Heavy menstrual bleeding (update)
Consultation on draft guideline - Stakeholder comments table
03/08/2017 – 13/09/2017

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
All-Party Parliamentary Group on Women's Health	Short	General	General	The All-Party Parliamentary on Women's Health is passionate about advocating for all women to be able to make an informed choice about their own healthcare and to be empowered to do so. It is vital that women are presented with all the necessary information around their condition, and possible treatment options, so that they can make an informed decision. In regards to HMB the group believes that women should be offered the full range of treatment options available, and be given all the relevant information in regards to the treatments, rather that pointed down any one particular pathway. We believe that patient focused information leaflets on their condition should be readily available, and that women should be given appropriate information, with reasonable timeframes to make a decision, around what that decision might be. Healthcare professionals should also discuss with women what their different options are, and present them with information on all of these options so that women can make a decision right for them. In the Group's recently released report *Informed Choice: Giving women control of their healthcare*, the group called for:	Thank you for your comment. In the previous 2007 guideline there were recommendations on "Information for women about HMB and treatments". Information for women was not included in the scope of the partial guideline update but the 2007 recommendations have been retained with minor editorial changes to reflect the current style of NICE recommendations. These recommendations include overarching principles stating that the health care professional should "provide information about all possible treatment options" and that discussions should cover the "benefits and risks of the various options". In addition there are recommendations about what discussion should cover for specific treatments such as hysterectomy. It was not part of the committee's remit to make recommendations on the provision and content of patient leaflets. The committee supports the views of the All-Party Parliamentary Group on women being able to make informed choices about their health care, e.g. "The health professional's role is to allow women to make informed choice by presenting the range of

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				Patient information leaflets (endorsed by the RCOG, BSGE, RCGP , RCN and RCR/BSIR and created in conjunction with specialist patient groups) to be used in GP practices, gynaecology clinics and for the general public in a generic format: • These should cover information on the condition and information on all treatment options – from hormonal contraception and pharmaceutical solutions, minimally invasive surgery and major surgical intervention. • Information should be available for patients and also for families. Information resources should be available, including in multiple languages, audio-visual materials and online website, blogs and testimonies. • This information should also cover coping with the emotional stress of these conditions, how to access support outside the NHS, and offer support to partners and families. Also information needs to be specially prepared to be age relevant. Not all treatment are appropriate for younger women, or women who have not had children etc. The group believes that all options should be discussed with the patient, along with relevant information around	management options and their particular benefits and harms" (see https://www.nice.org.uk/guidance/gid-ng10012/documents/evidence-review-2, page 8) The guideline recommendations do not steer the woman down a particular pathway unless indicated by the evidence on clinical and cost effectiveness. Many of the management recommendations contain a wide range of treatment alternatives.

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				side effects, benefits, impact on the woman more widely, possibility for further treatment and fertility. Giving patients a meaningful choice in their care is a critical step for improving outcomes for HMB. Achieving this will require clinicians to be aware of the full range of treatments available and to communicate this on to patients.	
All-Party Parliamentary Group on Women's Health	Short	General	General	In the same report the group also called to: Treat all patients with dignity and respect and empower women to make a choice by giving them all the information and access to the specialist services they need. Giving a meaningful choice to patients requires healthcare professionals to listen to and respect patient's wishes. Once patients have been a presented with necessary information and made their treatment choice, this should be respected by healthcare professionals and every effort should be made to deliver their care. The group is concerned that findings from the *Informed Choice* report highlight that women were often only offered a hysterectomy as a treatment option, rather than other options that are also widely available, and the Group is concerned that by making a hysterectomy a first line	Thank you for your comment. Hysterectomy is not recommended as a first-line treatment in preference to alternative treatments, however recommendation 1.5.10 is worded to allow hysterectomy to be a first-line alternative in order to facilitate women's choice where that is their preference. The committee does not anticipate that hysterectomy will be provided as a first-line treatment other than in exceptional circumstances where this reflects the woman's choice, she has severe symptoms and does not wish to preserve her uterus/fertility for example. The guideline is clear that women's preferences are important when agreeing treatment (see recommendation: "When agreeing the treatment options for HMB with the woman, take into account the woman's preferences") and therefore the committee did not

