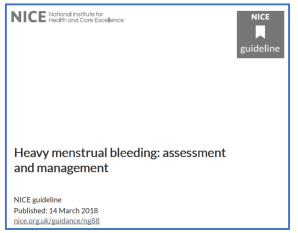
BSGE Meeting:
Contemporary management of heavy menstrual bleeding (HMB) in primary and secondary care:
(7th December 2018, RCOG)

# Investigating HMB- an evidence based approach

T. Justin Clark MB ChB, MD(Hons), FRCOG

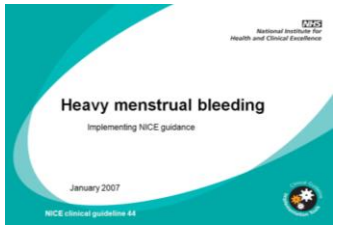
**Consultant Gynaecologist & Honorary Professor**
**Birmingham Women's & Children's Hospital & University of Birmingham**
**United Kingdom**

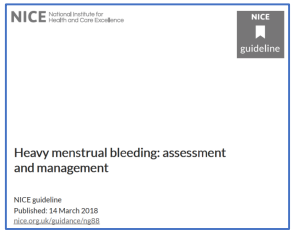
# NICE HMB Guidance 2018 Declarations of interest




- NICE HMB 2018 Guideline committee member
  - COIs – see NICE website / publication

# NICE HMB Guidance 2007 & 2018



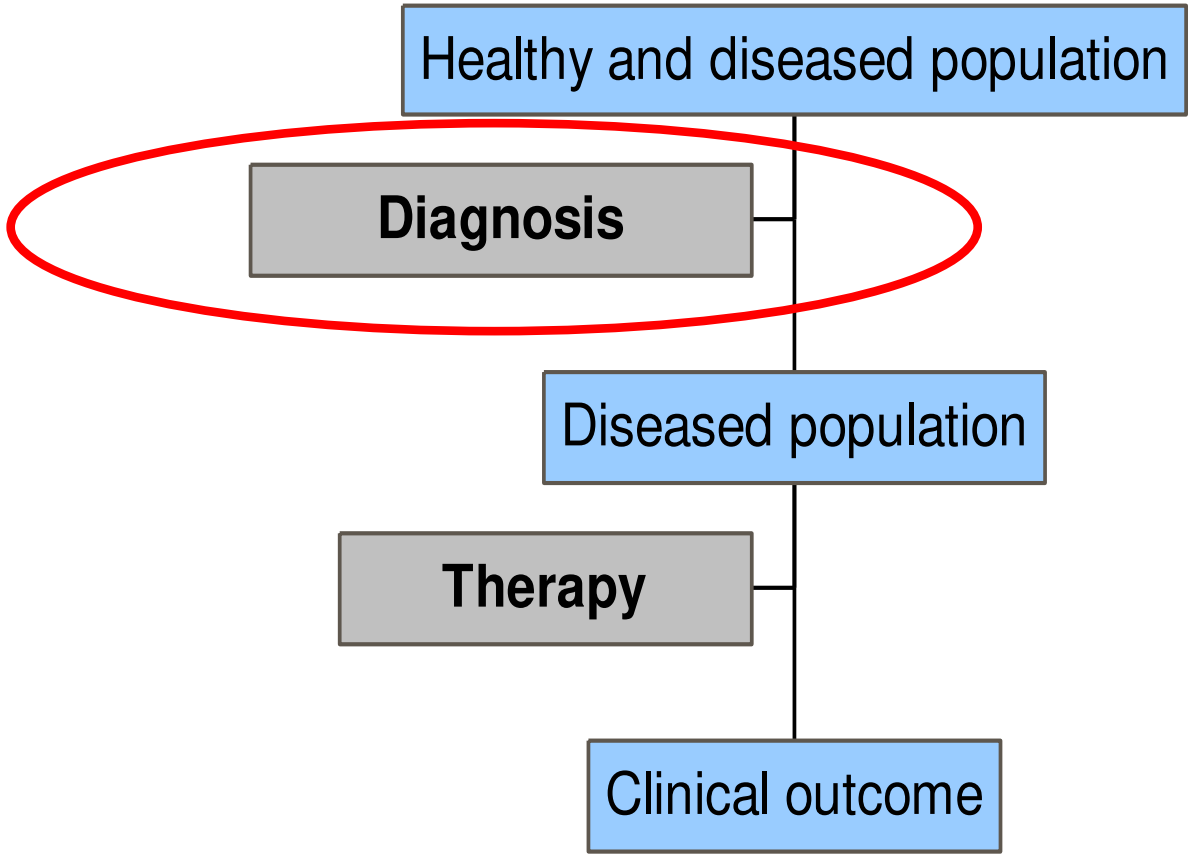

- Original 2007 guideline needed updating
  - New evidence; new pharmaceuticals, new diagnostic and therapeutic technologies
  - Some changes needed according to differing ‘expert opinion’

- Main areas of change in 2018 revised version:
  - Diagnostic work up
  - Treatment recommendations
    - Stratified by presence or absence of ‘significant’ fibroids
    - Pharmaceutical treatment
      - Ulipristal acetate
    - Hierarchy for treatment
      - Fibroid(s) >3cm
      - Submucosal fibroids

# Rationale for diagnosis: Causes of HMB

Investigating HMB- an evidence based approach

# Diagnosis: Clinical Process



NICE National Institute for Health and Care Excellence

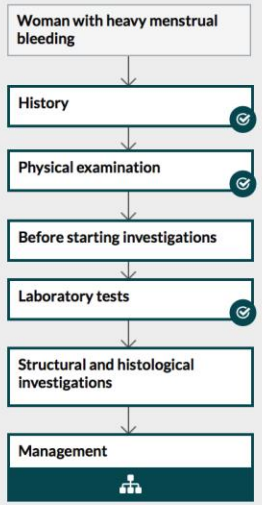
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# Diagnosing and assessing heavy menstrual bleeding



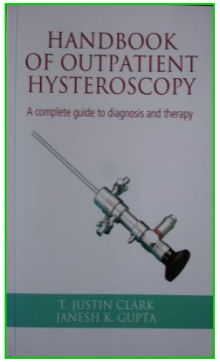

Heavy menstrual bleeding – everything NICE says in an interactive flowchart

About | Resources | Information for the public | Quality standards

- Heavy menstrual bleeding overview
- Diagnosing and assessing heavy menstrual bleeding
- Managing heavy menstrual bleeding
- Patient experience in adult NHS services

Your responsibility when using NICE advice

# Likely causes of heavy menstrual bleeding




**Common**

**Dysfunctional Uterine Bleeding**

- Ovular
- Anovular (endometrial hyperplasia)

**Fibroids**

- Submucous
- Intramural

**Less common**

**Gynaecological disease**

- Endometriosis
- Adenomyosis
- Diffuse myometrial hypertrophy
- Pelvic inflammatory disease
- Intrauterine polyps

**Pregnancy related**

- Retained products of conception

**Iatrogenic**

- Intrauterine contraceptive devices
- Exogenous sex hormones
- Anticoagulants

**Rare**

**Gynaecological cancer**

- Uterus
- Ovary (theca and granulosa cell tumours)

**Endocrine**

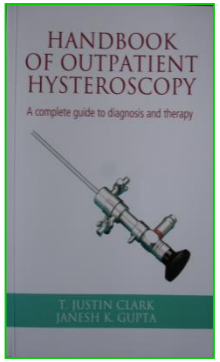
- Thyroid dysfunction

**Haematological**

- von Willebrand's disease
- Idiopathic thrombocytopenia

***From Clark TJ and Gupta JK. Handbook of Outpatient Hysteroscopy: A complete guide to diagnosis and therapy, Hodder Arnold, London 2005***

# Likely causes of heavy menstrual bleeding



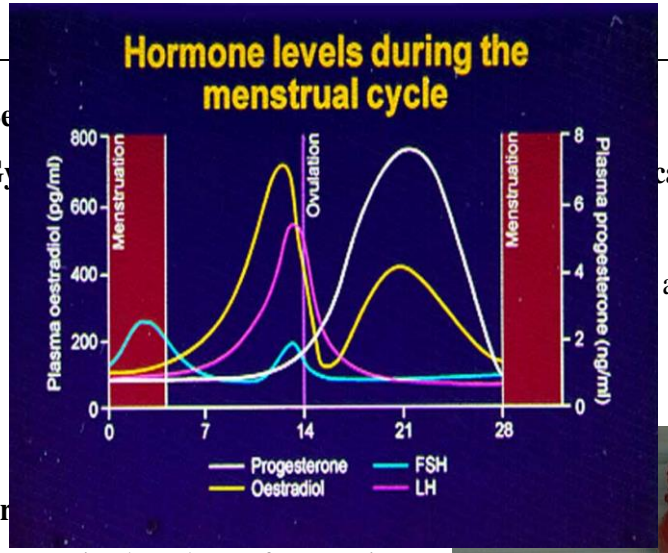

**Common**

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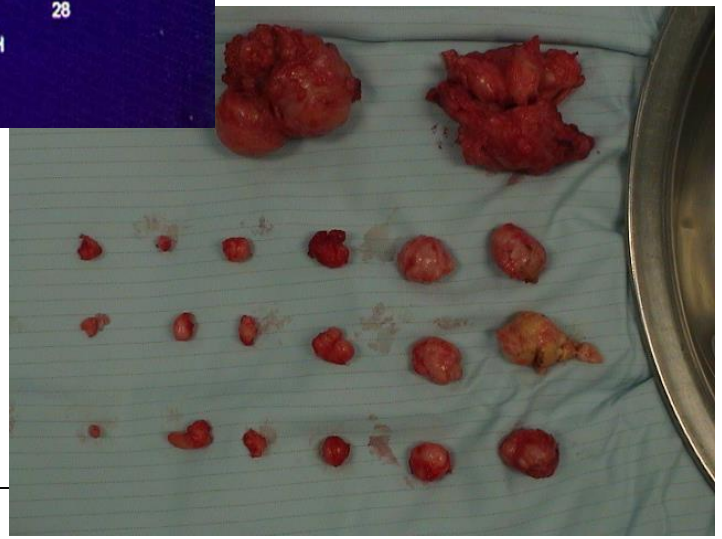
- Retained products of conception

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- Intrauterine contraceptive devices
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**cancer**

and granulosa cell tumours)



***From Clark TJ and Gupta JK. Handbook of Outpatient Hysteroscopy: A complete guide to diagnosis and therapy, Hodder Arnold, London 2005***

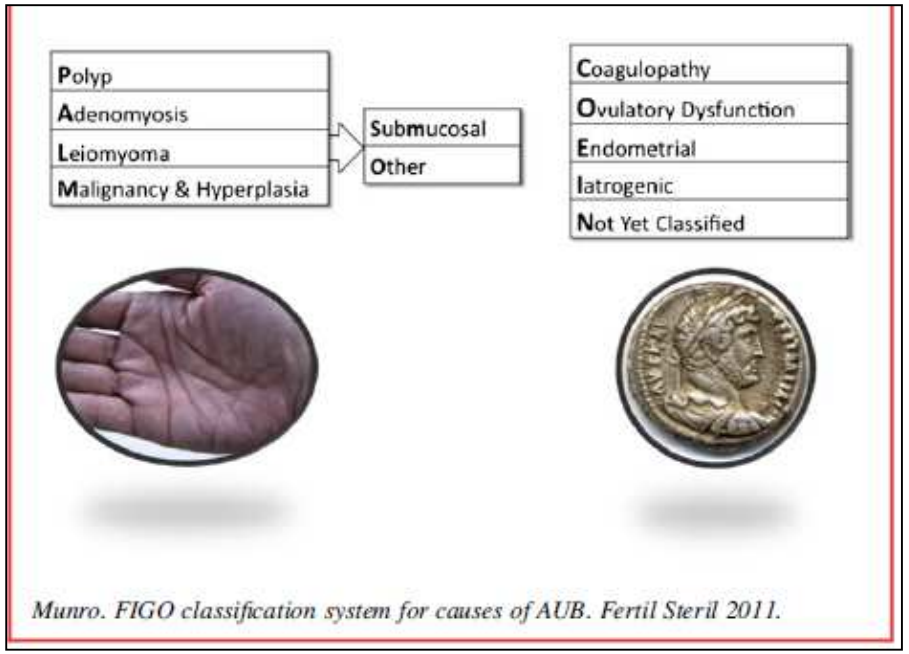
# Diagnosis and HMB: Intracavity pathology

**The FIGO classification of causes of abnormal uterine bleeding in the reproductive years**

*Malcolm G. Munro, M.D.,[a] Hilary O. D. Critchley, M.D.,[b] and Ian S. Fraser, M.D.,[c] for the FIGO Menstrual Disorders Working Group*

[a] Department of Obstetrics and Gynecology, David Geffen School of Medicine at UCLA and Kaiser Permanente, Los Angeles Medical Center, Los Angeles, California; [b] Department of Obstetrics and Gynecology, University of Edinburgh and the Royal Infirmary, Edinburgh, United Kingdom; and [c] Department of Obstetrics and Gynecology, University of Sydney Australia, and the Royal Prince Alfred Hospital, Sydney, New South Wales, Australia

At this juncture, clinical management, education for medical providers, and the design and interpretation of clinical trials have been hampered by the absence of a consensus system for nomenclature for the description of symptoms as well as classification of causes or potential causes of abnormal uterine bleeding (AUB). To address this issue, the Fédération Internationale de Gynécologie et d'Obstétrique (FIGO) has designed the PALM-COEIN (Polyp, Adenomyosis, Leiomyoma, Malignancy and Hyperplasia, Coagulopathy, Ovulatory Disorders, Endometrial Disorders, Iatrogenic Causes, and Not Classified) classification system for causes of AUB in the reproductive years. (Fertil Steril® 2011;95:2204–8. ©2011 by American Society for Reproductive Medicine.)

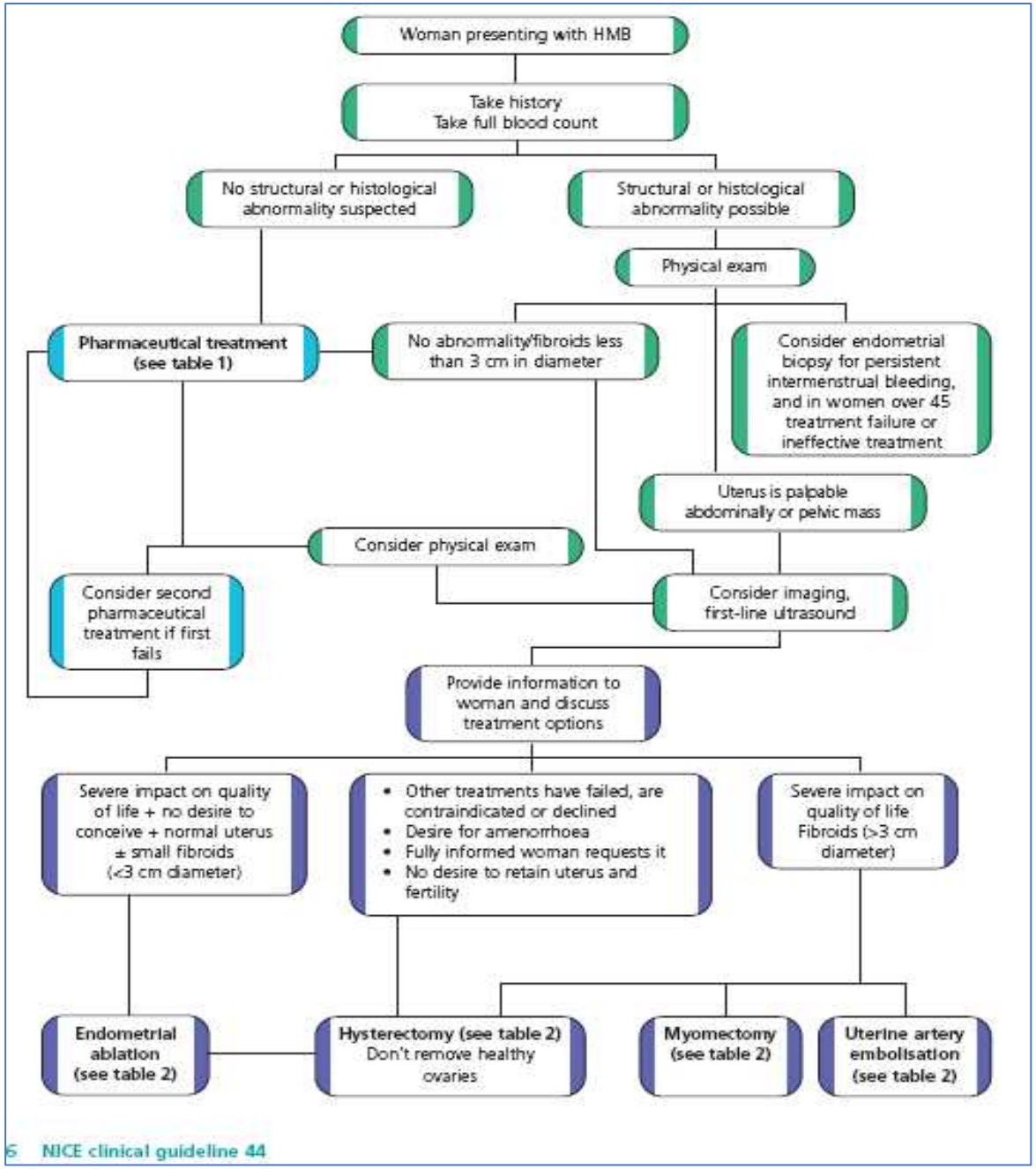



*Munro. FIGO classification system for causes of AUB. Fertil Steril 2011.*

| Diagnosis | Cause |
|---|---|
| | Structural |
| AUB-P | Polyps |
| AUB-A | Adenomyosis |
| AUB-L | Leiomyoma |
| AUB-M | Malignancy/Hyperplasia |
| | Non Structural |
| AUB-C | Coagulopathy |
| AUB-O | Ovulatory Dysfunction |
| AUB-E | Endometrial disorder |
| AUB-I | Iatrogenic |
| AUB-N | Non classified |

