Heavy menstrual bleeding (update)

NICE National Institute for Health and Care Excellence

Consultation on draft guideline – deadline for comments 5pm on 13/09/2017 email: HMB@nice.org.uk

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. We would like to hear your views on the draft recommendations presented in the short version and any comments you may have on the evidence presented in the full version. We would also welcome views on the Equality Impact Assessment. We would like to hear your views on these questions: 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) See section 3.9 of Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	**FEmISA – Fibroid Embolisation – Information Support and Advice, an independent, voluntary group supporting women with fibroids**
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**None, nor any financial interests**
Name of commentator person completing form:	Ginette Camps-Walsh

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Type		[office use only]		
Comment number	**Document** (**full** version, **short** version or the **appendices**	**Page number** Or **'general'** for comments on the whole document	**Line number** Or **'general'** for comments on the whole document	**Comments** Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	Draft Guidelines and all document	General Comment on the whole document	General Comment on the whole document	**N.B. NONE OF THE INFORMATION IN THIS SUBMISSION IS CONFIDENTIAL AND ALL CAN BE PUBLISHED EVEN IF IT IS HIGHLIGHTED OR UNDERLINED. ALL HIGHLIGHTING AND UNDERLINING IS FOR EMPHASIS** The current NICE Clinical Guidelines on Heavy Menstrual Bleeding published in 2007 made significant advances in giving women access to safer, less invasive treatments that had been formally reviewed for safety and efficacy and enabled women to retain their fertility. For the first time, hysterectomy, a treatment that has never been reviewed for safety and efficacy, was no longer a first line treatment for heavy menstrual bleeding and fibroids >3cm. The 2007 guidelines also sought to protect women to some extent from being pressurised into having very invasive treatments with relatively higher mortality rates and 'severe' complication rates leaving them sterile, by putting in place some safeguards to ensure that they were fully informed and able to make informed decisions about their own care. In particular the 2007 guidelines specifically forbad 'the removal of healthy ovaries'. This and many other safeguards for women have been deliberately removed. The recommendations in this review attempt to turn the clock back and recommend diagnostic procedures and treatment pathways that have never been formally or independently reviewed for safety and efficacy with hysterectomy as a first line treatment. They also recommend new or modified treatments that have never been reviewed for safety and efficacy proposing appently to just try them out on women. This is cavalier and absolutely unacceptable. If implemented it would result in significantly higher mortality and

				morbidity and considerably worse health outcomes for women with heavy menstrual bleeding and fibroids. Treatment options that have been positively reviewed by NICE for safety and efficacy have been left out or side-lined and safe procedures not performed by gynaecologists set aside. The significant problems of education of clinicians and informed consent for women, highlighted in a number of important reports, have been ignored. The NHS Constitute states – • **The patient will be at the heart of everything the NHS does** • **The NHS aspires to the highest standards of excellence and professionalism** NHS England - Shared Decision Making states - **No decision about me, without me. This can only be realised by involving patients fully in their own care, with decisions made in partnership with clinicians, rather than by clinicians alone.** The recommendations in this 'Review' are not compliant with the statements above. These recommendations would increase costs to women, their families, the NHS, employers and society. They are not patient-centred and are completely unacceptable.
2	Membership of Heavy Menstrual Bleeding (update) guideline Committee 2.0.3 DOC Cmte membership list	General Comment on the whole document	General Comment on the whole document	FEmISA submitted formal complaints to NICE at the beginning of this guidelines review on the membership of the guidelines committee and the organisation funded by tax-payers' money to run and manage this review. They have conflicts of interest and vested interests in the outcome. The National Collaborating Centre for Women's and Children's Health which is part of RCOG (The Royal College of Obstetrics and Gynaecology) is running and managing this Review and reports directly to the RCOG Board. Although many clinical specialities are involved in the diagnosis and treatment of HMB and fibroids, notably diagnostic radiologists in diagnosis and interventional radiologists provide 2 of the 4 in-patient treatments for fibroids, neither of these clinical specialities were represented on the original committee. An Interventional Radiologist was later co-opted, but no diagnostic radiologists specialising in gynaecology. Gynaecologist have no training or education in the interventional radiology treatments – UAE (uterine artery embolisation) or MRgFUS (magnet resonance-guided focused ultrasound) and lack knowledge about them.

<table>
<tr><td></td><td></td><td></td><td></td><td>No (x-ray) nurses or technicians (radiographers) are included on the committee with any experience or expertise in the nursing aspects of these treatments. Few GPs are knowledgeable about UAE or MRgFUS.

The recommendations from this Review will benefit gynaecologists and RCOG by increasing the referrals and self-referrals to gynaecologist in both the NHS and private sector. Hysterectomy is one of the commonest operations in the private sector after hip and joint replacement.</td></tr>
<tr><td>3</td><td>Heavy menstrual bleeding: assessment and 1 management Recommendations</td><td>General Comment on the whole document</td><td>General Comment on the whole document</td><td>The outcomes of these recommendations are likely to be –
1. Increased mortality and morbidity from hysteroscopy increase as first line diagnostic test

<table>
<tr><th>Hysteroscopy</th><th>No. Procedures p.a.</th><th>Mortality @ 90 days</th><th>Mortality Rate</th><th>No. Serious Complications - rate 3.4%</th></tr>
<tr><td>Current</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Diagnostic</td><td>55,377</td><td>148</td><td>0.3%</td><td>1,883</td></tr>
<tr><td>Therapeutic</td><td>31,573</td><td>32</td><td>0.1%</td><td>1,073</td></tr>
<tr><td>Total</td><td>86,950</td><td>180</td><td></td><td>2,956</td></tr>
<tr><td>Projected x 2</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Diagnostic</td><td>110,754</td><td>296</td><td>0.3%</td><td>3,766</td></tr>
<tr><td>Therapeutic</td><td>63,146</td><td>64</td><td>0.1%</td><td>2,147</td></tr>
<tr><td>Total</td><td>173,900</td><td>360</td><td></td><td>5,913</td></tr>
<tr><td>Projected x 3</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Diagnostic</td><td>166,131</td><td>444</td><td>0.3%</td><td>5,648</td></tr>
<tr><td>Therapeutic</td><td>94,719</td><td>128</td><td>0.1%</td><td>3,220</td></tr>
<tr><td>Total</td><td>260,850</td><td>572</td><td></td><td>8,869</td></tr>
</table>

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 3.4%

In addition, hysteroscopy cannot diagnose pathology outside the reproductive tract i.e. subserosal fibroids,</td></tr>
</table>

endometriosis so these women would undergo the mortality and morbidity risks above, but receive no diagnosis.

2. Increased mortality and morbidity from hysterectomy as first line treatment for HMB

Hysterectomy	No. Procedures p.a.	Mortality @ 90 days	Mortality Rate	No. Serious Complications -	Serious Complication Rate Maresh
Current					
Abdominal	31,086	**176**	0.6%	**111,910**	4.6%
Vaginal	7,236	**6**	0.10%	**26,050**	7.10%
Projected +20%					
Abdominal	37,303	**211**	0.6%	**134,292**	4.6%
Vaginal	8,683	**7**	0.10%	**31,260**	7.10%
Projected +30%					
Abdominal	40,412	229	0.6%	**145,482**	4.6%
Vaginal	9,407	8	0.10%	**33,864**	7.10%

3. Myomectomy – the mortality data for myomectomy is unknow, there are no HES statistics on it and the serious complication rate is also unknown. The risks to women are unknow and this needs research and a formal independent review of safety and efficacy.