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				treatment this will exacerbate this issue, further restricting the choice for women and the options that they have. Instead, they should be offered a wide range of treatment options including minimally invasive procedures. The Group believes that all of these treatment options should be presented to women.	want to include a recommendation that did not allow hysterectomy as a first-line treatment in any circumstances.
All-Party Parliamentary Group on Women's Health	Short	General	General	The Group has also strongly advocated for multi-disciplinary team working for diagnosing and treating patients, particularly around HMB. This was referenced in the *Informed Choice* report recommendations and includes all healthcare professionals, particularly in this case interventional radiologists and gynaecologists, but should include all others involved. This is vital to ensure that those most appropriate to offer certain treatments are involved in assessing patients and providing information and treatment where the patient wishes. The Group is concerned that other healthcare professionals who work within such a multi-disciplinary team were not equally represented on the NICE Committee for this Guideline – resulting in an overemphasis on procedures performed by gynaecologists, and underemphasising less invasive options available from other specialities.	Thank you for your comment. We acknowledge that specialists from a number of disciplines are involved in the day to day management of HMB. This is the ethos of management of HMB rather than a formalised "multidisciplinary approach" akin to the one existing in cancer management. Notwithstanding this acknowledgement, multi-disciplinary working was not part of the scope of this partial guideline update and therefore it was not possible to make recommendations on this. The constitution of the committee incorporated all the disciplines involved in the management of HMB. The size of the committee reflected the relative proportions of individual specialties involved in the management of HMB and content of the scope of this update. The committee included lay representatives (x2) in addition to representation from nursing (x2), gynaecology (x3), general practice/primary care (x2) and a co-opted

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					interventional radiologist. We consider this mix was the right balance to produce the guideline. We accept that there are value judgements with respect to the optimal composition of the committee and that some stakeholders might disagree with the final composition. Nevertheless, the guideline committee is constrained to work according to NICE methods and processes, making recommendations based on the best available evidence and being transparent in providing a rationale for those recommendations. The stakeholder consultation is a crucial part in scrutinising those recommendations (and rationale) and is open to all interested parties. Generally, the committee did not find evidence of a treatment hierarchy and management recommendations allow a wide variety of treatment alternatives (including less invasive options) to be considered.
All-Party Parliamentary Group on Women's Health	Short	General	General	You can download the report *Informed Choice: Giving women control of their healthcare* report here: https://static1.squarespace.com/static/5757c9a92eeb8124fc5b9077/t/58d8ca34f7e0ab027a19247c/1490602579808/APPG+Womens+Health+March+2017+web+title.pdf	Thank you for your comment and for sharing the link for the document. The guideline committee is aware of the report and has considered its messages during discussions. The committee hopes that the new guideline will improve care and increase women's choice for treatment of HMB.

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Bayer plc	Short App C	11	2	Recommendation 1.5.4 clearly states that for women with no identified pathology, fibroids less than 3 cm in diameter or suspected or diagnosed adenomyosis, referral to secondary care should be considered "*if treatment is unsuccessful*, *the woman declines pharmacological treatment* or *symptoms are severe"*. However, whilst the care pathway (Appendix C) clearly reflects the recommended referral pathway for those women who decline or have unsuccessful treatment, the direct line from *"no identified pathology, fibroids <3cm, or adenomyosis. Take into consideration severity of symptoms" to "consider referral to secondary care"* does not reflect that direct referral to secondary care should only be made when symptoms are severe. Indeed on page 68 of 'Evidence Review B' it is clear that the intention of this recommendation is to *"enable women to have surgery if this reflects their preference"*, and that *"this is likely to be a small subset of women with more significant symptoms or pathology"*. Also on p 103, where it states *"Where symptoms are severe, the committee agreed that women may benefit from referral to secondary care ..."* We suggest that the care pathway algorithm should be updated to be consistent with the recommendation. This is important to reduce the risk of inappropriate referrals of women without severe symptoms.	Thank you for your comment. As suggested we have amended the algorithm for clarity and consistency with the recommendations.
Bayer plc	Short	12	8	It is extensively acknowledged in 'Evidence Review B' (including on p68, 99 and 104), that the evidence on the clinical effectiveness of some pharmacological treatment options (such as the IUS, COCs and progestogens) for	Thank you for your comment. We realise that the cut-off of 3 cm used is arbitrary and the effective management of fibroids that are 3-