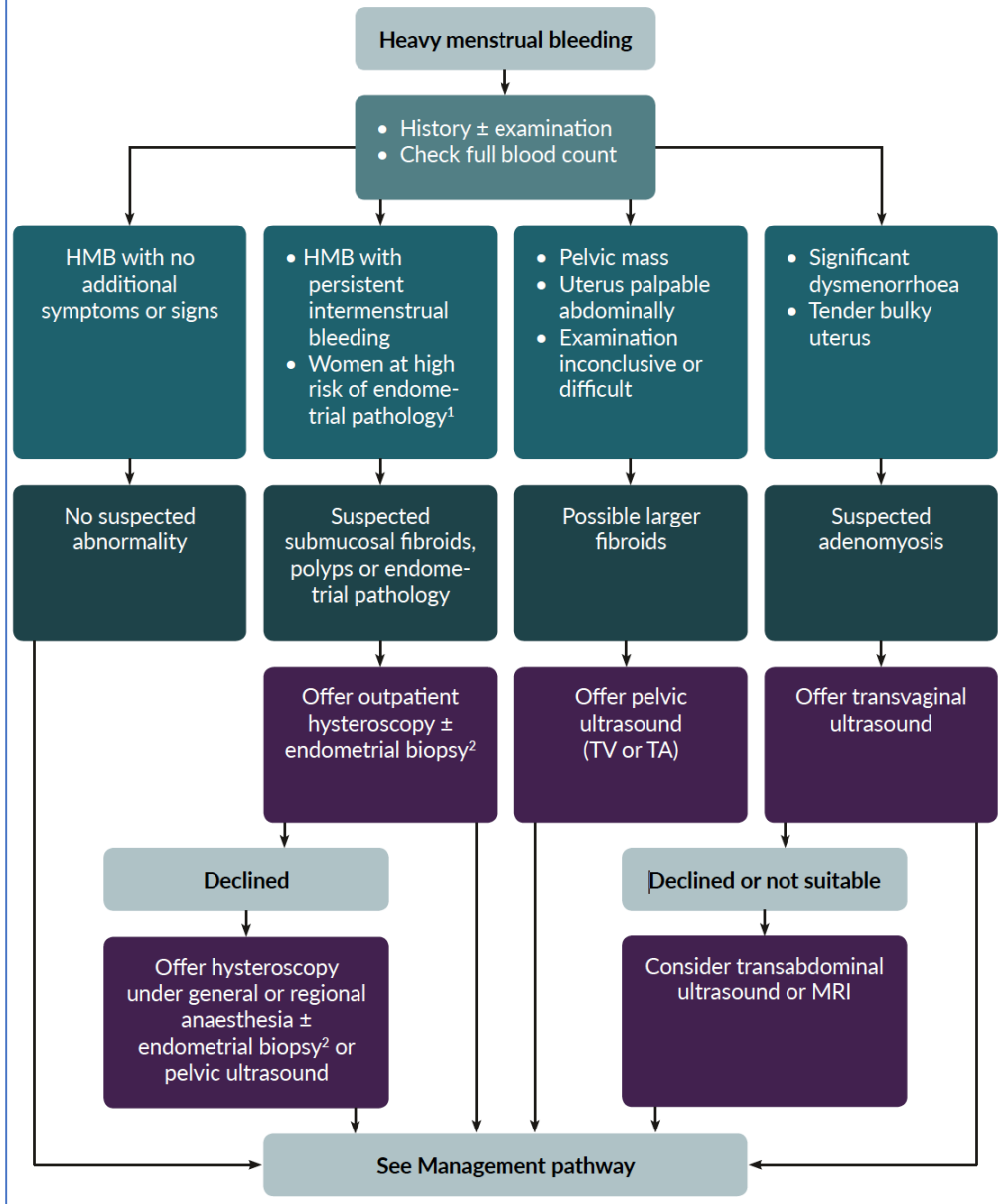
# Which tests?

Investigating HMB- an evidence based approach

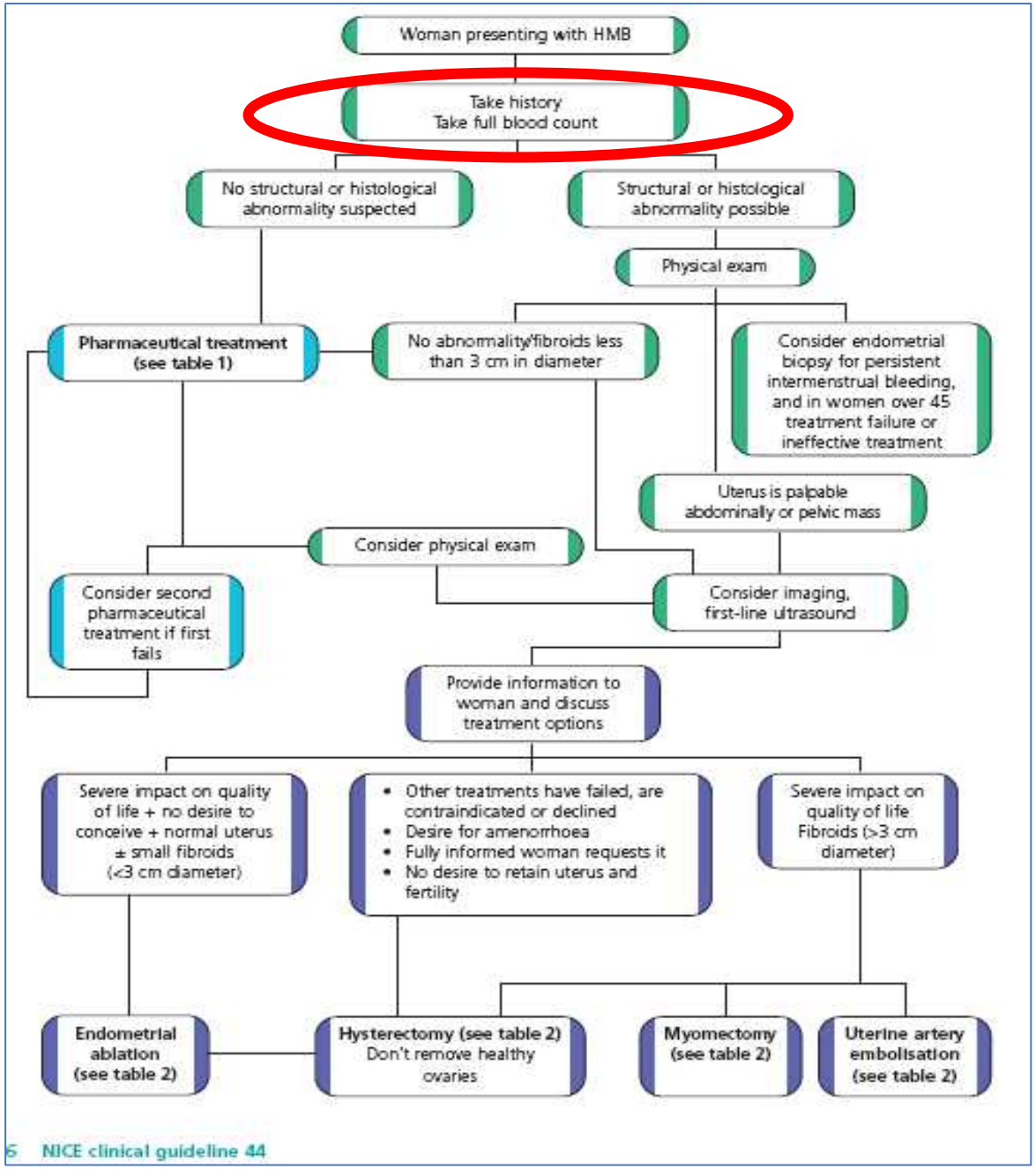





## Heavy menstrual bleeding: diagnosis

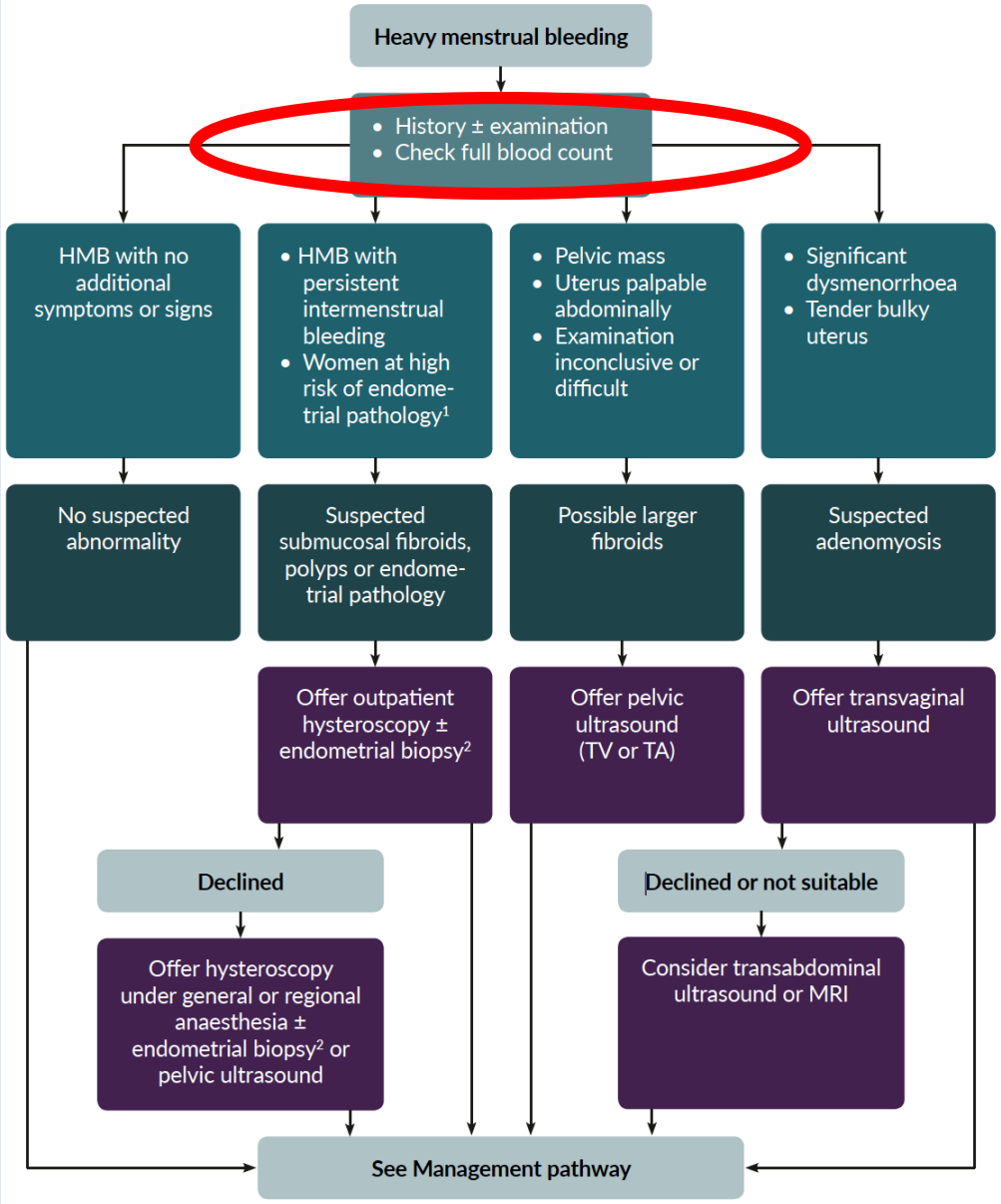



HMB: heavy menstrual bleeding; MRI: magnetic resonance imaging; TA: transabdominal; TV: transvaginal