The mortality and morbidity will rise significantly and at the high end of the projections potentially 800 women could die, a further 188,000 would suffer serious short-term complications and in addition there are unknown further complications from myomectomy and medium and long-term complications in addition.

In contrast to this UAE, an interventional radiology treatment, has had no reported deaths for a number of years, has a significantly lower complication rate, a 1-night hospital stay and a return to work of 1-3 weeks. Not only is it considerably safer, but women recover quicker and become economically productive again quicker. The procedure is also less expensive and the NHS can save

				Over £51million if 60% of fibroids were treated by UAE (women choose UAE when they have a fully informed choice – Heartlands Hospital) 70,200 bed days would be saved. The savings to employers and wider society would be an additional £76million from earlier return to work. See FEmISA web site – http://www.femisa.org.uk/index.php/cost-comparisons.
4	Heavy menstrual bleeding: assessment and 1 management Recommendations	General Comment on the whole document	General Comment on the whole document	**The figures above for mortality and morbidity do not include the unknown risks from proposed new treatments that have never been properly assessed notably – endometrial ablation for larger fibroids >3cm, hysteroscopy for submucosal fibroids and comparison studies with myomectomy and UAE are required.**
5	Heavy menstrual bleeding: assessment and 1 management Recommendations	4	10,11, 19,20	Taking a history does not give sufficient evidence to diagnose whether a woman has heavy menstrual bleeding of unknown original i.e. a diagnosis of HMB (which is a symptom not a diagnosis) or the symptom is caused by fibroids, endometriosis, adenomyosis or other disease. Women will not obtain a proper diagnosis or treatment and will suffer for an unnecessarily extended time as a result. The recent report "*Informed Choice? Giving women control of their healthcare*" published by the All-Party Parliamentary Group [APPG] on Women's Health surveyed over 2,600 women. They found that diagnosis of fibroids and endometriosis was inadequate. 40% of women with endometriosis needed 10 GP appointments or more before being referred. 25% of women received the wrong diagnosis. 12% of women surveyed with fibroids took 1-2 years from their diagnosis to get their treatment. https://static1.squarespace.com/static/5757c9a92eeb8124fc5b9077/t/58d8ca34f7e0ab027a19247c/1490602579808/APPG+Womens+Health+March+2017+web+title.pdf It is clear that taking a history is not sufficient or adequate to make a proper diagnosis and earlier referral to a safe, pain-free, non-invasive diagnosis such as abdominal ultrasound would alleviate suffering.
6	Heavy menstrual bleeding: assessment and 1 management Recommendations			From 2007 HMB Guidelines - 1.2.4 If the history suggests HMB with structural or histological abnormality, with symptoms such as intermenstrual or postcoital bleeding, pelvic pain and/or pressure symptoms, a physical examination and/or other investigations (such as ultrasound) should be performed. [2007] The part underlined has been removed from the new version and needs to be replaced otherwise proper

				diagnosis will be at the very least delayed. 1.2.5. from Current [2007] HMB Guidelines has been removed. It needs to be reinstated. It is important that whether the symptoms are a problem should be determined by the woman and not the GP or gynaecologists. Many doctors do not appreciate the toll HMB can make on the quality of a woman's life. *"Measuring menstrual blood loss either directly (alkaline haematin) or indirectly ('Pictorial blood loss assessment chart') is not routinely recommended for HMB. Whether menstrual blood loss is a problem should be determined not by measuring blood loss but by the woman herself. [2007]"* 1.2.5 from Draft New Guidelines replaced structural with intracavitary – why and what are the implications for the early diagnosis of endometriosis and other diseases causing HMB? 1.2.7 Current guideline has been removed - *"Women with fibroids that are palpable abdominally or who have intracavity fibroids and/or whose uterine length as measured at ultrasound or hysteroscopy is greater than 12 cm should be offered immediate referral to a specialist. [2007]"* This has been removed and needs to be reinstated as it will delay proper diagnosis and treatment.
7	Heavy menstrual bleeding: assessment and 1 management Recommendations	6	5	**1.3 Investigations for women with HMB** 1.3.2 Consider starting pharmacological treatment for HMB without investigating the cause if the woman's history and/or examination suggests a low risk of intracavitary or histological abnormality or adenomyosis. [2017] If this means start drug treatment, but do not investigate further this is unacceptable and will ensure many women have treatment that does not work, prolonged suffering and delayed diagnosis and effective treatment. However, drug treatment to alleviate symptoms while being diagnosed is helpful.
8	Heavy menstrual bleeding:	6	8-14	The 2007 version needs to be put back - 1.2.14 Imaging should be undertaken in the following circumstances:

	assessment and 1 management Recommendations			• The uterus is palpable abdominally. • Vaginal examination reveals a pelvic mass of uncertain origin. • Pharmaceutical treatment fails. [2007] 1.2.15 Ultrasound is the first-line diagnostic tool for identifying structural abnormalities. [2007] 1.2.16 Hysteroscopy should be used as a diagnostic tool only when ultrasound results are inconclusive, for example, to determine the exact location of a fibroid or the exact nature of the abnormality. [2007] 1.2.17 If imaging shows the presence of uterine fibroids then appropriate treatment should be planned based on size, number and location of the fibroids. [2007] **New guidelines** - Hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology This is unacceptable, too painful, expensive, will cost too much for women and the NHS and will miss any pathology outside the reproductive tract. It will also cause suffering while women have pro-longed waits for any diagnosis. Ultrasound should continue and where there is suspected pathology that will not show up on ultrasound MRI should be used. Hysteroscopy should only be used where it can be beneficial therapeutically such as polyp removal. Hysteroscopy has never been independently formally reviewed for safety and efficacy. **Pain for women** Hysteroscopy as a first line diagnosis for fibroids and endometriosis is unacceptable. It is very painful for many and not appropriate as an outpatient treatment. It has been described by Lyn Brown MP (West Ham) (Lab): in a parliamentary debate in 2013 from their women constituents experiencing it as '***absolute agony***' and Ms Brown went on to say "***This procedure, without anaesthesia, is barbaric. It is absolute torture. It needs to be stopped. At the very least, the patient should be informed that it could be extremely painful and have options explained and open for her. That way, she can make an informed decision as to whether to go ahead without anaesthesia."*** Another patient was given a hysteroscopy under local anaesthetic and commented - ***"the procedure was still very uncomfortable and painful. I have to say that I think offering a hysteroscopy without any form of***