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				women with fibroids of more than 3 cm or more in diameter is limited and restricted to women with fibroids not substantially greater than 3 cm in diameter (<5cm). Also that pharmacological treatment is not always the best option for fibroids that are substantially greater than 3 cm in diameter; on p68 it is noted that 'large' fibroids are *"more likely to be refractory to pharmacological treatment"* and that [women with more significant pathology] "*…are unlikely to get long term resolution of symptoms from pharmacological alternatives and will often ultimately receive surgical intervention."* However this is not adequately reflected in the recommendations. Indeed the guideline now recommends these pharmacological treatments as options for women with fibroids <3cm (recommendation 1.5.12) where no such recommendation existed in the previous iteration of the guideline. Confusingly, on page 68 it states that [the guideline] *"…could potentially produce a small saving by limiting less efficacious pharmacological treatment."* It is not clear how recommendation 1.5.12 could be seen as being helpful in limiting less efficacious pharmacological treatments when it appears to make a recommendation for their use. Whilst we appreciate that recommendation 1.5.11, *"Be aware that the effectiveness of some pharmacological treatments for HMB may be limited in women with fibroids that are substantially greater than 3 cm in diameter",* has been included, we find it illogical that an evidence based guideline would include recommendations for treatment	5 cm in diameter might be similar to the management of fibroids less than 3 cm in diameter while the effectiveness of pharmacological treatments (except ulipristal acetate) is either limited or unknown for large fibroids. However, given the varied clinical pictures and effects on women's quality of life, it is important to have a range of options for women and clinicians to consider. Some women with HMB with substantially larger fibroids but no significant impact on their quality of life might, for example, decline UAE or surgical treatment and opt for a simpler pharmacological treatment even when informed of their inferior effectiveness. It would be impractical to differentiate between the different clinical pictures in the recommendations and instead we believe that clinicians are able to use their clinical judgment when agreeing on the treatment with the woman. Regarding the comment about the guideline producing possible cost savings by limiting less efficacious treatments - this statement refers to the changes made to the guidance in the 2017 partial update that aim to allow women to opt for surgical treatment as first-line treatment if they so wish and therefore avoid going through trials of pharmacological treatments that might not be effective in the long-term.

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				options where the evidence base is so sparse, only to have to counter that recommendation with another to clarify that the effectiveness of those treatments may be limited. We suggest it would be more appropriate to conclude that due to a lack of evidence for these interventions (IUS, COCs and progestogens) in fibroids substantially greater than 3cm, recommendations for their use could not be made.	
Bayer plc	Short	12	16	It should be noted that the summary of product characteristics for Mirena® 20 micrograms/24 hours intrauterine delivery system (http://www.medicines.org.uk/emc/medicine/1829), includes the following as a contraindication to its use: *"Congenital or acquired abnormality of the uterus including fibroids if they distort the uterine cavity"*. This should be made clear in recommendation 1.5.12 where the LNG-IUS is recommended as a treatment option for women with fibroids of 3 cm or more in diameter.	Thank you for your comment. The guideline committee recognises the restrictions and the need for clinical considerations regarding the use of LNG-IUS as well as other treatment options. We have combined two recommendations in order to clarify this. The stem of the recommendation on different treatment options for women with fibroids 3 cm or more in diameter now says: 'Consider the following treatments for HMB in women with fibroids of 3 cm or more in diameter, taking into account the size, the location and the number of fibroids, and the severity of the symptoms ...'.
Boston Scientific Ltd	Short	General	General	We are concerned at the multiple additions of hysterectomy as a choice of treatment. The work of the APPG and it's report on informed choice highlighted that patients were not given a suitable broad choice of treatment options even when at an age where preserving fertility was important to them, and the referrals routinely went down a pathway which only offered hysterectomy. This increase in emphasis on hysterectomy might exacerbate this problem	Thank you for your comment. The guideline committee carefully reviewed the evidence for the most effective and safe treatments for HMB. The evidence did not show a clear hierarchy of the different treatment options and hysterectomy was one of the treatments that showed good outcomes in both the short and long term. The committee felt it was important to offer a range of