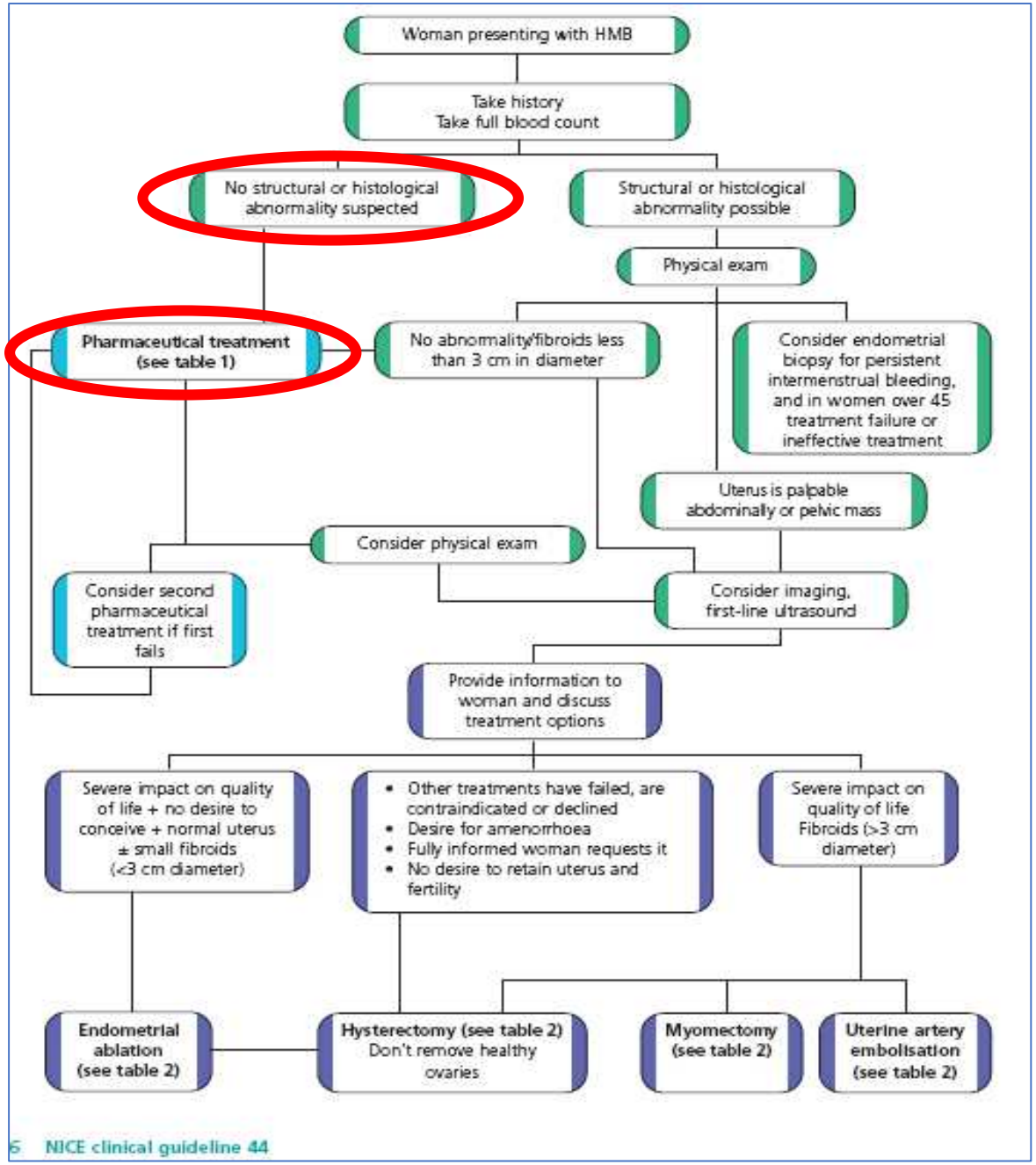





## Heavy menstrual bleeding: diagnosis

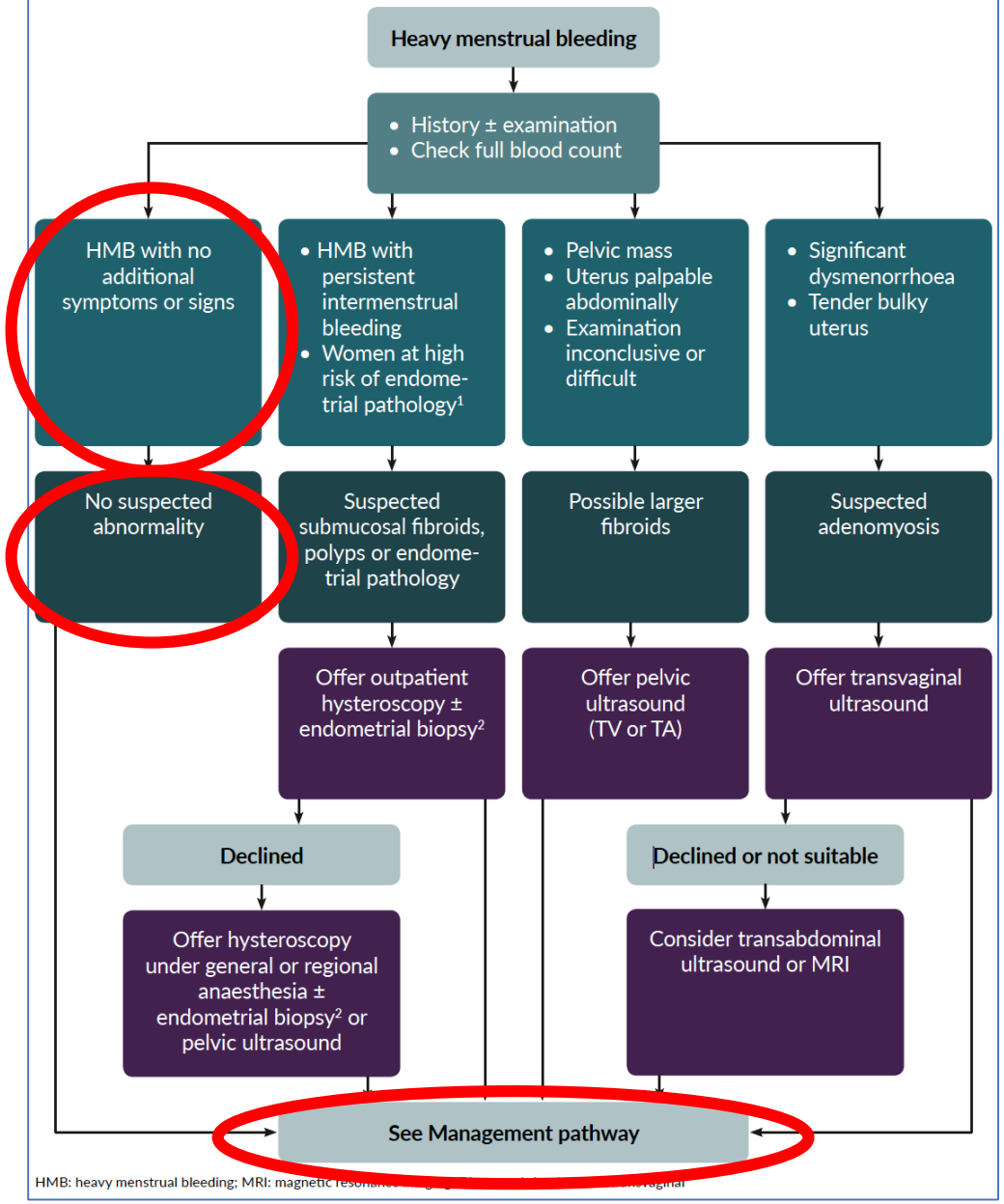



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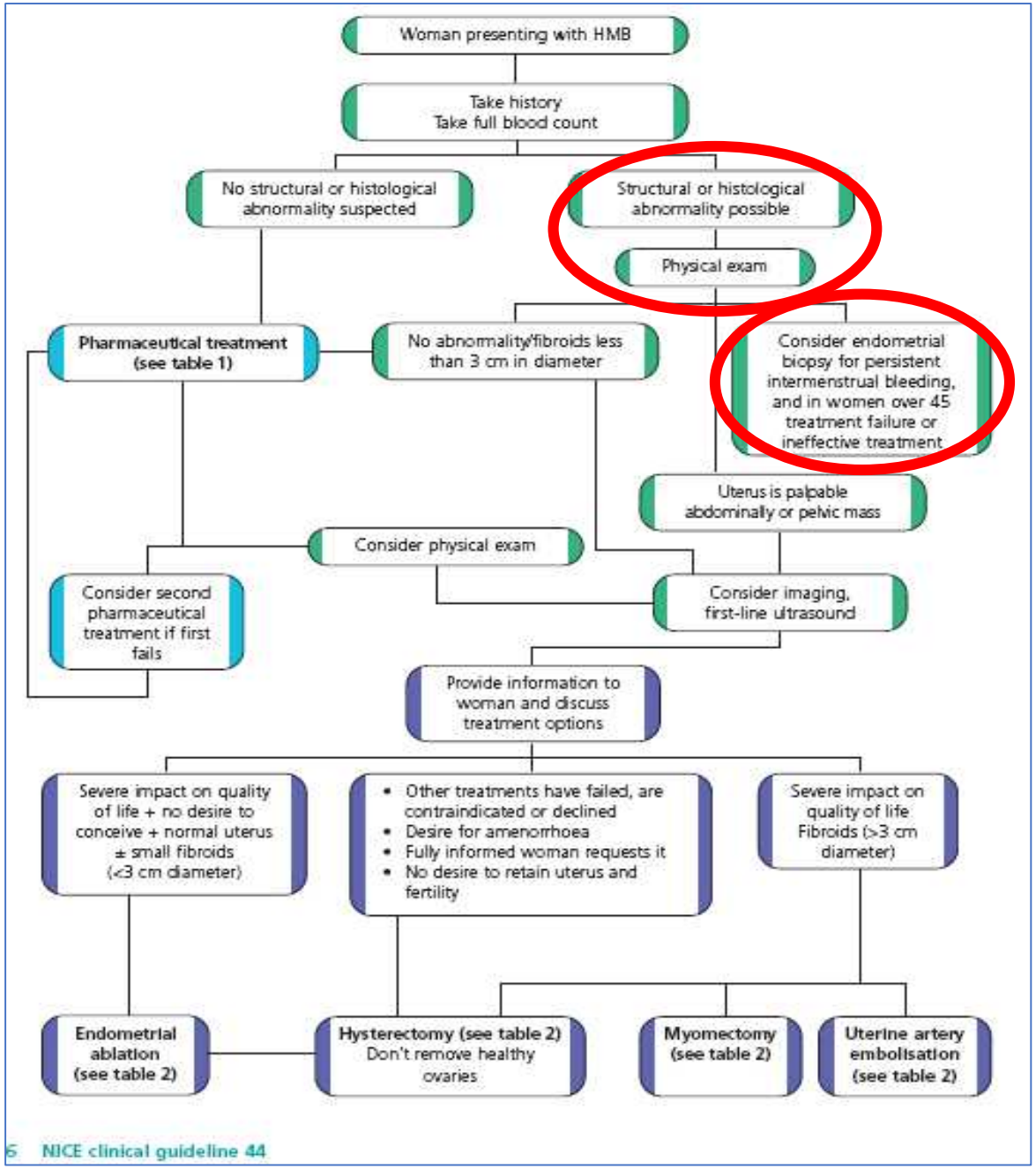





## Heavy menstrual bleeding: diagnosis

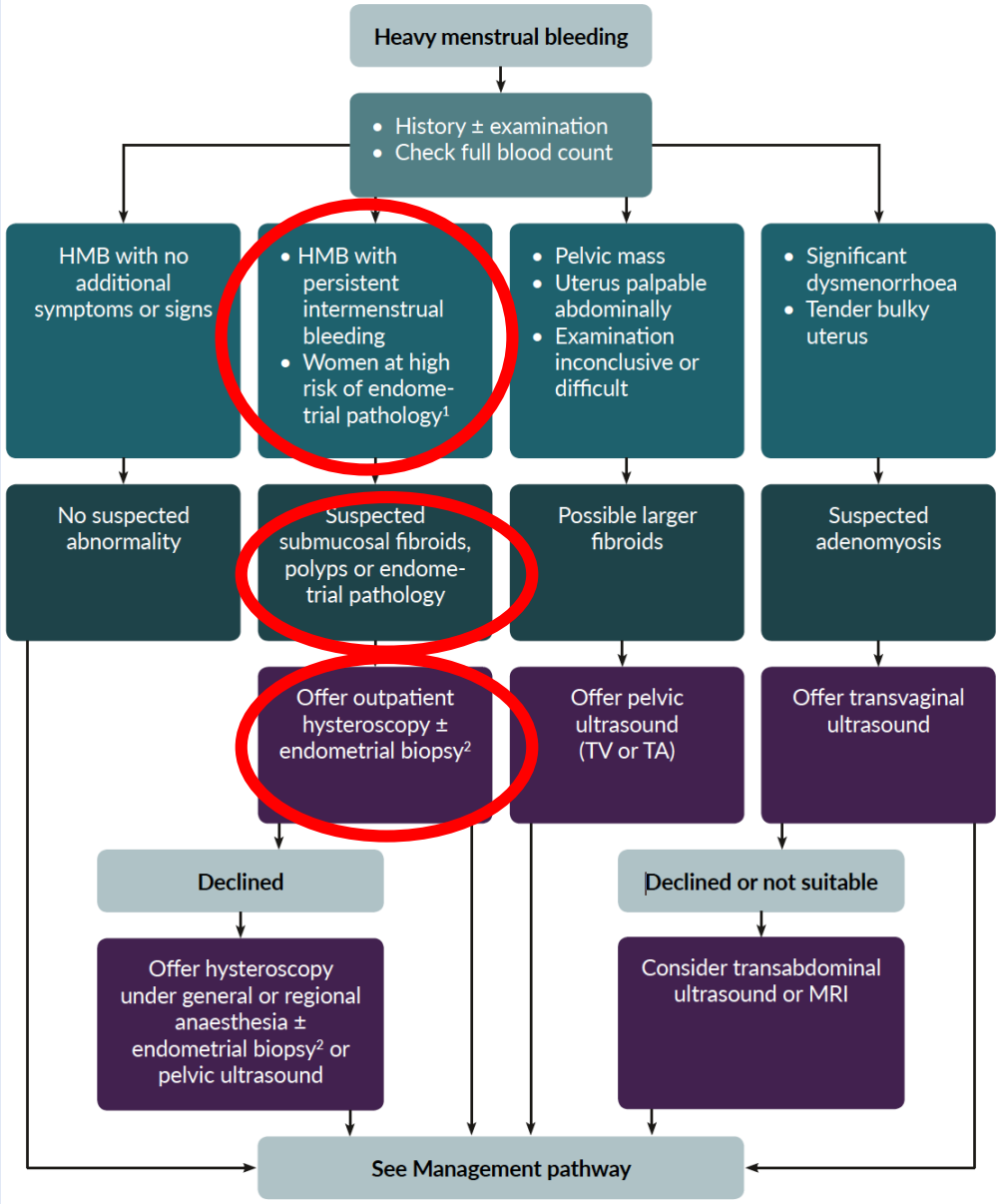



HMB: heavy menstrual bleeding; MRI: magnetic resonance





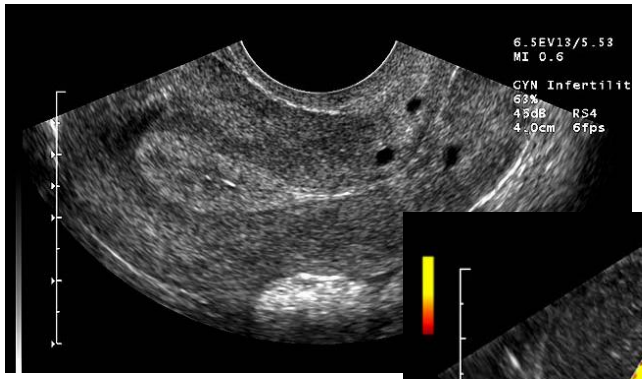

## Heavy menstrual bleeding: diagnosis

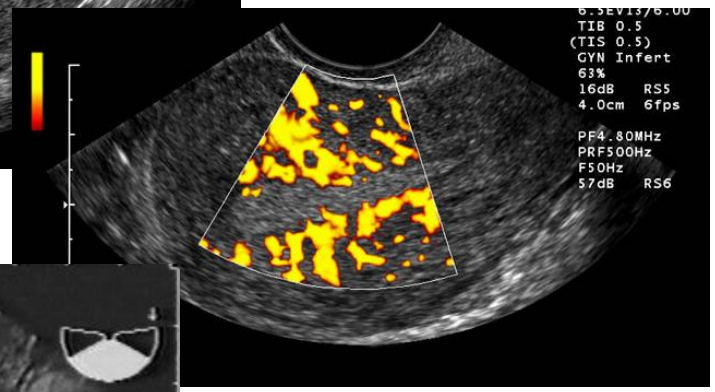



HMB: heavy menstrual bleeding; MRI: magnetic resonance imaging; TA: transabdominal; TV: transvaginal

# Minimally invasive diagnosis: Pelvic ultrasound









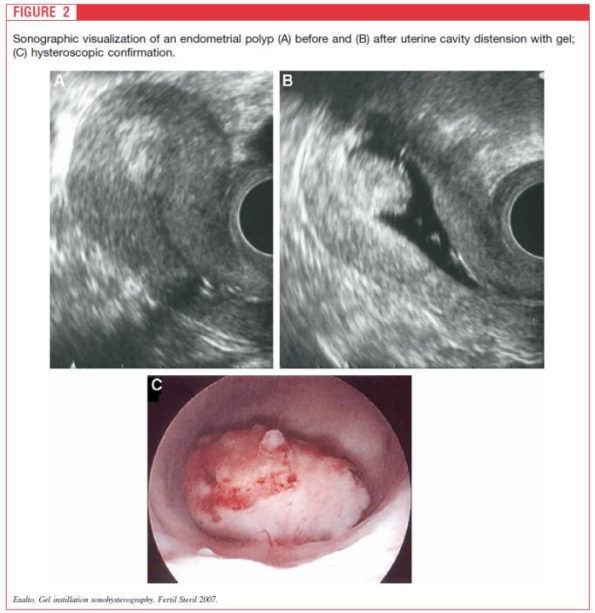






# Saline Infusion Sonography (SIS)




FIGURE 2

Sonographic visualization of an endometrial polyp (A) before and (B) after uterine cavity distension with gel; (C) hysteroscopic confirmation.