				anaesthetic is barbaric." Another woman asked about the pain said***" it was excruciating".*** There are many more such quotes directly from women who have experienced hysteroscopy. ***Bob Stewart MP : May I ask what percentage of women feel no pain whatsoever?*** There was no answer at the time, it is probably none – there are no women who do not suffer pain. Link to Hansard https://publications.parliament.uk/pa/cm201314/cmhansrd/cm131219/debtext/131219-0003.htm see down the page - 19 Dec 2013 : Column 956 2.31 pm Lyn Brown (West Ham) (Lab): to column 961 2.50pm ***A Cochrane Review Pain relief for outpatient hysteroscopy*** *Ahmad G, O'Flynn H, Attarbashi S, Duffy JMN, Watson A. Pain relief for outpatient hysteroscopy. Cochrane Database of Systematic Reviews 2010, Issue 11. Art. No.: CD007710. DOI:* *States – "Hysteroscopy is increasingly performed in an outpatient setting.* ***The primary reason for failure is pain."*** ***Conclusion - There was a significant reduction in the mean pain score with the use of analgesia during and within 30 minutes after outpatient hysteroscopy.*** **Safety** Hysteroscopy is unacceptably painful for some women to be carried out without significant analgesia or full anaesthesia. It is unsafe causing 148 deaths a year within 9 months of the procedure for diagnosis and a further 32 deaths for therapeutic procedures. **Preoperative ripening of the cervix before operative hysteroscopy - Review** Intervention Authors - Haya Al-Fozan, Belal Firwana, Hanan Al Kadri, Samar Hassan, Togas Tulandi

				First published: 23 April 2015 http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005998.pub2/full ***Possible complications of hysteroscopy include uterine perforation, bleeding, infection, damage to intra-abdominal organs, and fluid overload. In some cases fluid overload may occur, which can cause electrolytes imbalance and encephalopathy, and rarely death. The incidence of fluid overload is between 1.6% and 2.5% (Agostini A 2002a; Overton 1997). The incidence of uterine perforation is 0.014%, and infectious complications account for 0.3% to 1.6% of cases (Bradley 2002). Although rare, injury to internal organs can occur and this may require a laparotomy.*** *Difficulty in dilating the cervix is a complication that is infrequently discussed, despite the fact that almost 50% of hysteroscopic complications are related to difficulty with cervical entry (Bradley 2002). Potential complications include cervical tears, creation of a false passage, perforation, bleeding, or simply difficulty in entering the internal os with the hysteroscope (Bradley 2002; Cooper 1996; Loffer 1989). Adequate preparation of the cervix prior to hysteroscopy may reduce these potential complications (Bradley 2002; Ostrzenski 1994).* ***Intraoperative complications – 29 per 1000 0.29%*** ***Cervical laceration/tear – 25 per 1000 – 0.25%*** ***False track - 40 per 1000 – 0.4%*** ***Uterine perforation – 29 per 1000*** ***Uterine bleeding – 60 per 1000*** ***Side effects – 18 per 1000*** *BMJ. 2015 Mar 23;350:h1398. doi: 10.1136/bmj.h1398.* *Outpatient versus inpatient uterine polyp treatment for abnormal uterine bleeding: randomised controlled non-inferiority study.* *Cooper NA1, Clark TJ2, Middleton L3, Diwakar L4, Smith P5, Denny E6, Roberts T4, Stobert L7, Jowett S4, Daniels J3; OPT Trial Collaborative Group.* *Results: Failure to remove polyps was higher (19% v 7%; relative risk 2.5, 1.5 to 4.1) and acceptability of the procedure was lower (83% v 92%; 0.90, 0.84 to 0.97) in the outpatient group Quality of life did not differ significantly between the groups. Four uterine perforations, one of which necessitated bowel resection, all*

				occurred in the inpatient group.
				
				Just like hysterectomy and myomectomy it has never been formally reviewed for safety and efficacy and acceptability to women patients in an outpatient setting.
				
				Diagnostic Efficacy
				
				Hysteroscopy does not visualise the exterior of the uterus so any abnormality outside the uterus will not be detected e.g. subserosal fibroids and other pathology associated possibly with endometriosis, adenomyosis, pelvic congestion syndrome?
				
				Abdominal ultrasound will visualise tissue within the whole abdominal cavity, whereas hysteroscopy will only show the internal structure of reproductive tract and will therefore completely miss any abnormalities outside the uterus such as subserosal fibroids – outside the uterus. MRI gives better differentiation and diagnosis than ultrasound is safe non-invasive and costs between £114 and £164 depending on whether contract is used.
				
				Women will not have a proper diagnosis if they have endometriosis, subserosal fibroids, adenomyosis, pelvic congestion syndrome or any pathology outside the reproductive tract. They will be sent for hysteroscopy under general anaesthetic, which has a higher complication and mortality rate than in outpatients.
				The number of diagnoses are (HES 14/15) –
				• Fibroids and benign neoplasms of uterus – 64,500
				  ○ Of which ~5,000 subserosal
				  ○ 7,605 submucosal some of which can be resected with hysteroscopy
				  ○ 43,700 unspecified!
				• Polyps 40,051
				• Endometriosis 53,887 – new guidelines recommend u/s or MRI for diagnosis
				• Malignant neoplasm 37,615
				• Adenomyosis – no such diagnostic code

				• Total above – 196,053 • Those which could be treated by hysteroscopy – polyps - 40,000 and some fibroids – not all subserosal not all will be suitable - currently 55,377 diagnostic procedures and 31,573 therapeutic hysteroscopies pa • biopsy for malignancy – there are 30,156 Diagnostic endoscopic examination of uterus and biopsy of lesion of uterus a different procedural code and 38,000 diagnoses of malignant neoplasms Therefore, it appears that there are currently the correct number of hysteroscopies to treat the conditions where they might help. Obviously, the result of a diagnostic procedure is not known before it is carried out, so more diagnoses are required than patients who subsequently have disease. There seems to be little clinical rationale for increasing the number of hysteroscopies, although more therapeutic than diagnostic would be more logical and it does not take into account the number that are not completed or need re-doing as they are so painful for the women. Current number of hysteroscopies ~87,000 so approximately 40% of total diagnoses above. Therefore, the number of hysteroscopies is likely to rise by 100-200% **At least 5,000, but probably many more will have a hysteroscopy that does not diagnose their disease.** **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 **£29.5million**. 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..**

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9	Heavy menstrual bleeding: assessment and 1 management Recommendations	6	17	Taking oral analgesia at home is completely inadequate and 'Barbaric'. Where is the evidence base to show that this is acceptable to women and has been formally reviewed? It is not, as shown by evidence from women, nor are women always advised how painful the procedure is or offered alternatives. **The number of abandoned procedures and those that need to be readmitted have not been factored into the business case or economics. Hysteroscopy is not cost effective or safe as a first line diagnosis.**
10	Heavy menstrual bleeding: assessment and 1 management Recommendations	7	1	In the Scope Consultation, the Royal College of Pathologists commented – *"The draft scope will be considering recommendation of use of progesterone receptor modulators (PRM) in the management of heavy menstrual bleeding. These agents can cause changes in the endometrium that are collectively referred to as PRM associated endometrial changes (PAECs) and may mimic endometrial hyperplasia. If a biopsy is taken from a woman on PRM, it is important that the clinician provides this information so that the pathologist reporting on the biopsy will avoid this diagnostic pitfall."* This appears to have been ignored when considering biopsy.
11	Heavy menstrual bleeding: assessment and 1 management Recommendations	7	10-22	Ultrasound needs to remain as the first line diagnosis. Women with subserosal fibroids, endometriosis (new NICE Guidelines recommend ultrasound and MRI), adenomyosis etc cannot undergo the significant risks of hysteroscopy when it will not even give a diagnosis.
12	Heavy menstrual bleeding: assessment and 1 management Recommendations	7	22	Adenomyosis has been omitted. UAE is a safe effective treatment for it and has been assessed by NICE but this has been omitted - https://www.nice.org.uk/guidance/ipg473/chapter/1-Recommendations
13	Heavy menstrual bleeding: assessment and 1 management Recommendations	8	11	Amend to – use MRI as a second-line diagnosis as it is safe and cost effective to both the women and the NHS.