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					treatment options to women. The committee agreed that it is important to allow the choice of hysterectomy when it is considered appropriate. Hysterectomy is not recommended as a first-line treatment in preference to alternative treatments, however recommendation 1.5.10 is worded to allow hysterectomy to be a first-line alternative in order to facilitate women's choice where that is their preference. The committee does not anticipate that hysterectomy will be provided as a first-line treatment other than in exceptional circumstances where this reflects the woman's choice, she has severe symptoms and does not wish to preserve her uterus/fertility, for example. The guideline is clear that women's preferences are important when agreeing treatment (see recommendation: "When agreeing the treatment options for HMB with the woman, take into account the woman's preferences") and therefore the committee did not want to include a recommendation that did not allow hysterectomy as a first-line treatment in any circumstances. The committee supports the views of the All-Party Parliamentary Group on women being able to make informed choices about their health care, e.g. "The

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					health professional's role is to allow women to make informed choice by presenting the range of management options and their particular benefits and harms" (see https://www.nice.org.uk/guidance/gid-ng10012/documents/evidence-review-2, page 8). The guideline recommendations do not steer the woman down a particular pathway unless indicated by the evidence of clinical and cost effectiveness. Many of the management recommendations contain a wide range of treatment alternatives.
Boston Scientific Ltd	Short	6	20	The benefit of 'see and treat' may not be routine practice everywhere, thereby reducing the attractiveness of hysteroscopy as a first line diagnostic	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made. Whilst current practice is varied, we do appreciate that some changes to service will be required to ensure that hysteroscopy services are organised according to best practice (including a service organisation that enables 'see and treat' in a single

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					setting where feasible). We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term, which is why the recommendation acknowledges that a service organisation that enables 'see and treat' in a single setting may not always be feasible.
Boston Scientific Ltd	Short	11	8	Interventional Radiology current practice has evolved to treat fibroids of less than 3cm with Uterine Artery Embolisation successfully and in a minimally invasive fashion. We would like the panel to consider adding UAE as a treatment option at this stage, since it is proven to be effective, preserves normal physiology and fertility, and reduces future morbidity and costs associated with hysterectomy such as prolapse.	Thank you for your comment. We did not find evidence for the effectiveness, acceptability and safety of UAE on treatment of fibroids less than 3 cm in diameter. The guideline committee agreed that since its use for small fibroids is not widespread in clinical practice, and in the absence of clinical evidence, UAE should not be recommended for fibroids under 3 cm in diameter.
British Society for Gynaecological Endoscopy	Short	General	General	Introduction of hysteroscopy as first line investigation for all women with HMB in whom polyps, submucosal fibroids or endometrial pathology are suspected will have the biggest impact on local practice. In Sheffield we have a well-established outpatient diagnostic and treatment service with seven clinicians involved (4 consultant gynaecologists, one associate specialist, one nurse hysteroscopist, one staff grade/trust doctor). We would need to expand our service and probably increase the number of diagnostic hysteroscopes so that at least two clinics could be run each day, as well as our supply of treatmetn scopes. Our biggest challenge would be to offer more 'See and treat' clinics as our current practice is to have two trained nurses in the room for such sessions. This	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. Whilst current practice is varied, we do appreciate that some change to service will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. However, NICE recommendations are intended to reflect the

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				policy is already limiting the number of 'See and treat' sessions. There are no local community hysteroscopy services in the city (Sheffield). If one was to be established then a diagnostic service(s) using a device such as the EndoSee would be relatively easy to set up. However, it is not clear how an endometrial biopsy using hysteroscopic techniques, if indicated, would be performed with the EndoSee device, other than taking a 'blind' endometrial sample. However, establishing a community 'See and treat' hysteroscopy service would be significantly more costly in terms of staff (nursing and the hysteroscopist) and equipment. It is not clear how GPs would be able to have the manpower to set up hysteroscopy services given the current pressures on their time. Nurse hysteroscopists may be able to provide a community service. Training a second nurse hysteroscopist would be possible in our Trust, particularly given that the demands on the nurse colposcopists are falling (there are reduced referrals for colposcopy). The reduction in demand for colposcopy clinics would also mean less competition for use of the shared clinic rooms.	best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made.
British Society for	Short	General	General	Yes. An increase in the hysteroscopy service would mean that more hysteroscopes would be required in Secondary	Thank you for your comment.