*Exalto. Gel instillation sonohysterography. Fertil Steril 2007.*



# Gel SIS & 3D

TECHNIQUES AND INSTRUMENTATION

## Gel instillation sonohysterography: first experience with a new technique

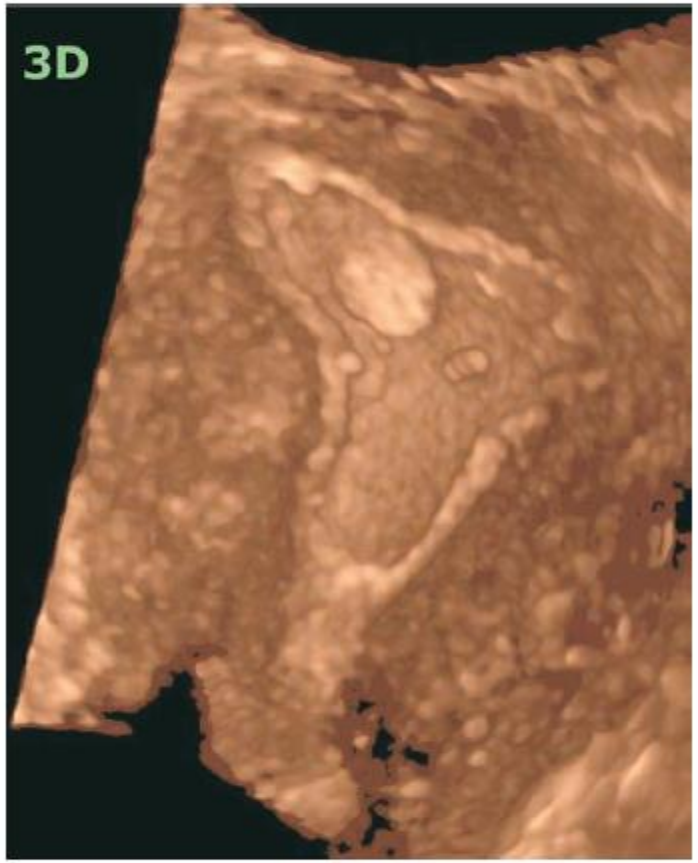
*Niek Exalto, M.D., Ph.D.,*[a] *Corry Stappers, C.N.P.,*[a] *Louisa A.M. van Raamsdonk, Pharm.D., and Mark Hans Emanuel, M.D., Ph.D.*[a]

[a] Department of Obstetrics and Gynecology and [b] Department of Clinical Pharmacy, Spaarne Ziekenhuis, Hoo The Netherlands

**Objective:** A practical attempt to simplify and improve the technique of artificial uterine cavity distens instilling gel instead of flushing saline.
**Design:** Prospective observational study.
**Setting:** Teaching hospital.
**Patient(s):** One hundred twenty patients with an indication for sonohysterography (abnormal uterine bl exclusion of congenital abnormalities, or preoperative or postoperative evaluation of submucous myomas, or synechiae).
**Intervention(s):** A hydroxyethylcellulose gel containing anesthetic and antiseptic agents was instilled uterine cavity through a plastic intrauterine insemination cannula attached to a flexible plastic tube and a s Transvaginal (3-dimensional) ultrasonography was performed concomitantly.
**Main Outcome Measure(s):** Stable filling of the uterine cavity allowing a high-quality ultrasonog visualization.
**Result(s):** An optimal distension of the uterine cavity could be achieved with an average of only 4 mL (rang mL) in 113 patients. As expected, a stable filling of the uterine cavity permitted a precise visualization of the cavity and its linings and offered an optimal presentation for a 3-dimensional ultrasound recording and reconst
**Conclusion(s):** Gel instillation is a simple technique with minimal inconvenience for the patient and seem an attractive alternative to saline infusion during sonohysterography. (Fertil Steril® 2007;87:152–5. ©2 American Society for Reproductive Medicine.)

**Key Words:** Gel instillation sonohysterography, uterine cavity, 3-dimensional ultrasound

Three-dimensional (3D) gel instillation sonohysterography (GIS) reconstruction of an endometrial polyp.



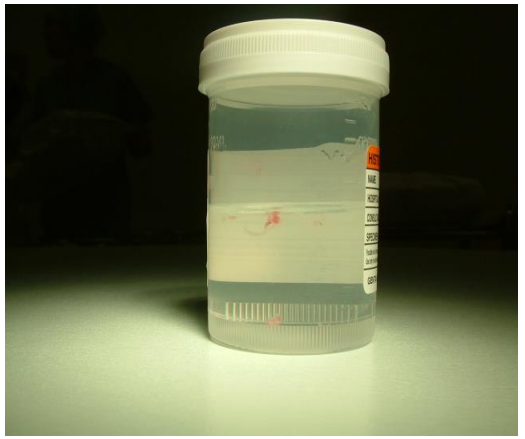

*Exalto. Gel instillation sonohysterography. Fertil Steril 2007.*

# Minimally invasive diagnosis: endometrial biopsy







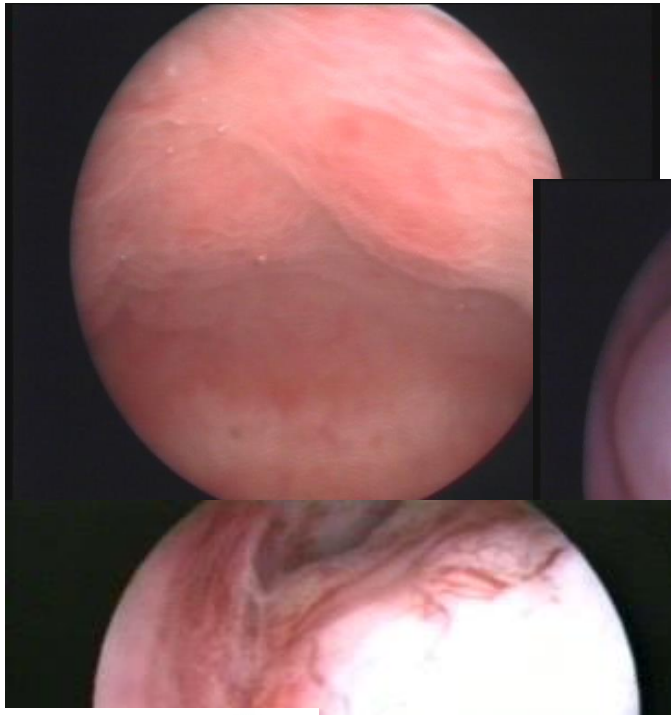


Contemporary use of MIS in AUB

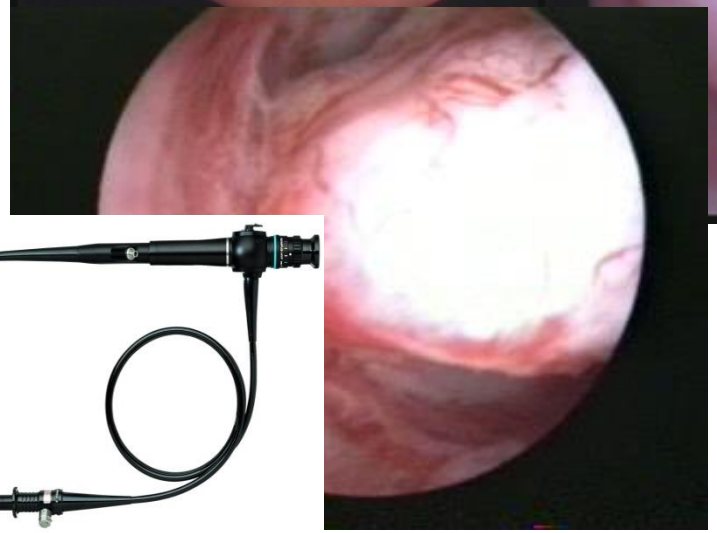
# Minimally invasive diagnosis: HYSTEROSCOPY

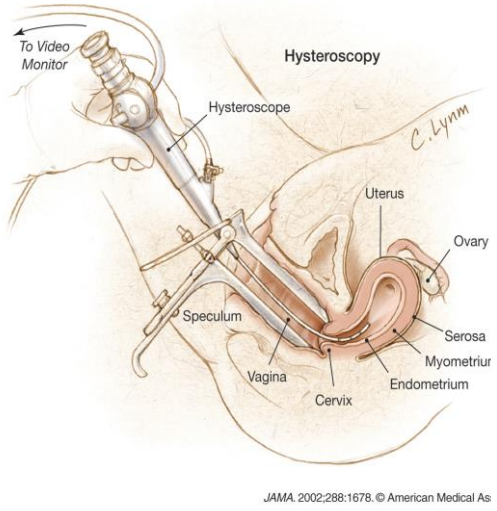












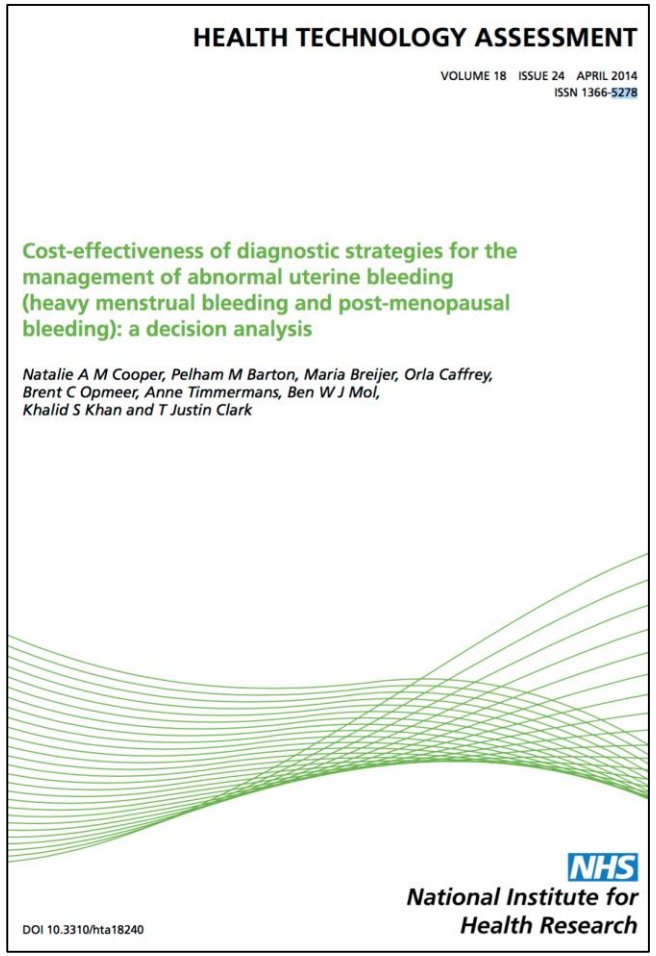
Contemporary use of MIS in AUB

# Diagnosis and the role of hysteroscopy



# Cost-effectiveness of testing in HMB:

- https://www.ncbi.nlm.nih.gov/books/NBK261900/pdf/Bookshelf_NBK261900.pdf



HEALTH TECHNOLOGY ASSESSMENT

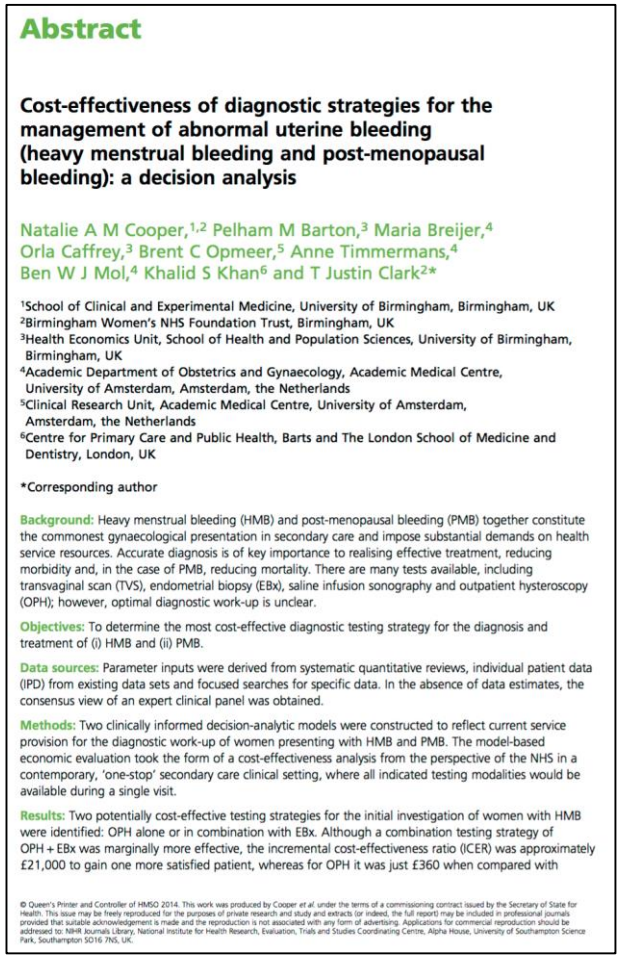
VOLUME 18 ISSUE 24 APRIL 2014
ISSN 1366-5278

Cost-effectiveness of diagnostic strategies for the management of abnormal uterine bleeding (heavy menstrual bleeding and post-menopausal bleeding): a decision analysis

*Natalie A M Cooper, Pelham M Barton, Maria Breijer, Orla Caffrey, Brent C Opmeer, Anne Timmermans, Ben W J Mol, Khalid S Khan and T Justin Clark*

NHS
National Institute for Health Research

DOI 10.3310/hta18240



## Abstract

**Cost-effectiveness of diagnostic strategies for the management of abnormal uterine bleeding (heavy menstrual bleeding and post-menopausal bleeding): a decision analysis**

Natalie A M Cooper,[1,2] Pelham M Barton,[3] Maria Breijer,[4] Orla Caffrey,[3] Brent C Opmeer,[5] Anne Timmermans,[4] Ben W J Mol,[4] Khalid S Khan[6] and T Justin Clark[2]*

[1]School of Clinical and Experimental Medicine, University of Birmingham, Birmingham, UK
[2]Birmingham Women's NHS Foundation Trust, Birmingham, UK
[3]Health Economics Unit, School of Health and Population Sciences, University of Birmingham, Birmingham, UK
[4]Academic Department of Obstetrics and Gynaecology, Academic Medical Centre, University of Amsterdam, Amsterdam, the Netherlands
[5]Clinical Research Unit, Academic Medical Centre, University of Amsterdam, Amsterdam, the Netherlands
[6]Centre for Primary Care and Public Health, Barts and The London School of Medicine and Dentistry, London, UK

*Corresponding author

**Background:** Heavy menstrual bleeding (HMB) and post-menopausal bleeding (PMB) together constitute the commonest gynaecological presentation in secondary care and impose substantial demands on health service resources. Accurate diagnosis is of key importance to realising effective treatment, reducing morbidity and, in the case of PMB, reducing mortality. There are many tests available, including transvaginal scan (TVS), endometrial biopsy (EBx), saline infusion sonography and outpatient hysteroscopy (OPH); however, optimal diagnostic work-up is unclear.

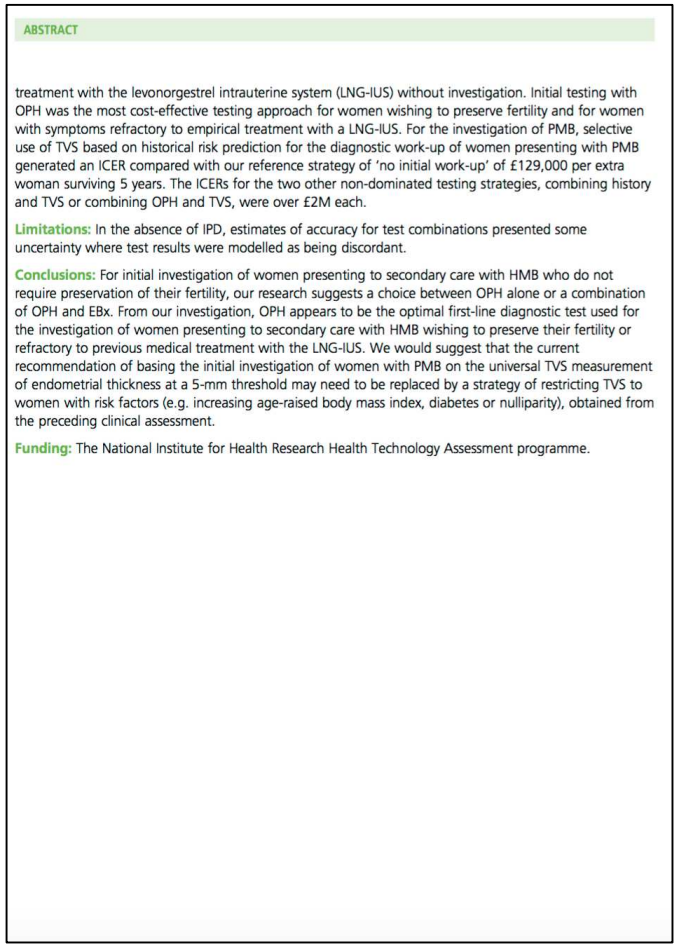
**Objectives:** To determine the most cost-effective diagnostic testing strategy for the diagnosis and treatment of (i) HMB and (ii) PMB.