14	Heavy menstrual bleeding: assessment and 1 management Recommendations	8		**2207 version -1.3 Education and information provision** 1.3.1 A woman with HMB referred to specialist care should be given information **before her outpatient appointment.** The Institute's information for the public is available. [2007] This is missing from the new version and needs to be reinstated as women are often not told about their treatment options and only offered hysterectomy. *FEmISA's report "Patient Choice and Nice Compliance Survey On Fibroid Treatment" shows that few hospitals actually comply with this, but they should and it should be audited.* *http://www.femisa.org.uk/images/femisa%20report%20on%20patient%20choice%20and%20nice%20compliance%209.17%20-%20final.pdf* Current patient information is totally inadequate, biased, not objective and incomplete. In a patient survey carried out and published by FEmISA GPs did not adequately women of their treatment options and do not keep up to date with NICE Guidelines or treatment options. ***Information from GPs*** *The GP is the first port of call for women with symptomatic fibroids and although fibroids are perhaps one of the commonest health issues affecting women the vast majority of GPs do not give women complete or up to date advice about treatment options. 43% did not discuss treatment options with their GP, and while 42% of GPs mentioned hysterectomy only 14% mentioned fibroid embolisation and 19% myomectomy (which is not a new treatment). The advice they do give appears to be out of date and they do appear to be aware of NICE Guidelines or to follow them.* Gynaecologists also did not adequately inform women of the treatment options and pushed women towards hysterectomy - ***Information and Choices from Gynaecologists*** *The differences in the treatments women are informed about and those offered is very disturbing. 73% are told about hysterectomy and 52% offered it. This contrasts with only 45% being told about fibroid embolisation and only 37% offered it and myomectomy 43% told about and only 21% offered. Drug treatment is normally only a temporary solution and 38% were told about this and only 28% offered it.*

				http://www.femisa.org.uk/images/stories/downloads/patient_information__%20choice_survey_report.pdf The report from the APPG on Women's Health Informed Choice? Giving women control of their healthcare - https://static1.squarespace.com/static/5757c9a92eeb8124fc5b9077/t/58d8ca34f7e0ab027a19247c/1490602579808/APPG+Womens+Health+March+2017+web+title.pdf *Shows that women are not being given information on their treatment or choice by gynaecologists-* *"Fibroids figures:* *70% of women were told about hysterectomy, however only 38% received a hysterectomy. These figures highlight how women are being pushed towards having a hysterectomy, often without being told about other treatments. This needs to change as more pharmaceutical and nonsurgical interventions become safer and should be more commonly available.* *The hysterectomy figures are much higher when compared to the percentage of women who were told about, offered or had other treatment – 47% of women were told about myomectomy, 54% were told about Uterine Fibroid Embolisation, and few were told about pharmaceutical options.* *43% of women were not satisfied with the information about their treatment choice.* *This is supported by the TOHETI report which stressed that women felt they lacked a voice.* *Over 20% of women sought a second opinion during their diagnosis and treatment.* *Time to treatment from diagnosis: - 23% took 1-3 months - 20% took 3-6months - 11% took 6-9 months - 7% took 9-12 months - 12% took 1-2 years. Given that fibroids can increase in size dramatically some of these waiting times are alarming. 'The waiting time was unacceptable given my symptoms and I had to pay a lot of money to accelerate my operation. '* *34% of women were not satisfied with their treatment."* *One of the main recommendations from the APPG on Women's Health Report - Informed Choice? Giving women control of their healthcare states –* *Recommendations* ***Information resources – women need to be offered written information on gynaecological issues with a full range of information about the condition and what their options are. These leaflets should be endorsed by the relevant clinical bodies and patient groups and the same generic, pre-approved leaflets***

				should be made available at all centres, Trusts and gynaecology clinics. GPs, secondary care clinicians and nurses should provide or signpost women to high quality information and resources about endometriosis and fibroids, their impact and treatment options.
15	Heavy menstrual bleeding: assessment and 1 management Recommendations	8	20	**The last question is discriminatory** and reflects the misogynistic attitude from many gynaecologists. Men with benign prostatic hyperplasia would not be asked if they wanted to be fathers or whether they wanted to retain their prostate gland, in fact there is little question of prostatectomy unless cancerous. This question will be used by gynaecologist to push women towards to hysterectomy without being fully and objectively informed of other treatment options. Women also need to be told • whether each treatment has been formally reviewed for safety and efficacy – neither hysterectomy nor myomectomy have ever been formally reviewed and neither has hysteroscopy • the risks and whether the risks are known or unknown as with myomectomy • long-term complications and side effects e.g. prolapse after hysterectomy, adhesions after myomectomy • Time in hospital • Nursing and care needed at home by a family member • Time to return to work and feeling completely well Add - The treatments for fibroids >3cm must include – • Hysterectomy – vaginal, hysteroscopic and abdominal • Myomectomy – vaginal, hysteroscopic and abdominal • UAE • **MRgFUS – which is missing completely, but unlike hysterectomy and myomectomy has been assessed positively by NICE for safety and efficacy** - https://www.nice.org.uk/Guidance/IPG413 **Add UAE for adenomyosis** - https://www.nice.org.uk/guidance/ipg473/chapter/1-Recommendations **Recommendations**

				Women must be objectively informed about the morbidity and mortality rates short and long-term complications Women must be told whether the procedure has been formally reviewed for safety efficacy and patient acceptability by NICE or some other clinically respected body. Both UAE and MRgFUS have been formally reviewed for safety and efficacy, hysterectomy and myomectomy have never been and the risks in myomectomy are unknown, particularly mortality, fibroid re-growth rates, adhesions and infertility.
16	Heavy menstrual bleeding: assessment and 1 management Recommendations	9	7	Myomectomy – add The mortality rate for myomectomy is unknown and it has never been reviewed for safety and efficacy. The complication rates are unknown and often not discussed with women. Adhesions can cause infertility and further intervention, but are rarely discussed with women. *TI: Minimally invasive surgical techniques versus open myomectomy for uterine fibroids* *SO: Cochrane Database of Systematic Reviews* *ID: CD004638* *: Bhave Chittawar, Priya : Franik, Sebastian : Pouwer, Annefloor W : Farquhar, Cindy* *US: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004638.pub3/abstract* *Authors' conclusions* *Laparoscopic myomectomy is a procedure associated with less subjectively reported postoperative pain, lower postoperative fever and shorter hospital stay compared with all types of open myomectomy. No evidence suggested a difference in recurrence risk between laparoscopic and open myomectomy.* ***More studies are needed to assess rates of uterine rupture, occurrence of thromboembolism, need for repeat myomectomy and hysterectomy at a later stage*** *Gupta JK, Sinha A, Lumsden MA, Hickey M. Uterine artery embolization for symptomatic uterine fibroids Cochrane Database Syst Rev. 2012 May 16;5:CD005073. doi: 10.1002/14651858.CD005073.pub3.* *http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005073.pub4/full* *Authors' conclusions*