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Gynaecological Endoscopy				Care. Any Primary Care service would have to be starting from scratch, the cost would depend on whether just a diagnostic service was provided or a treatment one. As regards treatment options these are unlikely to change significantly as we have already moved towards offering laparoscopic hysterectomy as a first-line option for women suspected of adenomyosis, with second generation endometrial ablation targeted at women without significant risk of this condition. We have a well-established outpatient service for EA	Your comments will be considered by NICE where relevant support activity is being planned. Whilst current practice is varied, we do appreciate that some change to service will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. However, NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made. The committee agree that the management recommendations are unlikely to lead to large changes in current practice.
British Society for Gynaecological Endoscopy	Short	General	General	My biggest concern is the implementation of Best Practice for outpatient hysteroscopy given the experiences described by some patients. Apparently, it is the same units about which patients' complain, but I do not know which these are. If specific units are confirmed as undertaking less than good practice perhaps targeted visits may be appropriate. Does there need to be some means of assessing units and could there be RCOG/BSGE led unit	Thank you for your comment. It is not within the remit of a NICE guideline committee to make recommendations about how to audit implementation of their recommendations nor is it within NICE's remit to assess practice in particular locations. However, NICE does produce tools for audit and service improvement for health

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				for inspecting outpatient services? How can patients attending these units be protected? Might there be some way of licensing units who have can confirm adherence to Best Practice guidelines? Training is clearly important, but trainees and new consultants are not necessarily able to influence the practice of senior colleagues with established ways of performing hysteroscopy.	care providers that may be useful in the circumstances described. See https://www.nice.org.uk/about/what-we-do/into-practice/audit-and-service-improvement
British Society for Gynaecological Endoscopy	Short	General	General	1.5.21 If dilatation is needed for non-hysteroscopic endometrial ablation: 8 □ confirm that there is no evidence of uterine perforation or false passage 9 □ use hysteroscopy before inserting the ablation device, to establish the 10 condition of the uterus 11 □ use ultrasound to ensure correct uterine placement of the ablation 12 device; if the device uses a balloon, keep this inflated during the 13 ultrasound scan. **[2007, amended 2017]** **Does this mean an USS has to be done during every ablation? This could have implications as not all gynaecologists can scan, USS may not be available etc.**	Thank you for your comment. We have amended the recommendation to say 'ultrasound may be used' to be consistent with the guidance from the Medicines and Healthcare products Regulatory Agency.

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British Society for Gynaecological Endoscopy	Short	6	10	1.3.3 Given that you haven't done an USS how are you going to suspect polyps, fibroids etc? I agree with the recommendation as it stands but not as 1st line investigation since the quality of USS has also improved since 2007 and the endometrium can be very clearly visualised. Neither investigation is diagnostic of endometrial pathology, only histology is diagnostic and so a biopsy will be needed and the size of directed biopsies using small hysteroscopes means that something could easily be missed. The guideline states that intermenstrual and post-coital bleeding are outside the scope of the guideline and so I assume this means the Committee is suggesting hysteroscopy for all which is not acceptable and I think will not be acceptable to a lot of gynaecologists competent in scanning. Also, it doesn't allow assessment of intra-mural or sub-serosal fibroids but it would appear these can be ignored completely. Many women find hysteroscopy unpleasant however carefully it is done whereas USS is rarely unacceptable. I will be very surprised if this recommendation is followed and will await the results of future audits with interest!	Thank you for your comment. Intermenstrual and post-coital bleeding as symptoms are outside the scope of this guideline unless presenting alongside HMB. Uterine cavity abnormalities, i.e. submucosal fibroids and endometrial polyps, would usually be suspected if HMB co-existed with persistent intermenstrual bleeding. For women with these symptoms/conditions, the guideline recommends outpatient hysteroscopy as the first-line diagnostic investigation since it gives the best visualisation of the inside of the uterine cavity and in our evidence review showed better accuracy in detecting submucosal fibroids and polyps than an ultrasound scan. Hysteroscopy would also aid in the visualisation of the endometrium for taking an endometrial biopsy when endometrial pathology is suspected or there is a high risk for it. As noted in the comment, hysteroscopy would not detect fibroids outside the uterine cavity, however, submucosal fibroids cause HMB more commonly than fibroids outside the uterine cavity. If the woman has large subseroal or intramural fibroids, they would likely be detected in physical examination and the woman would then be offered a pelvic ultrasound as a first-line investigation. The guideline aims to improve accuracy and