**Data sources:** Parameter inputs were derived from systematic quantitative reviews, individual patient data (IPD) from existing data sets and focused searches for specific data. In the absence of data estimates, the consensus view of an expert clinical panel was obtained.

**Methods:** Two clinically informed decision-analytic models were constructed to reflect current service provision for the diagnostic work-up of women presenting with HMB and PMB. The model-based economic evaluation took the form of a cost-effectiveness analysis from the perspective of the NHS in a contemporary, 'one-stop' secondary care clinical setting, where all indicated testing modalities would be available during a single visit.

**Results:** Two potentially cost-effective testing strategies for the initial investigation of women with HMB were identified: OPH alone or in combination with EBx. Although a combination testing strategy of OPH + EBx was marginally more effective, the incremental cost-effectiveness ratio (ICER) was approximately £21,000 to gain one more satisfied patient, whereas for OPH it was just £360 when compared with

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ABSTRACT

treatment with the levonorgestrel intrauterine system (LNG-IUS) without investigation. Initial testing with OPH was the most cost-effective testing approach for women wishing to preserve fertility and for women with symptoms refractory to empirical treatment with a LNG-IUS. For the investigation of PMB, selective use of TVS based on historical risk prediction for the diagnostic work-up of women presenting with PMB generated an ICER compared with our reference strategy of 'no initial work-up' of £129,000 per extra woman surviving 5 years. The ICERs for the two other non-dominated testing strategies, combining history and TVS or combining OPH and TVS, were over £2M each.

**Limitations:** In the absence of IPD, estimates of accuracy for test combinations presented some uncertainty where test results were modelled as being discordant.

**Conclusions:** For initial investigation of women presenting to secondary care with HMB who do not require preservation of their fertility, our research suggests a choice between OPH alone or a combination of OPH and EBx. From our investigation, OPH appears to be the optimal first-line diagnostic test used for the investigation of women presenting to secondary care with HMB wishing to preserve their fertility or refractory to previous medical treatment with the LNG-IUS. We would suggest that the current recommendation of basing the initial investigation of women with PMB on the universal TVS measurement of endometrial thickness at a 5-mm threshold may need to be replaced by a strategy of restricting TVS to women with risk factors (e.g. increasing age-raised body mass index, diabetes or nulliparity), obtained from the preceding clinical assessment.

**Funding:** The National Institute for Health Research Health Technology Assessment programme.

# Cost-effectiveness of testing in HMB:
## Objective

- To determine the most cost-effective diagnostic testing strategy for the diagnosis and treatment of heavy menstrual bleeding

**Direct link to this page:** http://www.hta.ac.uk/2145

### Details of HTA project

**Last updated: 3 September 2013 - Next update due: 10 September 2013**

| | |
|---|---|
| Research type: | Secondary Research (e.g. systematic review) |
| Project title: | **Cost-effectiveness of diagnostic strategies for the management of abnormal uterine bleeding (heavy menstrual bleeding and post-menopausal bleeding): Systematic reviews, IPD meta-analysis and model based economic evaluation** |
| Project ref: | 09/63/01 |
| Cost: | £53,945 |
| Chief Investigator : | Dr Justin Clark, Consultant Obstetrician and Gynaecologist, Obstetrics and Gynaecology, Birmingham Women's Hospital |
| Start Date: | December 2010 |
| Estimated date of publication in HTA journal series: | March 2014. This project is at the editorial review stage. Delays in the review process can cause the forecast publication date to be delayed. |
| Plain English Summary | Most women will suffer at some point in their life with abnormal patterns of vaginal bleeding usually in the form of heavy or unpredictable menstrual blood loss or anomalous bleeding after the menopause. The source of this abnormal bleeding is the uterus ('womb') and the underlying causes are varied. In women of reproductive age the causes are usually benign whereas between 5 and 15% of women bleeding after the menopause will have an underlying cancer of the womb lining. Thus accurate diagnosis is crucial to selecting the most appropriate treatment options so as to optimise the chances of a successful 'cure' and avoid the potential morbidity and costs associated with an otherwise avoidable hysterectomy (surgical removal of the womb). Modern diagnostic testing for abnormal uterine bleeding (AUB) is done in the outpatient setting using outpatient endometrial biopsy (a miniature device for taking a sample from the womb lining for analysis), pelvic ultrasound (imaging the uterus) or hysteroscopy (imaging the inside of the womb using tiny telescope). However, we do not know which test or combination of tests is most effective in managing women with AUB in terms of curing them of their problem. Moreover, health service resources are scarce and so we also need to urgently identify which approaches are the most cost-effective.<br>Published research in the form of literature reviews or primary research trials have been unable to answer this important question for two main reasons. Firstly because of difficulty in determining the accuracy of the available diagnostic tests when used in combination and secondly because of the varied causation of AUB and the variety of treatment options available. We propose to assess the cost-effectiveness of diagnostic testing strategies for women with AUB using precise information obtained from the literature allowing for the assessment of test accuracy when used in combination. In addition, by adopting an economic modelling approach we can overcome the problem of the complexity of causation and spectrum of treatments by building comprehensive models to encompass contemporary practice. The effectiveness outcomes to be evaluated will be cure rate / avoidance of hysterectomy (premenopausal women) and survival (postmenopausal women). The team includes researchers with a proven track record in health technology assessment and specifically clinical, epidemiological, diagnostic evaluation and economic expertise. The grant will employ a health economist to run the economic analysis and academic researchers to analyse the information. |

# Cost-effectiveness of testing in HMB:
## Methods

- A clinically informed decision analytic model was constructed to reflect diagnostic work up of women presenting with HMB

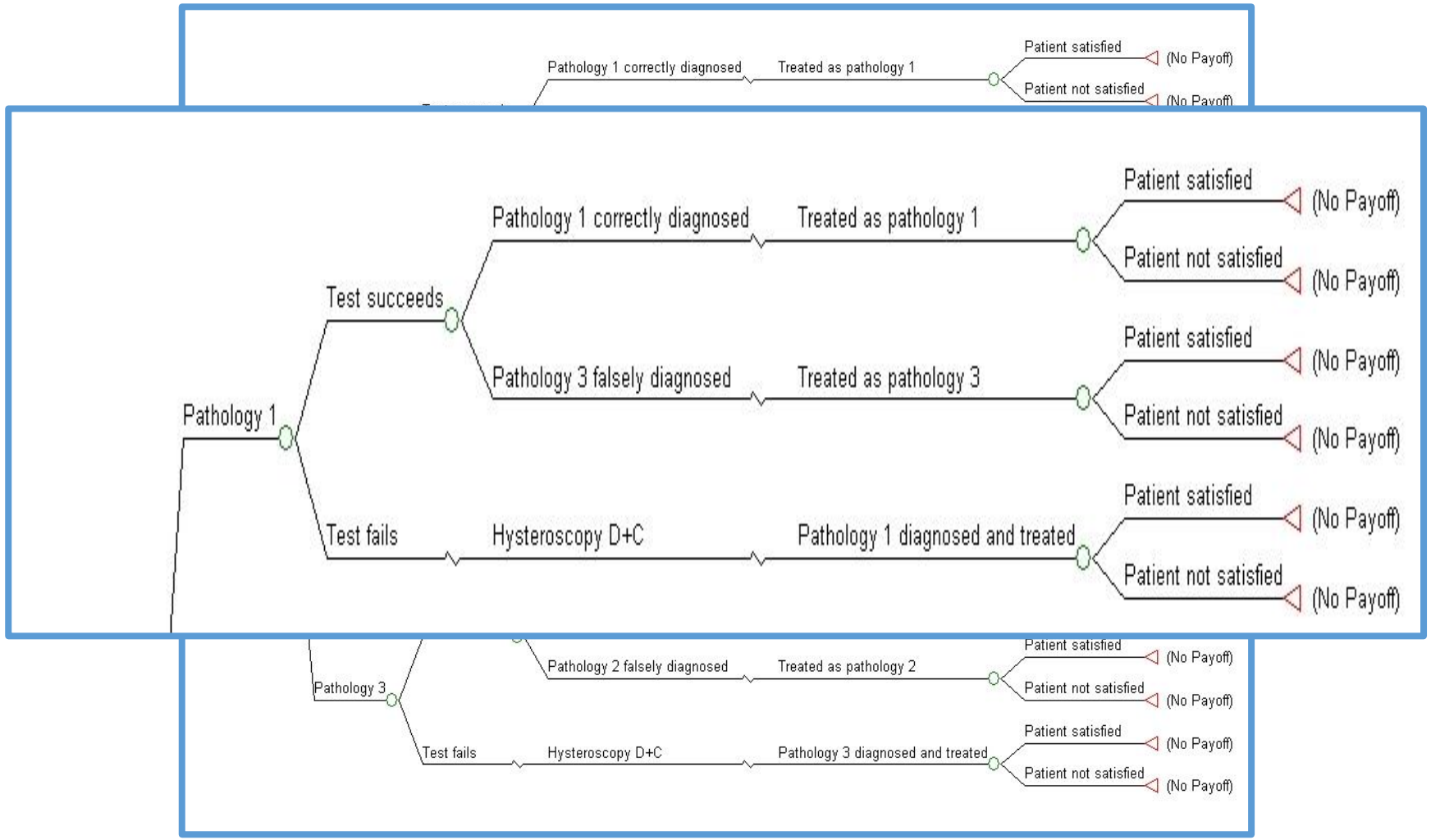
- The models were created to reflect the use of:
  - TVS
  - OPH
  - EBx
  - SIS

- Tests were evaluated alone and in combination.

- Treatment without investigation was also evaluated and used as a baseline strategy for comparison.

# Cost-effectiveness of testing in HMB:

## Overview of a decision tree within the model

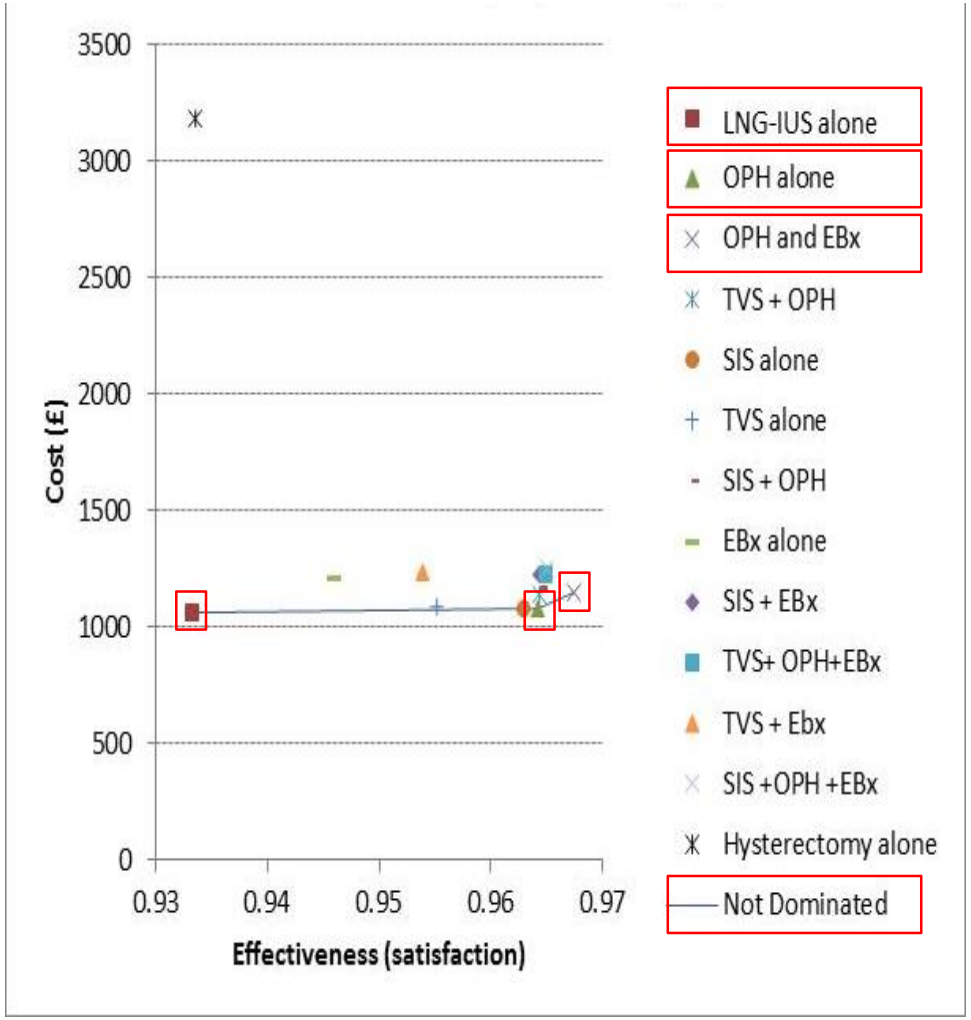


# Cost-effectiveness of testing in HMB: Analysis

- Expected cost, satisfaction and incremental cost-effectiveness ratios (**ICER**) were calculated for each strategy.
- The use of the levonorgestrel releasing intrauterine system was used as the **reference-case strategy** to compare all other testing strategies against
- The stability of the results was tested through deterministic and probabilistic **sensitivity** analysis

# Cost-effectiveness of testing in HMB:
## Results

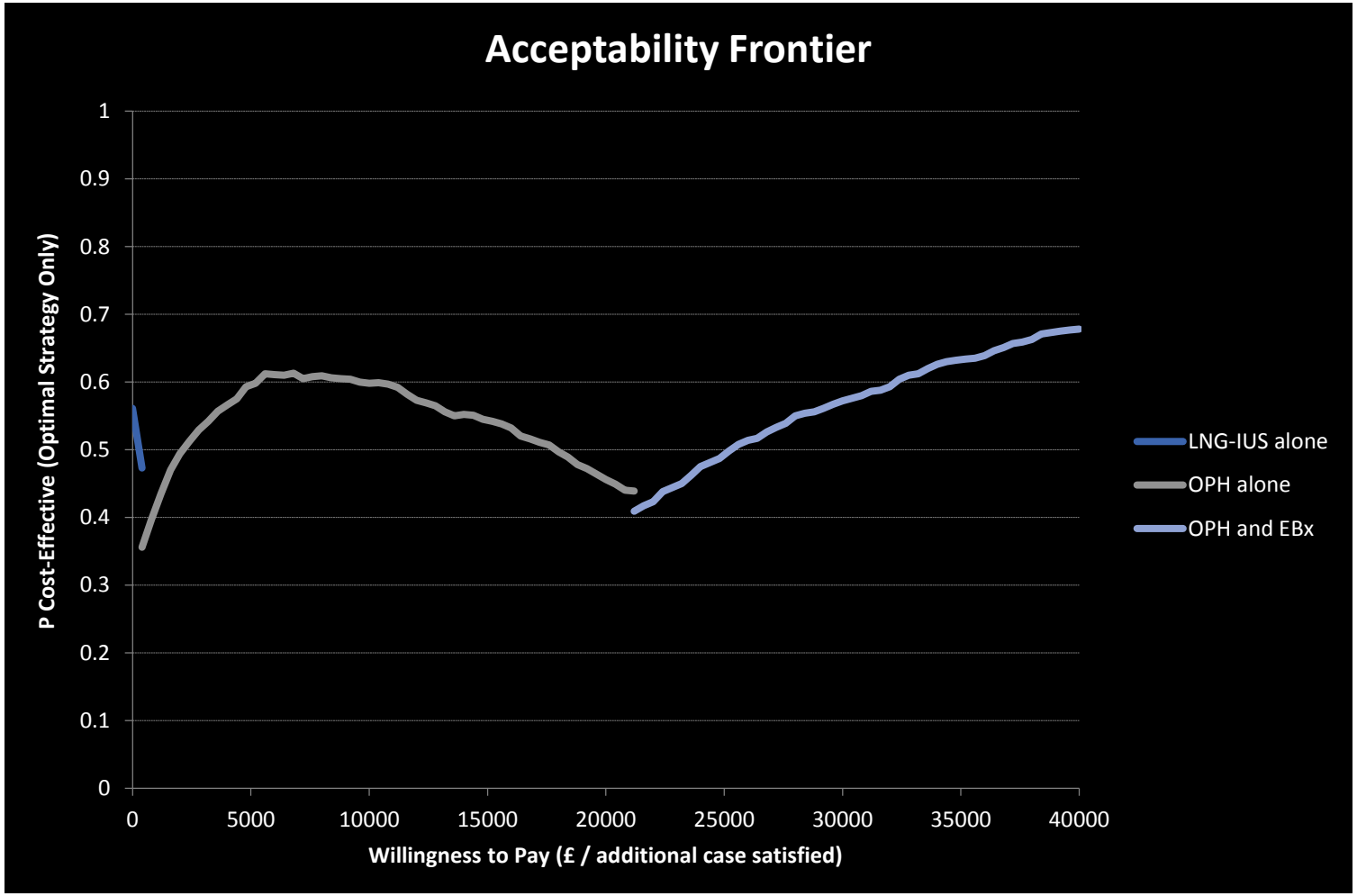
| Strategy | Cost (£) | Effectiveness (satisfaction) |
|---|---|---|
| LNG-IUS alone | 1067 | 0.933327 |
| OPH alone | | |
| SIS alone | 1083 | 0.962914 |
| TVS alone | | |
| TVS + OPH | 1139 | 0.964382 |
| OPH and EBx | | |
| SIS + OPH | 1170 | 0.96445 |
| EBx alone | | |
| SIS + EBx | 1223 | 0.964271 |
| TVS+ OPH+EBx | | |
| TVS + EBx | 1231 | 0.953851 |
| SIS +OPH +EBx | | |
| Hysterectomy alone | 3182 | 0.9335 |