				When we compared patient satisfaction rates at up to two years following UAE versus surgery (myomectomy or hysterectomy) our findings are that there is no evidence of a difference between the interventions. Findings at five year follow-up were similarly inconclusive. ***There was very low quality evidence to suggest that myomectomy may be associated with better fertility outcomes than UAE, but this information was only available from a selected subgroup in one small trial. ……*** It was also mentioned that the major complication rate for myomectomy***" is less well defined"*** i.e. unknown Explain to women that the evidence on myomectomy and fertility is "*low and needs further investigation*" – see 2 meta-analyses above.
17	Heavy menstrual bleeding: assessment and 1 management Recommendations	8-10	15-10	The recent report from FEmISA - " Patient Choice and NICE Compliance on Fibroid Treatment" shows that gynaecologists have no training or education on UAE or MRgFUS and so lack the knowledge to inform women objectively, fully or indeed at all. • *"NICE Interventional Procedures Guidance on UAE states that patient selection should be carried out by a multi-disciplinary team (gynaecologists and interventional radiologists working together). FEmISA advocates a multi-disciplinary outpatient clinic, so women are fully informed. Only 7 Trusts offer this and women report that otherwise it is very difficult to access UAE or to see an Interventional Radiologist who performs UAE.* • *Women are referred by their GP to a gynaecologist for hospital treatment of their fibroids. Only 3 hospitals stated that their gynaecologist received any training on UAE and that was informal training given by the local interventional radiologists. Gynaecologists therefore lack the knowledge to inform women about UAE or give them any advice as to whether they are suitable. This strengthens the case for multi-disciplinary fibroid clinics.* • *It is notable that where women have informed choice as at a hospital with a multi-disciplinary fibroid outpatient clinic e.g. Heartlands Hospital, that UAE rates are significantly higher than the average. Here they performed 241 UAE procedures over 2 years, significantly more than other hospitals.*

				• *At Heartlands Hospital over 2 years, of the 1077 women diagnosed with fibroids 392 (36%) had hysterectomy, 44 (4%) open myomectomy and 241 (22%) UAE. (This echoes findings in a previous MTG survey where at the same hospital, 61% of women had UAE compared with an average nationally of 10% UAE, 61% abdominal hysterectomy 6% laparoscopic, 6% vaginal and 16% myomectomy.[1]) This must be a benchmark nationally for UAE."* **RECOMMENDATIONS** 1. All NHS Trusts and CCGs must have a policy to ensure that all patients are fully, properly and objectively informed about all their treatment options and their risks and told about the complications and morbidity and mortality rates. This must be audited at least annually in a detailed patient questionnaire where patients are asked about the treatment options and information they were given. It is not sufficient to ask 'did you receive all the information you needed?' since this does not determine if they were fully and properly informed. 2. National patient information leaflets need to be developed by the relevant Royal Colleges and Medical Societies and importantly the patient support groups. In this instance for fibroid diagnosis and treatment they would be - RCOG, BSIR, RCR, The Hysterectomy Association, FEmISA, The Fibroid Network, the British Fibroid Trust, TOHETI etc. These need to be available nationally – on hospital web sites, in GP surgeries, NHS Choices and hospital outpatients. 3. **Multidisciplinary fibroid clinics with gynaecologists and interventional radiologists should be set up in all hospitals where in-patient fibroid treatment is offered to ensure that women are fully, objectively and properly informed about all their treatment options. Where hospitals do not offer UAE and refer patients to another hospital it should be ensured that all patients have the opportunity to be referred to the interventional radiologist to discuss UAE in detail before making any decision about the treatment they want.**

[1] http://www.mtg.org.uk/wp-content/uploads/2016/07/UFEResearchReport.pdf

				4. RCOG needs to work with BSIR to set up training for gynaecologists on UAE, so they are better informed. They also need to work together for the benefit of patients, which all too rarely happens at the moment, to the detriment of women. Gynaecologists, as well is lacking knowledge on interventional radiology treatments including UAE and MRgFUS (magnetic resonance-guided focused ultrasound) appear to see them as competing treatments provided by a different speciality that must be avoided at all costs. Women patients must be the first priority and are not at the moment.
18	Heavy menstrual bleeding: assessment and 1 management Recommendations	11	15	For women with submucosal fibroids, consider hysteroscopic removal. This should be moved under fibroid treatment. This is not acceptable and gives women no choice. A diagnostic ultrasound is required to visualise the size, position and type of all the fibroids. The comparative risks, pain, morbidity and mortality should be explained to the patients so she can make an informed decision. Hysteroscopic removal should not be considered if other fibroid types are present and it would involve 2 different treatments.
19	Heavy menstrual bleeding: assessment and 1 management Recommendations	11	17-20	The size, location, number and type of fibroids will only be known if the women had a previous MRI scan.
20	Heavy menstrual bleeding: assessment and 1 management Recommendations	11-13	25-3	Add MRgFUS to list of treatments Add - Discuss with the women the pros and cons and with her Inform the woman that all pharmaceutical treatments are short-term and will only mask symptoms not treat the underlying cause of fibroids and any other diagnosis should be carried out at the same time so as not to delay any in-patient treatment ulipristal acetate – can only be given for 1 year. There has been a recent association with miscarriage, which needs further investigation to determine the safety. A number of miscarriages have been reported after Ulipristal acetate, so women need to be warned about this, along with thickening of the endometrium. This medicine does not treat fibroids, only the symptoms and symptoms return at the end of the treatment.

				http://www.fertstert.org/article/S0015-0282(14)02024-X/pdf
21	Heavy menstrual bleeding: assessment and 1 management Recommendations	13	4	Endometrial ablation has never been formally and independently reviewed for safety and efficacy for fibroids of 3cm or more. The previous HMB Guidelines 2007 only considered it for fibroids <3cm. The safety and efficacy must be fully assessed before trying it out on women. **It is absolutely unacceptable to try new or modified treatments on women without prior review by NICE Interventional Procedures Review**. This cavalier attitude is completely unacceptable and is a theme throughout this Review.
22	Heavy menstrual bleeding: assessment and 1 management Recommendations	17	13	The original version needs to be reinstated to protect women and ensure they are allowed to make an informed choice – 1.8 Hysterectomy 1.8.1 Hysterectomy ***should not be used as a first-line treatment*** solely for HMB. Hysterectomy should be considered only when: other treatment options have failed, are contraindicated or are declined by the woman there is a wish for amenorrhoea the woman (who has been fully informed) requests it the woman no longer wishes to retain her uterus and fertility. [2007] 1.8.2 Women offered hysterectomy should have a full discussion of the implication of the surgery before a decision is made. The discussion should include: sexual feelings, fertility impact, bladder function, need for further treatment, treatment complications, the woman's expectations, alternative surgery and psychological impact. [2007] 1.8.3 Women offered hysterectomy should be informed about the increased risk of serious complications (such as intraoperative haemorrhage or damage to other abdominal organs) associated with hysterectomy when uterine fibroids are present. [2007] 1.8.4 Women should be informed about the risk of possible loss of ovarian function and its consequences, even if their ovaries are retained during hysterectomy. [2007]