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					effectiveness of diagnosis and avoid unnecessary imaging and blind biopsies that can miss existing pathology. At the same time, the guideline committee emphasises that outpatient hysteroscopy should be done according to best practice guidelines to improve patient acceptability and satisfaction and to reduce pain. Ideally, outpatient hysteroscopy could also be used as a one-stop 'see-and-treat' service in which submucosal fibroids or endometrial polyps can be removed.
British Society for Gynaecological Endoscopy	Short	6	18 19	Under 1.3.4 Ensure that outpatient hysteroscopy services are organised and the procedure is performed according to best practice, including: 'vaginoscopy as the standard technique, using miniature hysteroscopes (smaller than 3.5 mm)' *I suggest (smaller or equal to 3.5 mm), as many of the smaller/miniature hysteroscope sheaths are 3.5 mm diameter.*	Thank you for your comment. We have changed the recommendation to say 'smaller or equal to 3.5 mm' as suggested.
British Society for Gynaecological Endoscopy	Short	6	27	Under **Endometrial biopsy at the time of hysteroscopy** 1.3.7 Do not offer 'blind' endometrial biopsy to women with HMB. [2017] *This comment is confusing and ambiguous. 'Blind' endometrial biopsy is not defined in this document.* *Does 'blind' equate with 'global'?*	Thank you for your comment. The guideline committee agrees that the former wording of the recommendation was ambiguous. What was meant was the second suggestion in the comment and we have amended the recommendation to state 'Only obtain an endometrial sample in the context of diagnostic hysteroscopy. Do not offer 'blind' endometrial biopsy to women with HMB.'

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				It needs to be clear whether it means: *1) Do not obtain an endometrial sample using a device such as a Pipelle sampler.* *OR* *2) Only obtain an endometrial sample in the context of diagnostic hysteroscopy, you may then use a global device such as a Pipelle sampler.* *OR* *3) Do not obtain an endometrial sample using a device such as a Pipelle sampler even at hysteroscopy, but only take obtain endometrial tissue with a directed biopsy performed hysteroscopically (indications for obtaining an endometrial biopsy see 1.3.8).* *It must be remembered that a 'blind' endometrial sample with a device such as a Pipelle is cheap to perform and provides an accurate diagnosis, especially when supplemented with diagnostic hysteroscopy. It may be painful, but only for a brief time and often not more that the diagnostic hysteroscopy even when best practice is followed. Also, hysteroscopic techniques for removing tissue, such as the tissue removal systems (morcellators) are very expensive. Fine for removing polyps or fibroids as a 'see and treat' procedure and so avoiding two visits or even an inpatient procedure, but not a cost effective method of obtaining a global biopsy as a matter of routine.*	Therefore, a global device such as Pipelle can indeed be used as long as it is performed after visualisation of the endometrium via hysteroscopy. The definition of 'blind biopsy' can be found in the glossary in the Supplementary material document and we have amended the definition to 'biopsy taken without initial visualisation of the endometrium'. We hope these amendments make it clearer.