# Cost-effectiveness of testing in HMB:
## Results- non-dominated options

| Strategy | Total Cost (£) | Incremental Cost (£) | Effectiveness (satisfaction) | Incremental effectiveness | ICER |
|---|---|---|---|---|---|
| LNG-IUS alone | 1067 | | 0.9333 | | |
| OPH alone | 1078 | 11 | 0.9641 | 0.0308 | 359 |
| OPH and EBx | 1149 | 71 | 0.9674 | 0.0033 | 21500 |
| | | | | | |

# Cost-effectiveness of testing in HMB: Probabilistic sensitivity analysis



# Cost-effectiveness of testing in HMB: Results – Women wishing to preserve their fertility

| Strategy | Cost (£) | Incremental cost (£) | Effectiveness (satisfaction) | Incremental effectiveness | ICER |
|---|---|---|---|---|---|
| LNG-IUS alone | 421 | | 0.6557 | | |
| SIS alone | 800 | 378 | 0.8467 | 0.1910 | 1980 |
| OPH alone | 844 | 44 | 0.8629 | 0.0162 | 2720 |
| SIS + OPH | 94455 | 100 | 0.8649 | 0.0020 | 50300 |

# Cost-effectiveness of testing in HMB:

## Results – Women refractory to treatment with LNG-IUS

| Strategy | Cost (£) | Incremental Cost (£) | Effectiveness | Incremental Effectiveness | ICER |
|---|---|---|---|---|---|
| LNG-IUS alone | 1355 | | 0.9039 | | |
| OPH alone | 1681 | 326 | 0.9633 | 0.0594 | 5480 |
| TVS + EBx | 1980 | 299 | 0.9639 | 0.0006 | 516000 |

# Cost-effectiveness of testing in HMB: Conclusions

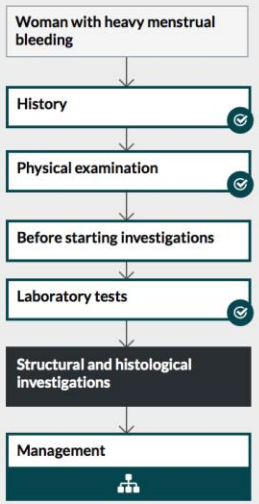
- For initial investigation of women presenting to secondary care with HMB who do not require preservation of their fertility there is a choice between **outpatient hysteroscopy alone** or a combination of **outpatient hysteroscopy and endometrial biopsy.**

- **Outpatient hysteroscopy** appears to be the most cost-effective strategy for investigating women with HMB regardless of desire for fertility or prior treatment with the LNG-IUS

# NICE HMB Guidelines 2018

Investigating HMB- an evidence based approach

# Diagnosing and assessing heavy menstrual bleeding




Heavy menstrual bleeding – everything NICE says in an interactive flowchart

## Structural and histological investigations

### Hysteroscopy or ultrasound

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

See why we made the recommendation on hysteroscopy or ultrasound.

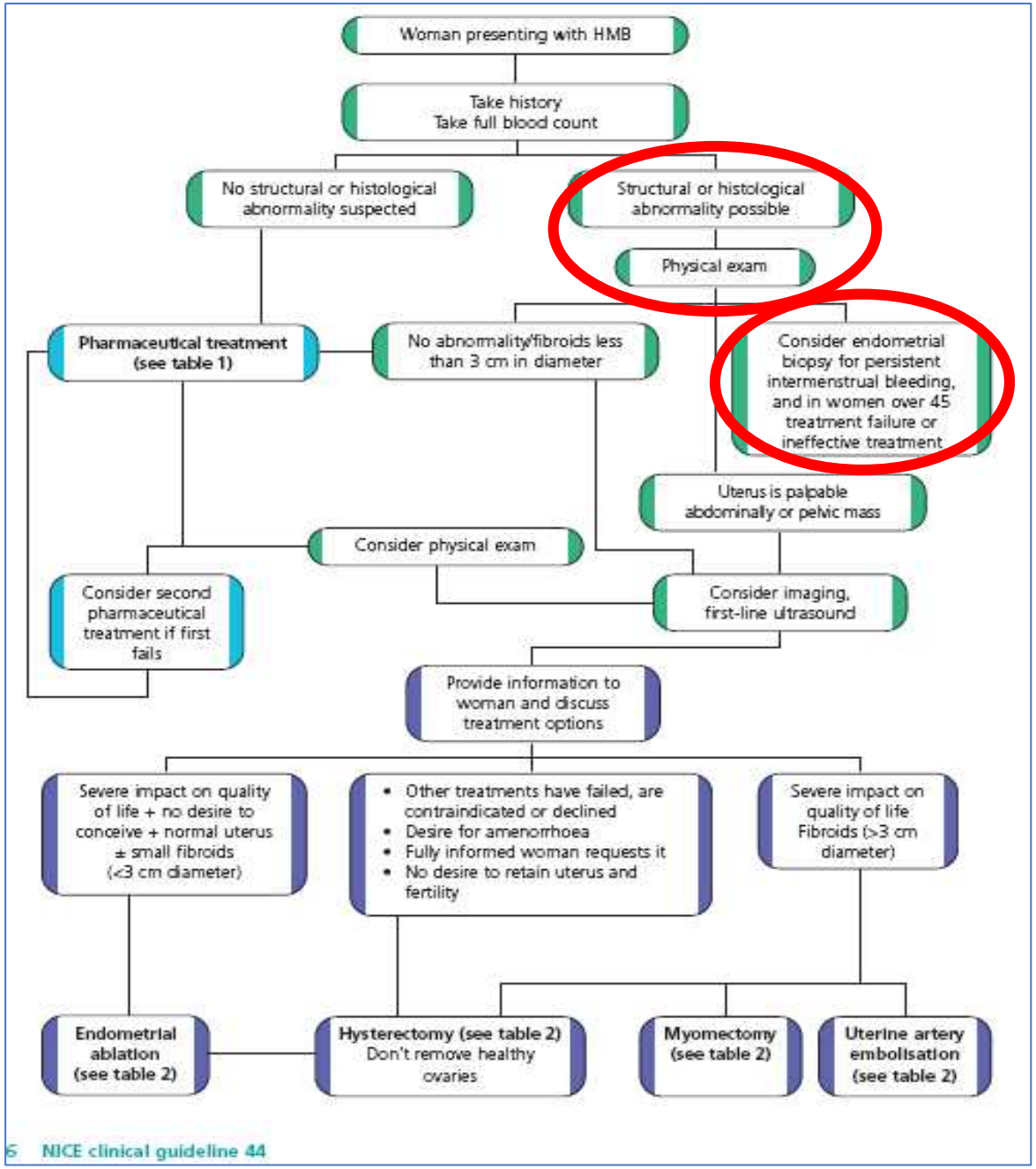
#### *Suspected submucosal fibroids, polyps or endometrial pathology*

Offer outpatient hysteroscopy to women with heavy menstrual bleeding 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 below).

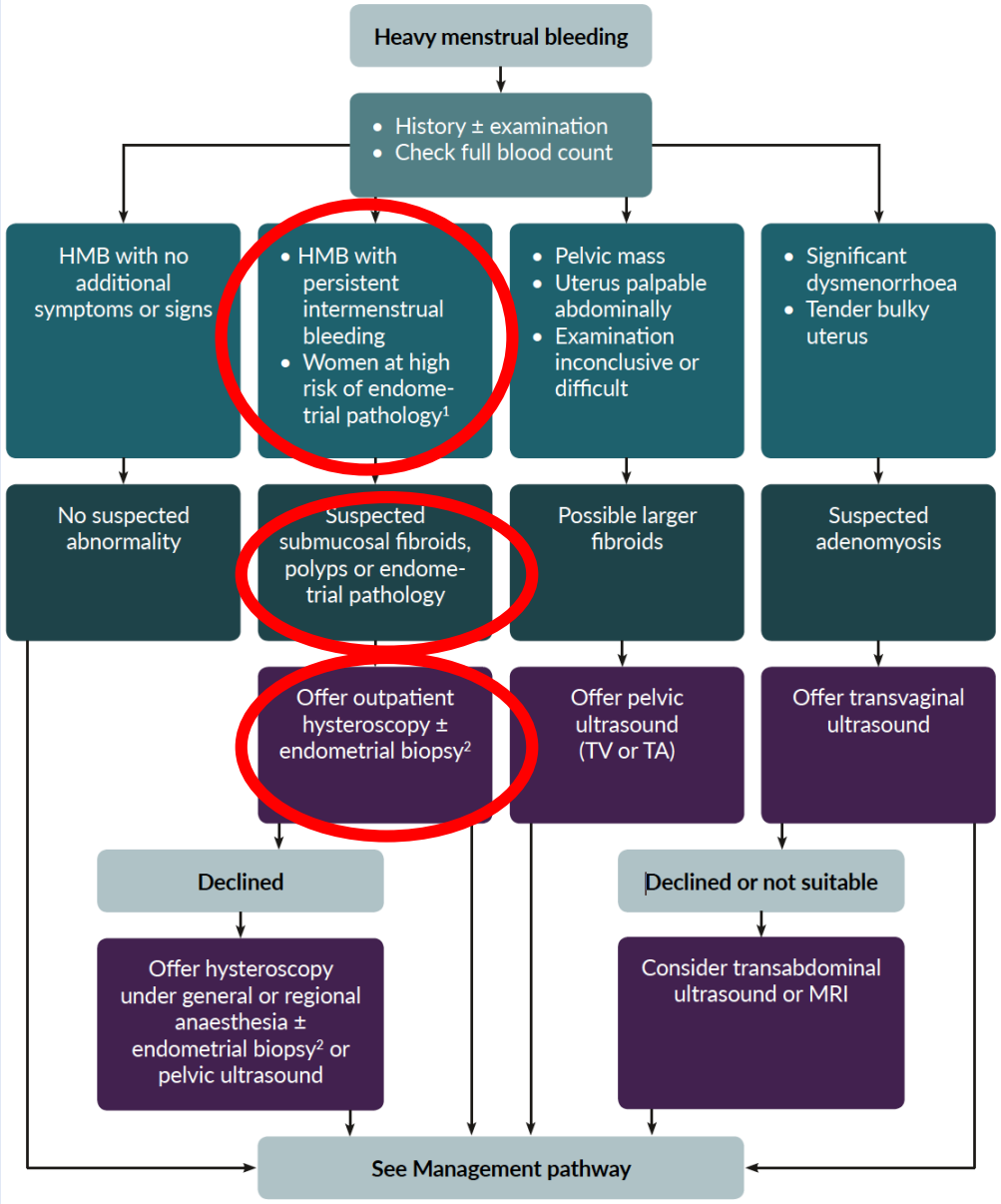
Ensure that outpatient hysteroscopy services are organised and the procedure is performed according to best practice, including:

- advising women to take oral analgesia before the procedure
- vaginoscopy as the standard diagnostic technique, using miniature