				1.8.5 Individual assessment is essential when deciding the route of hysterectomy. The following factors need to be taken into account: presence of other gynaecological conditions or disease uterine size presence and size of uterine fibroids mobility and descent of the uterus size and shape of the vagina history of previous surgery. [2007] 1.8.6 Taking into account the need for individual assessment, the route of hysterectomy should be considered in the following order: first line vaginal; second line abdominal. [2007] 1.8.7 Under circumstances such as morbid obesity or the need for oophorectomy during vaginal hysterectomy, the laparoscopic approach should be considered, and appropriate expertise sought. [2007] 1.8.8 When abdominal hysterectomy is decided upon then both the total method (removal of the uterus and the cervix) and subtotal method (removal of the uterus and preservation of the cervix) should be discussed with the woman. [2007]
23	Heavy menstrual bleeding: assessment and management Recommendations 1	14	1-4	1.5.19 Only remove ovaries with hysterectomy with the express wish and informed consent of the woman, after discussion of all associated risks and benefits. [2007, amended 2017] 2 3 This removes the safeguard for women of being bullied into the removal of healthy ovaries that will not benefit her and put her into immediate menopause with an urgent need for HRT. HRT carries a double prescription charge, which the women would be expected to pay and has been associated with an increase in breast cancer.

				It is very concerning that removal of ovaries – oophorectomy, salpingoophorectomy etc has increased alarmingly since 2005/6 (before the first HMB guidelines were published). In 2005/6 there were 3,873 procedures for Bilateral - salpingoophorectomy, salpingectomy and oophorectomy (Q22.1-.3) [HES]In 2015/16 (latest HES available) the figure had risen to 7,545 an increase of 94%. Cancer Research UK states - Ovarian cancer incidence rates have remained stable since the early 1990s, UK. The old guidelines must be reinstated – below, to protect women. There is no evidence or rationale offered to defend this change which is detrimental to women. 1.9 Removal of ovaries (oophorectomy) with hysterectomy 1.9.1 Removal of healthy ovaries at the time of hysterectomy should not be undertaken. [2007] 1.9.2 Removal of ovaries should only be undertaken with the express wish and consent of the woman. [2007] 1.9.3 Women with a significant family history of breast or ovarian cancer should be referred for genetic counselling prior to a decision about oophorectomy[11]. [2007] 1.9.4 In women under 45 considering hysterectomy for HMB with other symptoms that may be related to ovarian dysfunction (for example, premenstrual syndrome), a trial of pharmaceutical ovarian suppression for at least 3 months should be used as a guide to the need for oophorectomy. [2007] 1.9.5 If removal of ovaries is being considered, the impact of this on the woman's wellbeing and, for example, the possible need for hormone replacement therapy (HRT) should be discussed. [2007] 1.9.6 Women considering bilateral oophorectomy should be informed about the impact of this treatment on the risk of ovarian and breast cancer. [2007]

				The full version of the old guidelines stats that " 1.48% of women born today will be diagnosed with cancer of the ovary at some time during their lifetime). Information on this is published elsewhere." [531–538] All men, if they live long enough, will get cancer of the prostate gland, although most will die of something else. Men are not normally offered prophylactic removal of their prostate gland. Prophylactic removal of healthy ovaries is discriminatory and again exhibits misogyny.
24	Heavy menstrual bleeding: assessment and 1 management Recommendations	Training - Missing		This section is missing completely from the new recommendations and needs to be reinstated from current 2007 version **1.10 Competencies** **Training** 1.10.1 All those involved in undertaking surgical or radiological procedures to diagnose and treat HMB should demonstrate competence (including both technical and consultation skills) either during their training or in their subsequent practice. [2007] 1.10.2 The operative competence of healthcare professionals who are acquiring new skills in procedures to diagnose and treat HMB should be formally assessed by trainers through a structured process such as that defined within training schemes of the Postgraduate Medical Education and Training Board, the Royal Colleges and/or the Society and College. [2007] 1.10.3 Training programmes must be long enough to enable healthcare professionals to achieve competency in complex procedures when these are appropriate (for example, operations for fibroids that are large or in an awkward position, or using laparoscopic techniques). These training programmes will usually be located in units with a particular interest and sufficient workload to allow experience of these procedures. [2007] Add – gynaecologists should be fully trained in laparoscopic and hysteroscopic techniques and acquire a competency certificate in this as is being considered in other leading EU countries – In other EU countries – Belgium, France, Germany, South Africa they advocate specialist education and a diploma in hysteroscopy to increase quality and minimise complications. RCOG run courses which run for a few hours, but do not appear to offer any diplomas.

				Gynecol Surg. 2016; 13: 133–137. *Published online 2016 Jun 21. doi: 10.1007/s10397-016-0957-1* *PMCID: PMC4949291* *Gynaecological endoscopic surgical education and assessment. A diploma programme in gynaecological endoscopic surgery* *Rudi Campo, Arnaud Wattiez, Vasilis Tanos, Attilio Di Spiezio Sardo, Grigoris Grimbizis, Diethelm Wallwiener, Sara Brucker, Marco Puga, Roger Molinas, Peter O'Donovan, Jan Deprest, Yves Van Belle, Ann Lissens, Anja Herrmann, Mahmood Tahir, Chiara Benedetto, Igno Siebert, Benoit Rabischong, and Rudy Leon De Wilde* *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4949291/*
25	Heavy menstrual bleeding: assessment and 1 management Recommendations	Training - Missing		Gynaecologists have no education or training in interventional radiology treatments for fibroids – UAE and MRgFUS. They lack any knowledge to inform or advise women about these treatments, particularly their suitability, but they frequently do giving incorrect advice. All gynaecologist seeing or treating women with HMB and fibroids should be required to attend a course on these treatments devised and agreed with BSIR and sit an exam set by BSIR. However, this training does not replace the need for multi-disciplinary working with interventional radiologists in join fibroid clinics. See FEmISA report – "Patient Choice and NICE Compliance Survey on Fibroid Treatment – previously cited
26	Heavy menstrual bleeding: assessment and 1 management Recommendations	Maintenance - missing		From 2007 version needs reinstating Maintenance 1.10.4 Maintenance of surgical, imaging or radiological skills requires a robust clinical governance framework including audit of numbers, decision making, case-mix issues and outcomes of all treatments at both individual operator and organisational levels. These data should be used to demonstrate good clinical practice. [2007] 1.10.5 Established healthcare professionals should be able to demonstrate that their training, experience and current practice meets or exceeds the standards laid out for newly trained professionals. [2007] Governance 1.10.6