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British Society for Gynaecological Endoscopy	Short	7	1	1.3.8 Intermenstrual bleeding should be reviewed as a separate symptom and does not appear to have been reviewed separately. Many women with fibroids do not have IMB and vice versa. (check)) Scope)and presumably, therefore, has not been reviewed. It's inclusion is likely to affect the whole of the earlier points in the diagnosis section	**T**hank you for your comment. Women with intermenstrual bleeding are outside the scope of this guideline. The comment refers to the need for a review on intermenstrual bleeding and this has been passed to the NICE surveillance team.
British Society for Gynaecological Endoscopy	Short	13	17	The BSGE would like to thank the committee for all their hard work and for producing an excellent guideline. Comments from many members of the BSGE relate to the lack of guidance on route of Hysterectomy. Many BSGE members felt it is remarkable that there is no guidance offered on the route of hysterectomy. It is now accepted that Laparoscopic hysterectomy has considerable advantages over open hysterectomy; namely that blood loss is reduced, hospital stay is reduced and wound complications are reduced. Patients return to work and normal activities sooner, so there is a financial advantage to the state. Historic studies on complications associated with laparoscopic hysterectomy showed a higher rate of ureteric injury, but these studies were performed whilst many surgeons were still on their learning curve and at the inception of the procedure. These studies are now accepted as out of date and current experience has improved immensely leading to rapid growth in the technique. Indeed HES data presented at the 2017 BSGE ASM confirmed that over recent years laparoscopic	Thank you for your comment. The route of hysterectomy was not within the scope of the review as no new evidence had been identified in the surveillance review. However given current feedback from stakeholders, the topic of routes of hysterectomy has been flagged with the NICE surveillance review team. The committee performed an editorial review of the old recommendations relating to route of hysterectomy, and used their consensus to amend these to better reflect modern practice. The committee agreed that women should be given clear information about the routes of hysterectomy and that their preferences should be taken into account (see recommendation 1.5.17).

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				hysterectomy has been increasingly used and that in 2017 laparoscopic hysterectomy for benign indications is more commonly performed than open hysterectomy. So irrespective of out-dated publications, the most used route of hysterectomy is becoming laparoscopic by default. This is likely a reflection of surgeon experience and confidence, along with patient preference. NICE recommends the laparoscopic route for hysterectomy in patients with endometrial cancer as it aids faster recovery and is less morbid in obese patients who may otherwise have to risk poor wound healing with an open procedure. In addition, NICE recommends the laparoscopic route for patients with endometriosis, and we note that the new guideline on endometriosis is linked with this guideline, so it is unclear why the same recommendation is not present in the HMB guidelines. Why are patients with Heavy Menstrual Bleeding not being given clear information about the routes of hysterectomy and the advantages of the laparoscopic approach?	
British Society for Gynaecological Endoscopy	Short	18	22 - 24	**Endometrial biopsy at the time of hysteroscopy** 'Blind' endometrial biopsy is not recommended because it may not identify treatable lesions and it is painful for women. *The term 'blind' is ambiguous and confusing. Does it mean do not take a global endometrial biopsy with a device such as a Pipelle sampler, or other similar device? If not a global sample then a directed biopsy with a tiny 5 french*	Thank you for your comment. The guideline committee recommends that endometrial biopsy should be taken in the context of hysteroscopy but not necessarily with a hysteroscopic technique, i.e. once the endometrium has been visualised, a global sampler such as Pipelle could be used. The definition of 'blind biopsy' can be found in the glossary in the Supplementary material document and we amended it to 'biopsy taken without initial

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				grasper (miniscule sample), or a very expensive tissue removal device (Truclear, Myosure)? The latter are great to use for removing polyps and small submucosal fibroids, or when obtaining a substantial sample of polypoid endometrium is wanted, but to replace all global sampling devices?? The cost! Also, please note the diameter of the tissue removal systems, Truclear is 5mm without the outflow sheat, 5.6 mm with; Myosure is 6.25 mm diameter. *If not the tissue removal systems, then what is being suggested for taking an endometrial biopsy if performing a diagnostic hysteroscopy with a 3.5 mm, or less, sheathed hysteroscope?* *Yes, global endometrial sampling can be painful, but it is not for long, and not necessarily more painful than the hysteroscopic examination.* *Is this the end for all endometrial-sampling devices? What about when monitoring women with known endometrial hyperplasia undergoing treatment? Are we supposed to be offering them diagnostic hysteroscopy instead? Surely, this would be much more expensive and invasive than a simple endometrial sample? What is the evidence that this would be less painful? What is the evidence that it is less accurate?*	visualisation of the endometrium', which we hope is less confusing. We have also amended the recommendation on endometrial biopsy to state 'Only obtain an endometrial sample in the context of diagnostic hysteroscopy. Do not offer 'blind' endometrial biopsy to women with HMB.' for clarity. We have also amended the wording of the recommendation on outpatient hysteroscopy to specifically refer to diagnostic hysteroscopy when referring to vaginoscopic technique with miniature hysteroscopes. We recognise that a bigger hysterosope would have to be used for removal of fibroids or polyps. The guideline committee thinks that currently many women undergo painful endometrial biopsies unnecessarily. The new guidance aims to clarify when endometrial biopsy should be taken and to improve the effectiveness of the biopsy by taking it only with hysteroscopic visualisation of the endometrium.
British Society for	Short	19	22 - 15	Under **How the 2017 recommendations might affect practice**	Thank you for your comment. The guideline committee thinks that currently many women