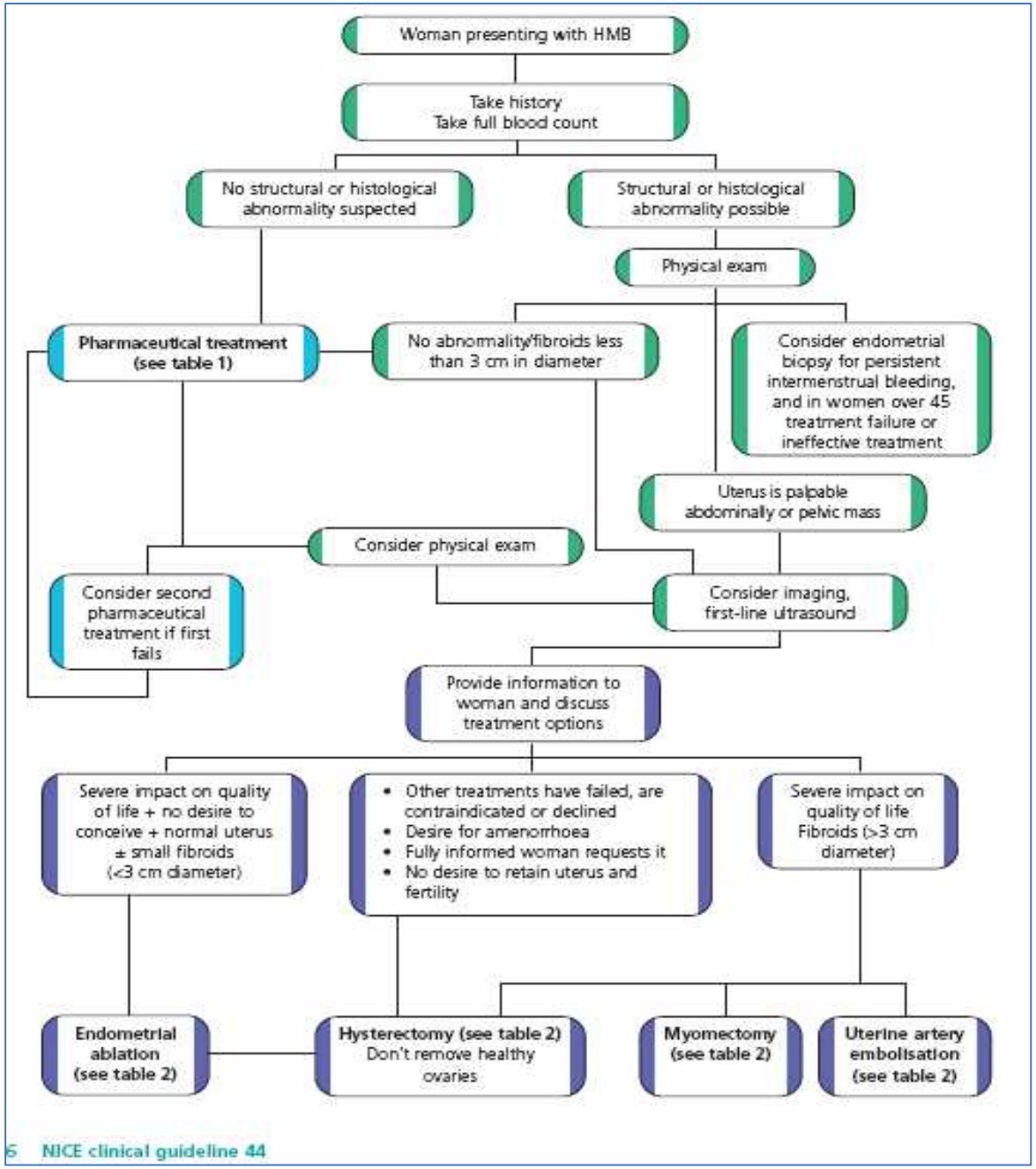





## Heavy menstrual bleeding: diagnosis

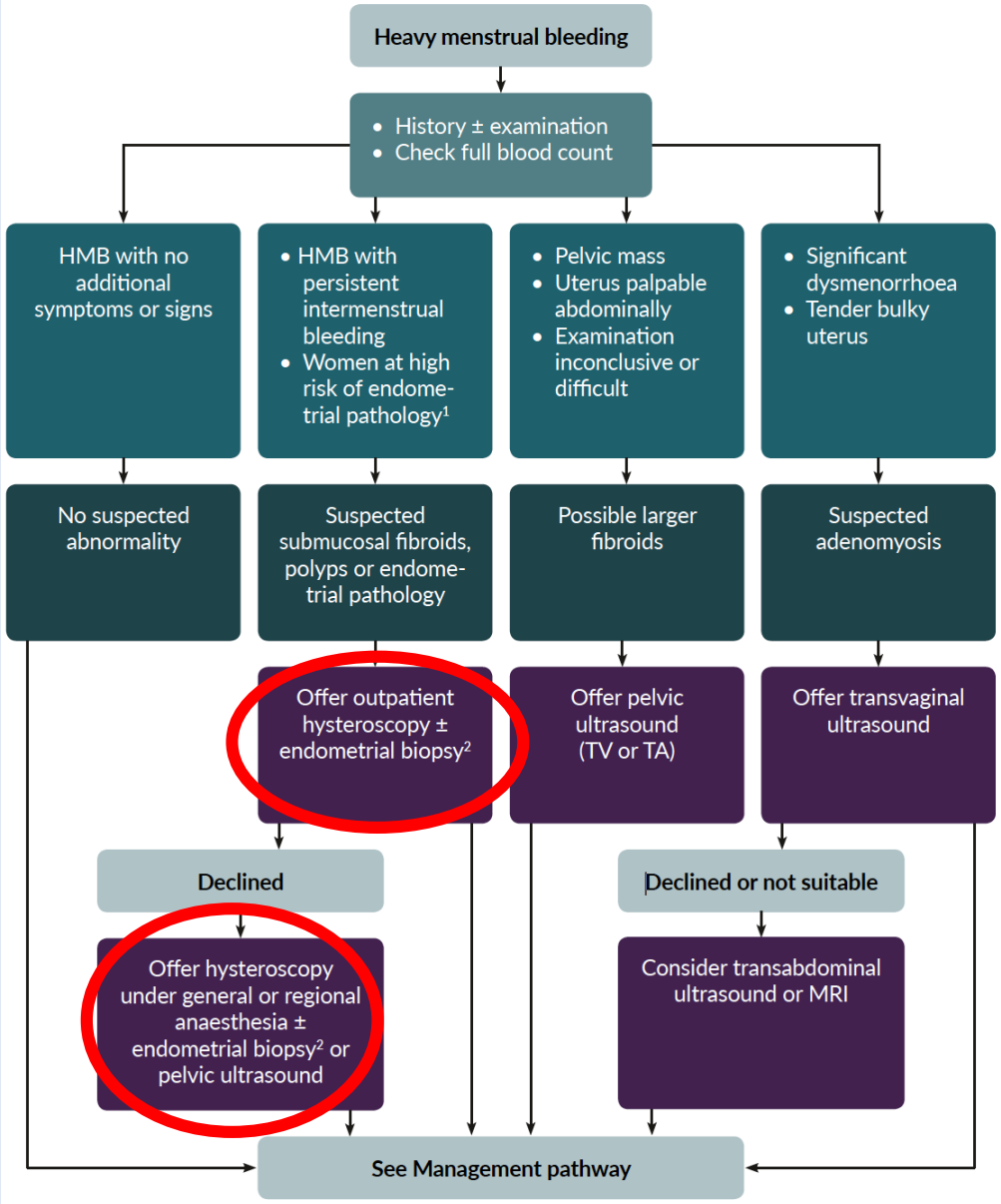



HMB: heavy menstrual bleeding; MRI: magnetic resonance imaging; TA: transabdominal; TV: transvaginal



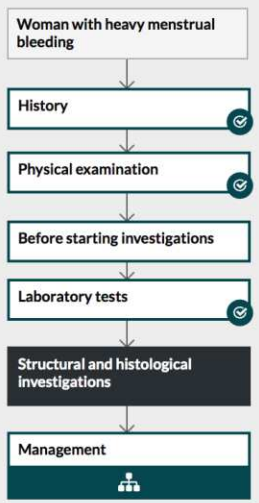



## Heavy menstrual bleeding: diagnosis




HMB: heavy menstrual bleeding; MRI: magnetic resonance imaging; TA: transabdominal; TV: transvaginal

# Diagnosing and assessing heavy menstrual bleeding




Heavy menstrual bleeding – everything NICE says in an interactive flowchart

## *Suspected submucosal fibroids, polyps or endometrial pathology*

Offer outpatient hysteroscopy to women with heavy menstrual bleeding 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 below).

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).

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

Explain to women with heavy menstrual bleeding who are offered outpatient hysteroscopy what the procedure involves and discuss the possible alternatives.

If a woman declines outpatient hysteroscopy, offer hysteroscopy under general or regional anaesthesia.

Royal College of Obstetricians and Gynaecologists

Bringing to life the best in women's health care

BSGE

Green-top Guideline No. 59

March 2011

# Best Practice in Outpatient Hysteroscopy

**RCOG/BSGE Joint Guideline**

NHS Evidence accredited provider

NHS Evidence - provided by NICE www.evidence.nhs.uk

THE LANCET

## Diagnosis of heavy menstrual bleeding: a change in direction

The Lancet

DOI: https://doi.org/10.1016/S0140-6736(18)30627-5 · Check for updates

PlumX Metrics

Article Info

Figures

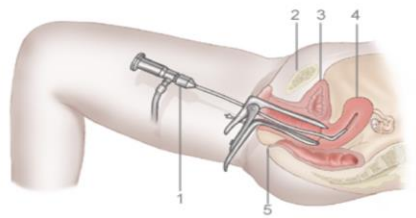
Menorrhagia is a debilitating condition that negatively affects quality of life, with accompanying symptoms sometimes including severe abdominal pain and persistent and irregular bleeding outside the menstrual cycle. The UK's National Institute for Health and Care Excellence (NICE) estimates that menorrhagia affects up to 25% of women of reproductive age, accounting for 12% of all UK gynaecological specialist referrals.

On March 14, NICE published a substantial update to their 2007 clinical guideline, *Heavy menstrual bleeding: assessment and management*. The new treatment pathway recommends investigating the symptoms and causes of menorrhagia, which in many cases will now lead to a hysteroscopy, previously only considered after pelvic and transvaginal ultrasounds. A hysteroscopy is a low-risk but invasive procedure, mostly carried out in an outpatient setting, and usually tolerable with oral analgesia. A general anaesthetic might be appropriate in some cases or by request, and NICE advise that the risks are outweighed by the benefits of more accurate diagnosis. Although the number of annual hysteroscopies in the UK will increase from 5000 to 15 000, requiring training, new skills, and equipment, NICE expect it to be cost-effective.

The update also covers women with suspected uterine fibroids, and adenomyosis (for whom an initial pelvic ultrasound is still recommended), but not those with suspected endometriosis or extra-uterine and large fibroids, for whom surgery remains the likely endpoint, without a standardised diagnostic path. The guideline also updates pharmacological recommendations, anticipating a reduction in ineffective prescriptions.

This update embodies 11 years of progress in the understanding of menorrhagia, with rapid and personalised diagnosis now recognised as a priority, but there remains a need for better underlying scientific evidence. There also remain shortcomings in guidance for more complex cases. If further investment in research and randomised clinical trials—as called for by NICE—also provides evidence for the most effective treatments after diagnosis, then this will contribute to a positive clinical development for women, and for gynaecological medicine in the UK.

www.HysteroscopyAction.org.uk - Campaign Against Painful Hysteroscopy




Home

Home

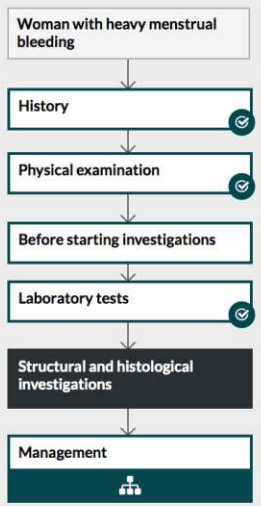
Welcome to HYSTEROSCOPY ACTION – the website of the Campaign Against Painful Hysteroscopy

We are a group of UK patients who have had hysteroscopies and/or womb biopsies. We are concerned that a sizeable minority (5%-25%) of UK hysteroscopy patients have reported severe pain during these outpatient procedures.

We are campaigning for all hysteroscopy/uterine biopsy patients to have

- Full written information about the hysteroscopy/biopsy procedure including the risk of severe pain

# Diagnosing and assessing heavy menstrual bleeding




Heavy menstrual bleeding – everything NICE says in an interactive flowchart

For women who decline hysteroscopy, consider pelvic ultrasound, explaining the limitations of this technique for detecting uterine cavity causes of heavy menstrual bleeding.

### Endometrial biopsy

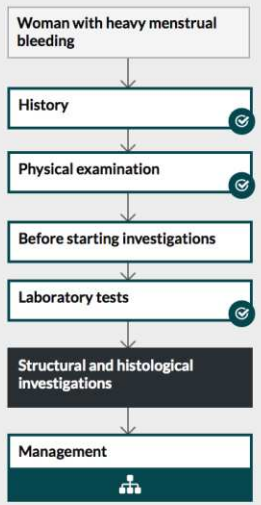
Consider endometrial biopsy at the time of hysteroscopy for women who are at high risk of endometrial pathology, such as:

- 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 heavy menstrual bleeding has been unsuccessful.

Obtain an endometrial sample only in the context of diagnostic hysteroscopy. Do not offer 'blind' endometrial biopsy to women with heavy menstrual bleeding.

See why we made the recommendations on investigations for suspected submucosal fibroids, polyps or endometrial pathology.

# Diagnosing and assessing heavy menstrual bleeding




Heavy menstrual bleeding – everything NICE says in an interactive flowchart

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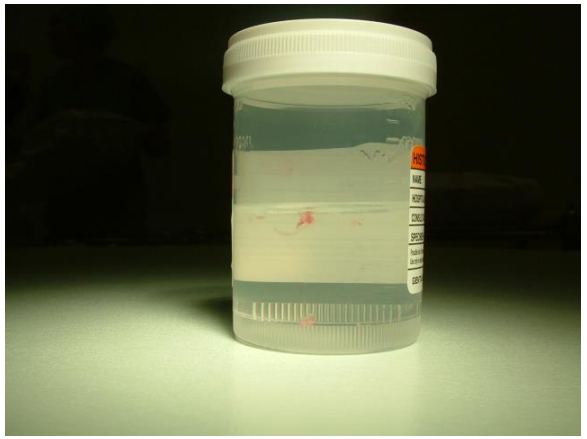
See why we made the recommendations on investigations for suspected submucosal fibroids, polyps or endometrial pathology.

# Blind endometrial biopsy







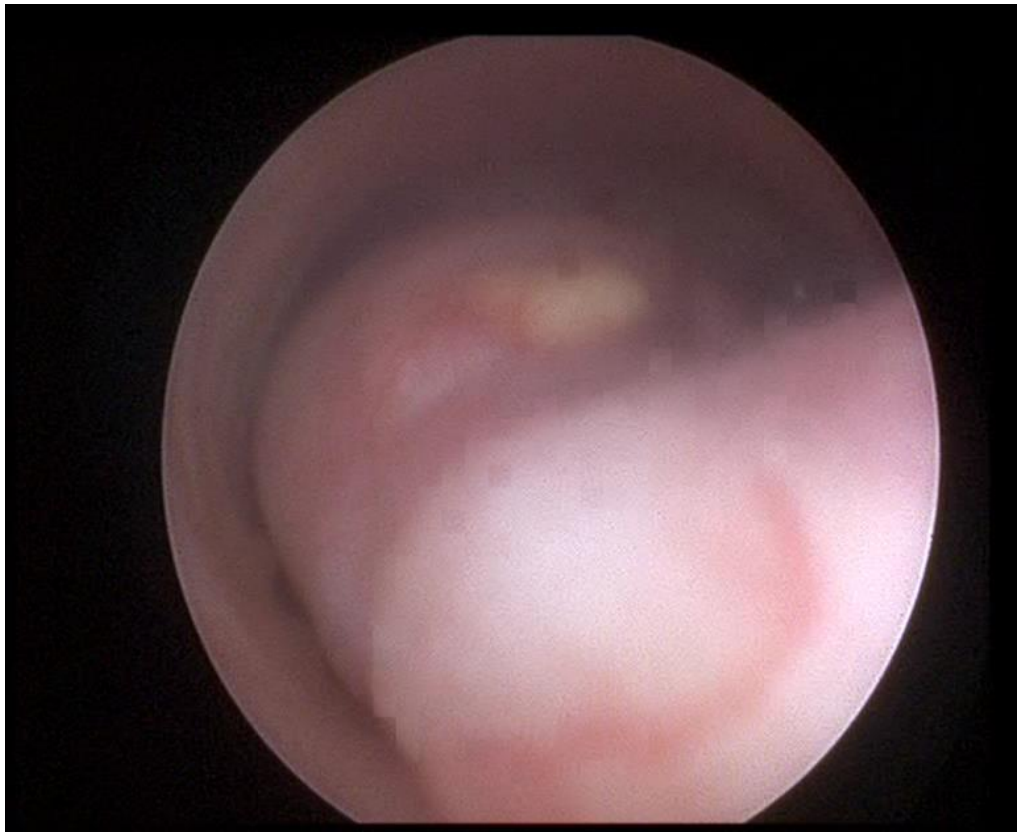


# Hysteroscopically directed biopsy: mechanical grapsers or tissue removal systems









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

## Rationale

### Outpatient hysteroscopy

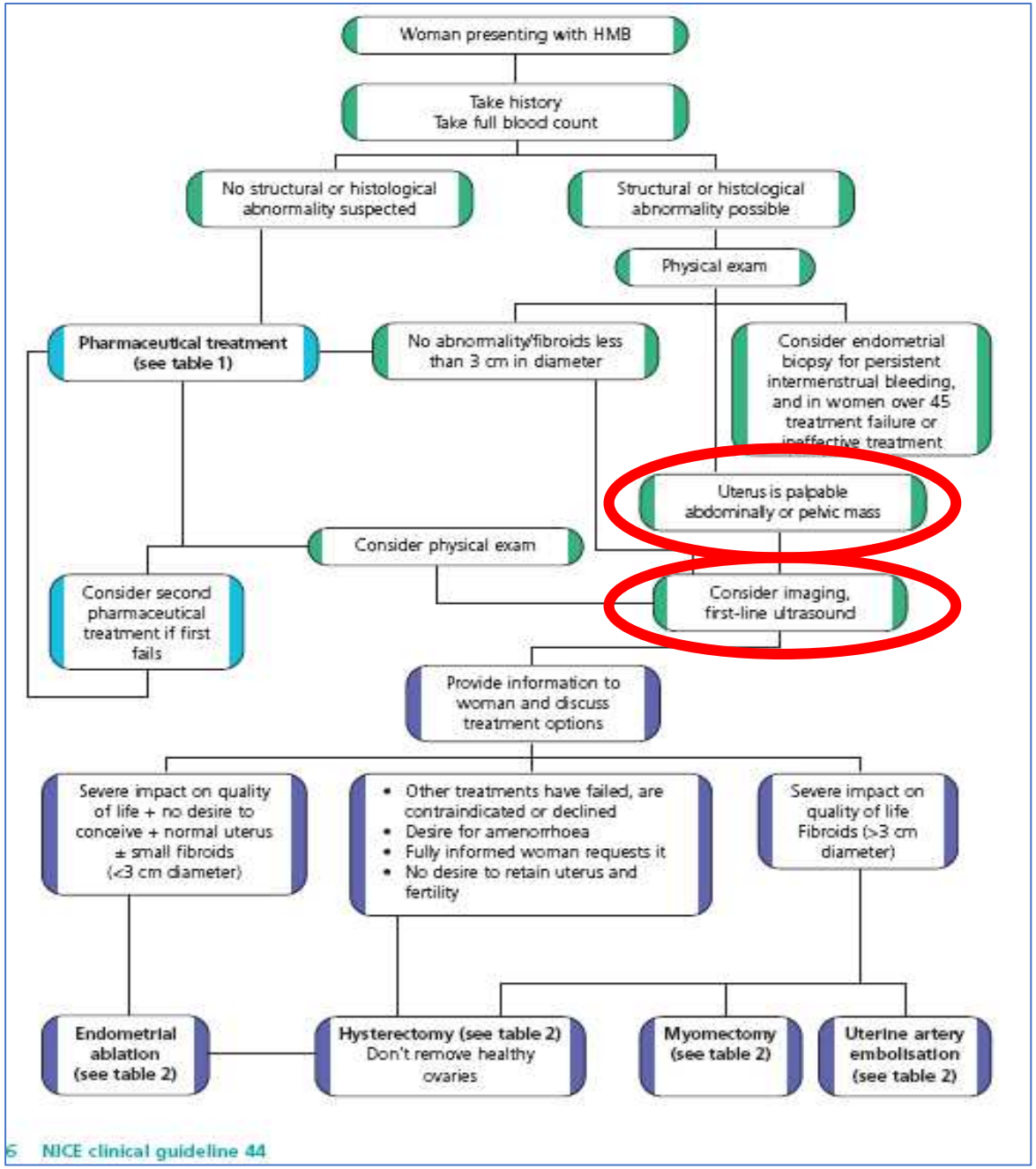
- is recommended for women with HMB if uterine cavity abnormalities or endometrial pathology are suspected because: the evidence showed that it is more accurate (higher sensitivity and specificity) in identifying them than pelvic ultrasound
    - it is safe and has a low risk of complications
    - it is acceptable to women if done according to best practice guidelines
    - it is cost-effective as part of a diagnosis and treatment strategy.
        - women can have submucosal fibroids and polyps removed during the procedure, and targeted biopsy if needed
- For women who decline outpatient hysteroscopy, hysteroscopy under general or regional anaesthetic should be offered, because the benefits of accurate identification outweigh the risks of anaesthesia.