				If a healthcare professional lacks competence to undertake a procedure then they should refer the woman to a professional with the appropriate skill. Organisations that commission services should be responsible (through service specification based on robust audit data) for identifying and contracting professionals with appropriate skills. [2007] The full old guidance states – "An individual surgeon's figures should be available publicly." **These figures are not available for gynaecologist from RCOG and need to be published as with other surgeons, as mortality and morbidity rates are so variable and need to be improved**. Gynaecology has the second highest litigation rate – NHS Litigation after obstetrics and this needs to be improved with better training, better communication and better information and choice for patients.
27	Heavy menstrual bleeding: assessment and 1 management Recommendations	14-15	15-16	No, this research question is very biased and invalid clinically and not in the interests of women or their welfare. The question should be – ***What is the safest, most clinical and cost effective diagnostic pathway for heavy menstrual bleeding, which is acceptable to women between ultrasound, MRI and hysteroscopy?*** Also, there should be a formal review of the safety and efficacy of hysteroscopy and cost effectiveness and acceptability to woman, especially pain. It has never been formally reviewed and should be. There should also be research into the effectiveness of analgesia to find adequate management rather than ignoring the considerable pain many women suffer.
28	Heavy menstrual bleeding: assessment and 1 management Recommendations	16	18	Is hysteroscopic removal of submucosal fibroids more effective and cost-effective 21 than other uterine-sparing treatments for the management of HMB? No this is not a suitable research topic.

				1. The safety and efficacy needs to be established by a NICE Interventional Procedures Review. 2. A full study needs to be carried out on the acceptability to women, adequate pain control, mortality and morbidity short, medium and long-term 3. A full comprehensive study needs to be carried out comparing the safety, morbidity, mortality etc of this, UAE and myomectomy. **Until this happens it cannot go in the Guidelines or be recommended.**
29	Heavy menstrual bleeding: assessment and 1 management Recommendations	16	Additional	Add What is the safety, efficacy and clinical and cost effectiveness of myomectomy? This needs to be reviewed and researched. This treatment has never been reviewed, but is being used on women. The mortality is unknow and risk to women is unknown, particularly longer-term complication and side effects such as adhesions, reintervention rates – long-term and infertility.
30	Management of heavy menstrual bleeding Evidence reviews Evidence reviews for management of heavy menstrual bleeding	General		Although MRgFUS is mentioned in this document no evidence is included and it has been excluded from recommendations – which is unacceptable. Here is a list of the papers that the committee forgot to include – 1. Focused Ultrasound Treatment, Present and Future. Abe K, Taira T. Neurol Med Chir (Tokyo). 2017 Aug 15;57(8):386-391. doi: 10.2176/nmc.ra.2017-0024. Epub 2017 Jun 28. PMID: 28659546 [PubMed - in process] Free PMC Article Similar articles 2. Magnetic Resonance Imaging-Guided Focused Ultrasound Surgery for the Treatment of Symptomatic Uterine Fibroids. Geraci L, Napoli A, Catalano C, Midiri M, Gagliardo C. Case Rep Radiol. 2017;2017:2520989. doi: 10.1155/2017/2520989. Epub 2017 May 3. PMID: 28553555 [PubMed] Free PMC Article Similar articles

				3. Efficacy of single-dose gonadotropin-releasing hormone agonist administration prior to magnetic resonance-guided focused ultrasound surgery for symptomatic uterine fibroids. Park H, Yoon SW. Radiol Med. 2017 Aug;122(8):611-616. doi: 10.1007/s11547-017-0754-6. Epub 2017 Mar 24. PMID: 28341966 [PubMed - indexed for MEDLINE] Similar articles 4. Uterine fibroid therapy using interventional radiology mini-invasive treatments: current perspective. Masciocchi C, Arrigoni F, Ferrari F, Giordano AV, Iafrate S, Capretti I, Cannizzaro E, Reginelli A, Ierardi AM, Floridi C, Angileri AS, Brunese L, Barile A. Med Oncol. 2017 Apr;34(4):52. doi: 10.1007/s12032-017-0906-5. Epub 2017 Feb 24. Review. PMID: 28236104 [PubMed - indexed for MEDLINE] Similar articles 5. Usefulness of modified BRB technique in treatment to ablate uterine fibroids with magnetic resonance image-guided high-intensity focused ultrasound. Jeong JH, Hong KP, Kim YR, Ha JE, Lee KS. Obstet Gynecol Sci. 2017 Jan;60(1):92-99. doi: 10.5468/ogs.2017.60.1.92. Epub 2017 Jan 19. PMID: 28217678 [PubMed] Free PMC Article Similar articles 6. Expulsion of Fibroids to the Endometrial Cavity after Magnetic Resonance Imaging-guided High Intensity Focused Ultrasound Surgery (MRgFUS) Treatment of Intramural Uterine Fibroids. Jeong JH, Hong GP, Kim YR, Hong DG, Ha JE, Yeom JI, Kim EJ, Kim HI, Lee KS. J Menopausal Med. 2016 Dec;22(3):139-145. doi: 10.6118/jmm.2016.22.3.139. Epub 2016 Dec 31. PMID: 28119893 [PubMed] Free PMC Article

				Similar articles 7. Magnetic resonance texture parameters are associated with ablation efficiency in MR-guided high-intensity focussed ultrasound treatment of uterine fibroids. Hocquelet A, Denis de Senneville B, Frulio N, Salut C, Bouzgarrou M, Papadopoulos P, Trillaud H. Int J Hyperthermia. 2016 Oct 28:1-8. [Epub ahead of print] PMID: 27790950 [PubMed - as supplied by publisher] Similar articles 8. A retrospective study of magnetic resonance-guided focused ultrasound ablation for uterine myoma in Taiwan. Tung SL, Chou TY, Tseng HS, Lee CM. Taiwan J Obstet Gynecol. 2016 Oct;55(5):646-649. doi: 10.1016/j.tjog.2015.03.011. PMID: 27751409 [PubMed - indexed for MEDLINE] Free Article Similar articles 9. Intraoperative Monitoring and Evaluation of MRI in Women of Reproductive Age After Previously Performed Uterine Artery Embolization (UAE) and MRgFUS Ablation of Fibroids. Porotikova IE, Adamyan LV, Gavrilova TY, Kulabukhova EA. J Minim Invasive Gynecol. 2015 Nov-Dec;22(6S):S235. doi: 10.1016/j.jmig.2015.08.827. Epub 2015 Oct 15. No abstract available. PMID: 27679142 [PubMed - as supplied by publisher] Similar articles 10. Clinical Consideration of Treatment to Ablate Uterine Fibroids with Magnetic Resonance Imaging-guided High Intensity Focused Ultrasound (MRgFUS): Sonalleve. Jeong JH, Hong GP, Kim YR, Ha JE, Lee KS.