### Pelvic ultrasound

- can be considered for women who decline hysteroscopy, provided that they understand and accept that it is less accurate in detecting uterine cavity abnormalities and endometrial pathology.

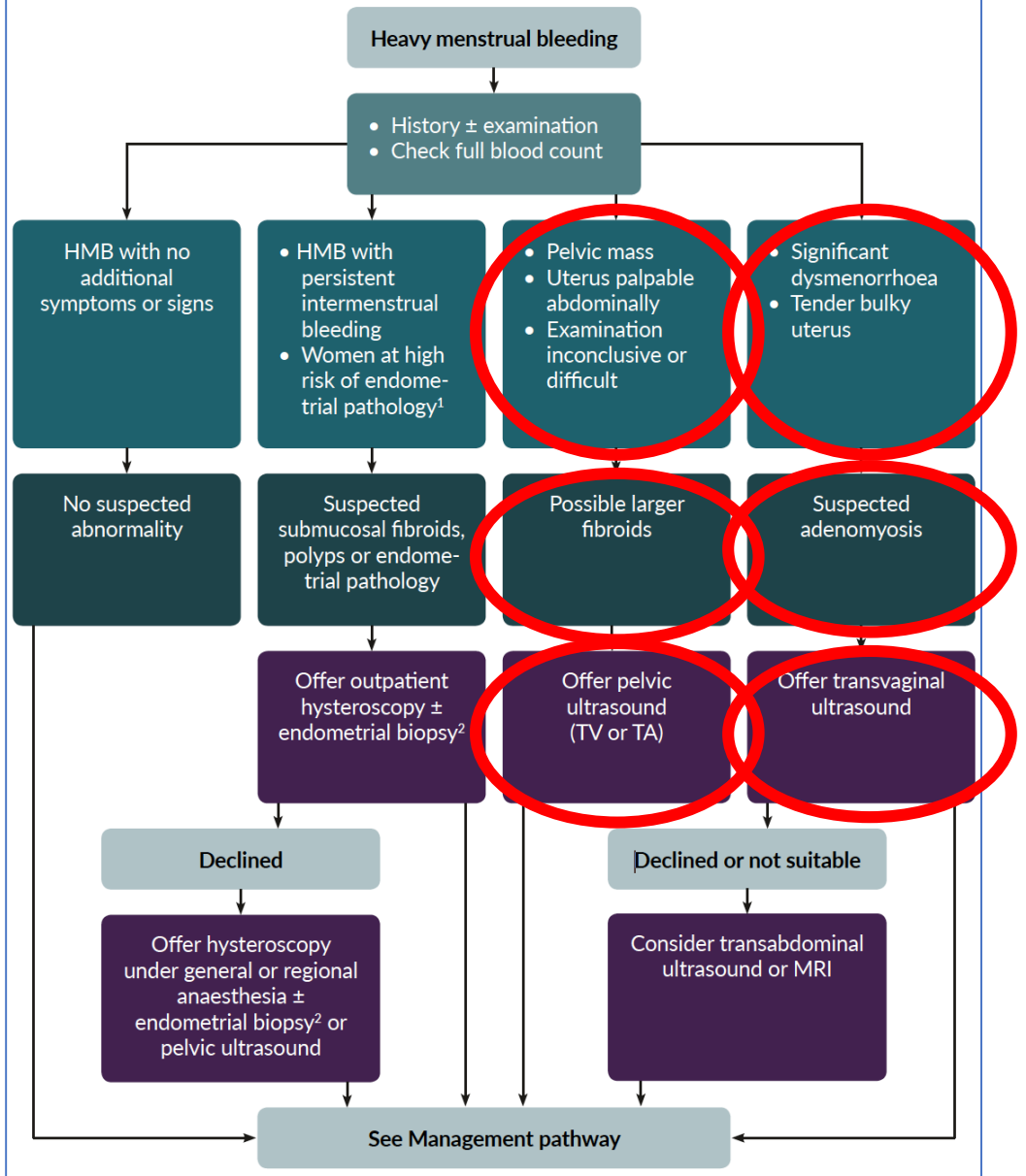
### Endometrial biopsy

- should only be taken in the context of hysteroscopy and only from women who a have a high risk of endometrial pathology, to avoid unnecessary and painful biopsies.
- 'Blind’ endometrial biopsy is not recommended because it may not identify treatable lesions.



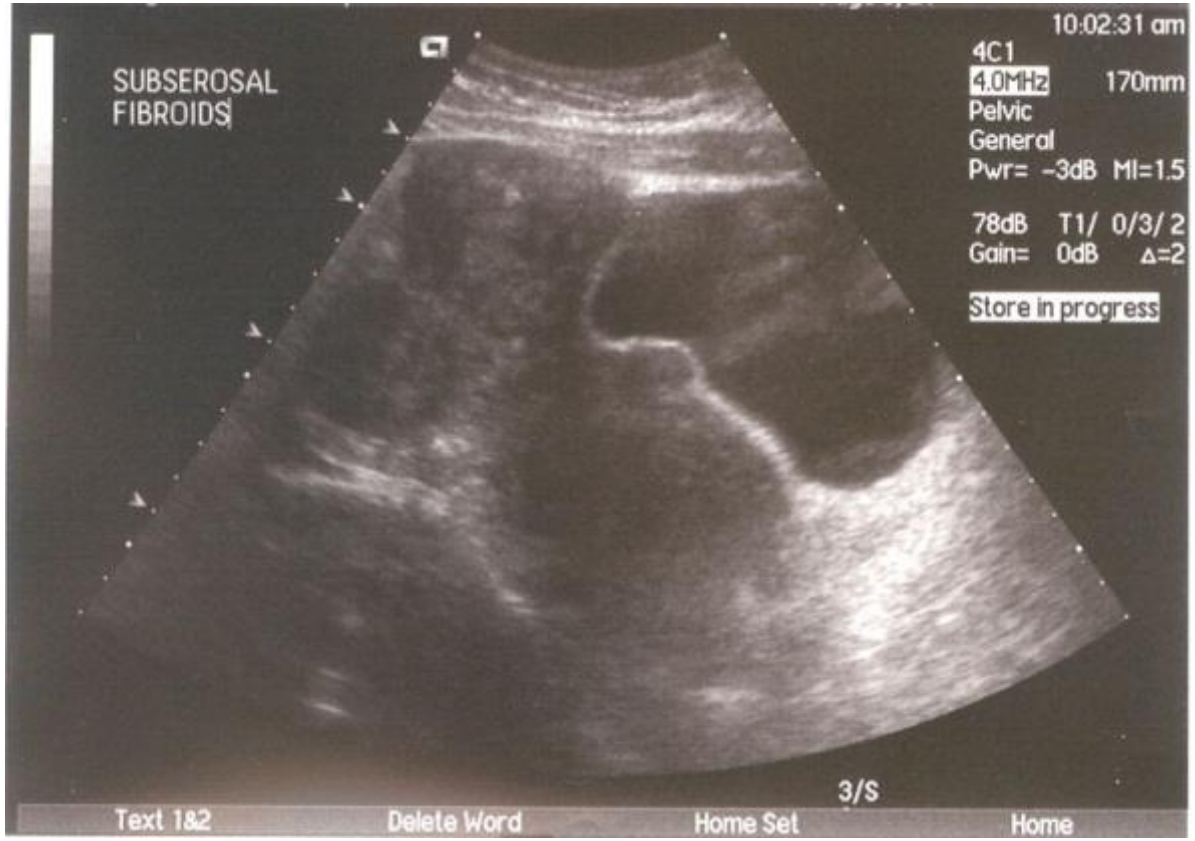


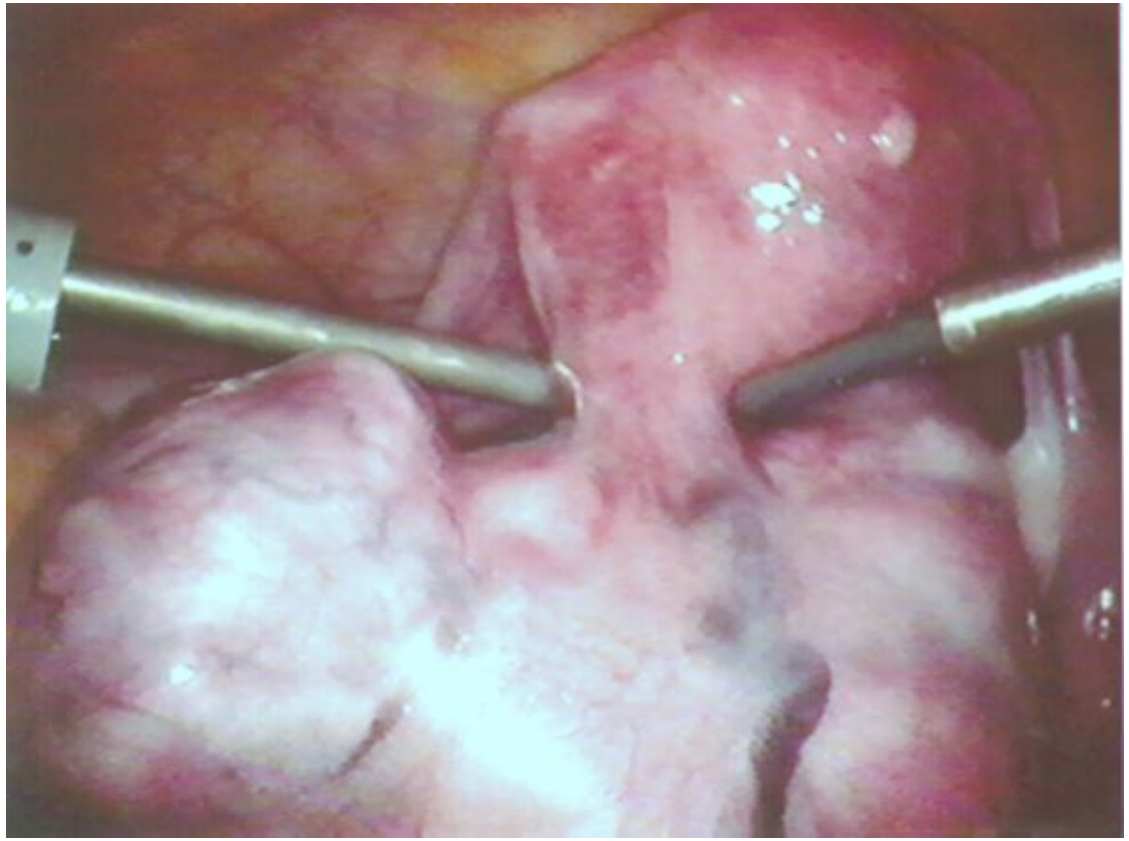

## Heavy menstrual bleeding: diagnosis



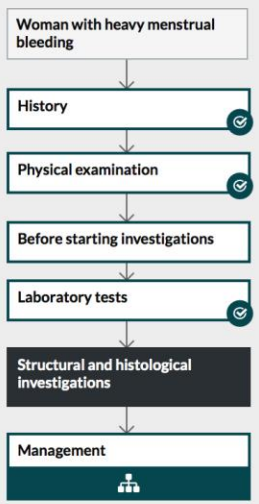

HMB: heavy menstrual bleeding; MRI: magnetic resonance imaging; TA: transabdominal; TV: transvaginal

# Fibroids and HMB:



# Diagnosing and assessing heavy menstrual bleeding




Heavy menstrual bleeding – everything NICE says in an interactive flowchart

## *Possible larger fibroids*

Offer pelvic ultrasound to women with heavy menstrual bleeding 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.

See why we made the recommendations on investigations for possible larger fibroids.

## *Suspected adenomyosis*

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

- significant dysmenorrhoea (period pain) **or**
- a bulky, tender uterus on examination that suggests adenomyosis.

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

Be aware that pain associated with heavy menstrual bleeding may be caused by

# Investigation - Women with possible larger fibroids
## Rationale

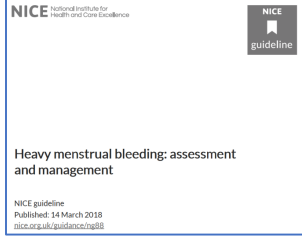
- Hysteroscopy
  - is not able to detect abnormalities outside the uterine cavity, such as subserous or intramural fibroids, or adenomyosis. If an examination suggests a large fibroid or several fibroids,

- Pelvic ultrasound (transvaginal or transabdominal)
  - is recommended instead of hysteroscopy and is likely to be particularly cost-effective in this context.

  - If abdominal or vaginal examination is difficult to perform or inconclusive (for example, because the woman is obese), pelvic ultrasound would be helpful to identify any abnormalities that might have otherwise been suggested by examination.

# Research recommendations

Investigating HMB- an evidence based approach




# NICE HMB Guidance 2018: Research recommendations (https://www.nice.org.uk/guidance/ng88/chapter/Recommendations-for-research)

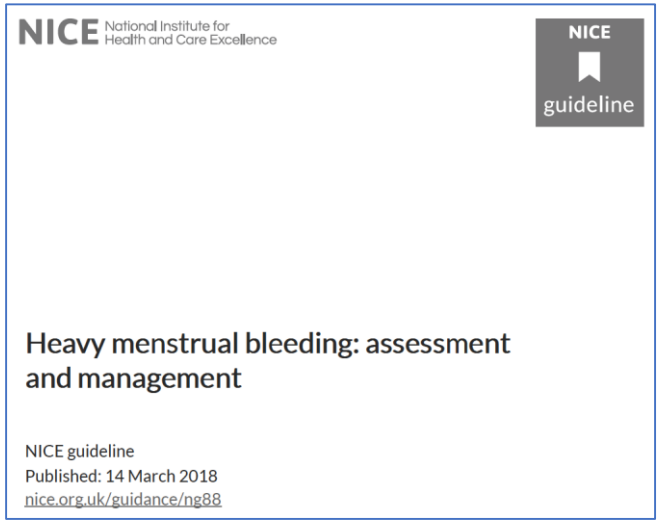
- Of all diagnostic testing strategies, modelling has shown that the uncertainty is between first-line testing protocols based upon outpatient hysteroscopy or transvaginal ultrasound
  - Proposed RCT:
    - Hysteroscopy compared with ultrasound or empiric pharmacological treatment in the diagnosis and management of heavy menstrual bleeding (HMB)

# Conclusion

Investigating HMB- an evidence based approach

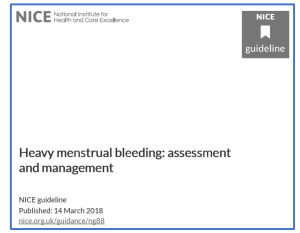
# Conclusion
# Evidence based diagnosis in HMB

- See NICE HMB Guidance 2007 & 2018
  - Main areas of change in 2018 revised version:
    - Diagnostic work up
      - Greater role for outpatient  hysteroscopy
      - Research recommendation: diagnostic work up strategies



# Acknowledgments


- Natalie AM Cooper




# Thank you for listening

# Questions?