				J Menopausal Med. 2016 Aug;22(2):94-107. doi: 10.6118/jmm.2016.22.2.94. Epub 2016 Aug 30. PMID: 27617244 [PubMed] Free PMC Article Similar articles 11. First experience of real-time elastography with transvaginal approach in assessing response to MRgFUS treatment of uterine fibroids. Marigliano C, Panzironi G, Molisso L, Pizzuto A, Ciolina F, Napoli A, Ricci P. Radiol Med. 2016 Dec;121(12):926-934. Epub 2016 Sep 1. PMID: 27586131 [PubMed - indexed for MEDLINE] Similar articles 12. Nonsurgical Alternatives for Uterine Fibroids. Zupi E, Centini G, Sabbioni L, Lazzeri L, Argay IM, Petraglia F. Best Pract Res Clin Obstet Gynaecol. 2016 Jul;34:122-31. doi: 10.1016/j.bpobgyn.2015.11.013. Epub 2015 Nov 25. PMID: 26711881 [PubMed - indexed for MEDLINE] Similar articles 13. PROMISe trial: a pilot, randomized, placebo-controlled trial of magnetic resonance guided focused ultrasound for uterine fibroids. Jacoby VL, Kohi MP, Poder L, Jacoby A, Lager J, Schembri M, Rieke V, Grady D, Vittinghoff E, Coakley FV. Fertil Steril. 2016 Mar;105(3):773-780. doi: 10.1016/j.fertnstert.2015.11.014. Epub 2015 Dec 1. PMID: 26658133 [PubMed - indexed for MEDLINE] Similar articles 14. Potential of minimally invasive procedures in the treatment of uterine fibroids: a focus on magnetic resonance-guided focused ultrasound therapy.

				Fischer K, McDannold NJ, Tempany CM, Jolesz FA, Fennessy FM. Int J Womens Health. 2015 Nov 13;7:901-12. doi: 10.2147/IJWH.S55564. eCollection 2015. Review. PMID: 26622192 [PubMed] Free PMC Article Similar articles 15. Review of nonsurgical/minimally invasive treatments and open myomectomy for uterine fibroids. Chittawar PB, Kamath MS. Curr Opin Obstet Gynecol. 2015 Dec;27(6):391-7. doi: 10.1097/GCO.0000000000000223. Review. PMID: 26536205 [PubMed - indexed for MEDLINE] Similar articles 16. Combining split-and-merge and multi-seed region growing algorithms for uterine fibroid segmentation in MRgFUS treatments. Rundo L, Militello C, Vitabile S, Casarino C, Russo G, Midiri M, Gilardi MC. Med Biol Eng Comput. 2016 Jul;54(7):1071-84. doi: 10.1007/s11517-015-1404-6. Epub 2015 Nov 3. PMID: 26530047 [PubMed - indexed for MEDLINE] Similar articles 17. Magnetic resonance-guided high-intensity focused ultrasound for uterine fibroids: Mid-term outcomes of 36 patients treated with the Sonalleve system. Thiburce AC, Frulio N, Hocquelet A, Maire F, Salut C, Balageas P, Bouzgarrou M, Hocké C, Trillaud H. Int J Hyperthermia. 2015;31(7):764-70. doi: 10.3109/02656736.2015.1063169. Epub 2015 Sep 14. PMID: 26367772 [PubMed - indexed for MEDLINE] Similar articles 18. T2-based temperature monitoring in abdominal fat during MR-guided focused ultrasound treatment of patients with uterine fibroids.

				Ozhinsky E, Kohi MP, Ghanouni P, Rieke V. J Ther Ultrasound. 2015 Sep 11;3:15. doi: 10.1186/s40349-015-0036-5. eCollection 2015. PMID: 26366288 [PubMed] Free PMC Article Similar articles 19. Effectiveness of Magnetic Resonance-guided Focused Ultrasound Surgery (MRgFUS) in the uterine adenomyosis treatment: technical approach and MRI evaluation. Ferrari F, Arrigoni F, Miccoli A, Mascaretti S, Fascetti E, Mascaretti G, Barile A, Masciocchi C. Radiol Med. 2016 Feb;121(2):153-61. doi: 10.1007/s11547-015-0580-7. Epub 2015 Sep 9. PMID: 26349572 [PubMed - indexed for MEDLINE] Similar articles 20. A fully automatic 2D segmentation method for uterine fibroid in MRgFUS treatment evaluation. Militello C, Vitabile S, Rundo L, Russo G, Midiri M, Gilardi MC. Comput Biol Med. 2015 Jul;62:277-92. doi: 10.1016/j.compbiomed.2015.04.030. Epub 2015 Apr 28. PMID: 25966922 [PubMed - indexed for MEDLINE] Similar articles 21. Scaled signal intensity of uterine fibroids based on T2-weighted MR images: a potential objective method to determine the suitability for magnetic resonance-guided focused ultrasound surgery of uterine fibroids. Park H, Yoon SW, Sokolov A. Eur Radiol. 2015 Dec;25(12):3455-8. doi: 10.1007/s00330-015-3806-0. Epub 2015 May 9. PMID: 25956935 [PubMed - indexed for MEDLINE] Similar articles 22. Perfusion volume correlates, percentage of involution, and clinical efficacy at diverse follow-up

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31	Economic Model	General	Missing or incorrect information	**Treatment alternatives** – includes hysterectomy as 1st line treatment for fibroids>3cm, but not UAE or MRgFUS. This is not correct. **Test Accuracy** – Does not include abdominal ultrasound the current 1st line treatment, which should be restored as such. Does not include MRI, which it should do. Endometrial biopsy will not diagnose any of the diseases, but excludes cancer Adenomyosis and endometriosis are missing

Hysteroscopy cannot diagnose adenomyosis, subserosal fibroids, endometriosis of any pathology outside the reproductive tract
Hysterectomy is not a diagnostic test and should not be included,

Diagnostic Consultation and Costs-
Missed abdominal ultrasound £40
Missed MRI £114-64
Missed repeat hysteroscopy due to pain and its incidence.
Missed costs to women – hysteroscopy 1 day off work, time off work for family member to transport to hospital
Missed mortality and complication costs to women, which are significant

Treatment Costs
Missed myomectomy –

Major, Laparoscopic or Endoscopic, Upper Genital Tract Procedures, with CC Score 2+	-	2,609
Major, Laparoscopic or Endoscopic, Upper Genital Tract Procedures, with CC Score 0-1	-	2,217

Missed cost of ulipristal acetate which is significant and there are problems with prescription costs in primary care. Many CCGs will not cover it.

Operative Complications
These figures are not correct and do not include myomectomy, UAE or MRgFUS as treatment options or hysteroscopy which has significant complications and deaths.
It also does not state whether long-term complications and costs to women are included – they probably aren't e.g. Px HRT after hysterectomy for early menopause which carries a double Px charge
Costs of complication in days off work etc

Treatment Gain
It is untrue to show that UAE, myomectomy, MRgFUS etc have no treatment gain for fibroids >3cm

Population and Health State Utility

				It appears to be assumed that women are 42, but while this is the average age for HMB and fibroid treatment the variance is very great from approx. late teens till well over 55. It also appears to assume that the women will benefit for the rest of her life. She will not. Theoretically she will only benefit for the time when she produces female hormones or is on HRT. Also, hysterectomy causes prolapse in later years and myomectomy adhesions, which is an additional cost in later years. **Complication Costs** These are not based in reality. Prolapse may require several major procedures. As only one example. The costs to the women, her family and employer have not been considered and possible litigation. The high complication costs of hysteroscopy have not been included, which include rupture of the uterus and reproductive tract.

Insert extra rows as needed

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