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Gynaecological Endoscopy		20		*There is no reference here to the avoidance of obtaining endometrial pathology, which is an important proposed change in practice as many gynaecologists, nurse hysteroscopists and some GPs will have learnt to obtain an endometrial sample in women with HMB just because of their age, that is 45 years or more. If age alone is no longer regarded as a risk factor for endometrial pathology (ie. hyperplasia or malignancy) than this would helpful to have it clearly stated as part of the main guideline and not just in the* Recommendations that have been deleted or changed. *Conversely, does it mean that all women with HMB who have any risk factor (BMI, PCOS, infrequent but heavy menses) for endometrial pathology should be offered diagnostic hysteroscopy and endometrial biopsy regardless of their age, so women from early 30's onwards, for example?*	undergo painful endometrial biopsies unnecessarily. While the clinicians see it a simple intervention, there is growing body of evidence showing that it is a painful procedure for the woman and one that adversely affects satisfaction with treatment. We recommend that endometrial biopsies should only be taken when there is a suspected increased risk for endometrial pathology. The guideline committee considered the cut-off of 45 years to be arbitrary and no longer an appropriate indicator for increased risk for endometrial pathology whereas other clinical factors, such as obesity and polycystic ovary syndrome outweigh the age of 45 years as a risk factor. This was, however, an old recommendation which was only amended by the 2017 guideline committee and therefore, wider discussion of this is not part of the evidence review reports.
British Society for Gynaecological Endoscopy	Short	38	General	Under **Recommendations that have been deleted or changed** use ultrasound to ensure correct uterine placement of the ablation device; if the device uses a balloon, keep this inflated during the ultrasound scan. (1.5.21)	Thank you for your comment. We have amended the recommendation to say 'ultrasound may be used' to be consistent with the guidance from the Medicines and Healthcare products Regulatory Agency.

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				The MHRA document providing guidance on endometrial ablation February 2011 states: • Immediately after dilatation of the cervix and prior to positioning the device for treatment, assess cavity for perforation, false passage or even trauma to the uterine wall, using hysteroscopy • Ultrasonography following insertion of the device, and before activation, may be used by those fully trained in its use to help ensure that the myometrium has not been partially penetrated or even perforated • If an operator has any doubts that the device is not correctly positioned, remove the device and re-check the cavity with the hysteroscope, if any evidence of myometrial trauma the procedure must be abandoned. *There is no recommendation by the MHRA that ultrasound **should** be used. It was recognised by the committee at the time, of which I was a member, and remains the case, that not all hysteroscopists are also skilled sonographers. Also, it was felt by the committee that the more difficult balloon insertions were with the acutely retroverted uterus when a view of the balloon in the cavity was more difficult and not necessarily possible, regardless of scan expertise. Viewing*	

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				the uterine cavity hysteroscopically following cervical dilatation was regarded as the most useful investigation to avoid treating a perforated uterine cavity.	
British Society for Gynaecological Endoscopy	General	General	General	Were there any experts in Ultrasound on the Committee?	Thank you for your comment. The constitution of the committee incorporated all the disciplines involved in the management of HMB. The size of the committee reflected the relative proportions of individual specialties involved in the management of HMB and content of the scope of this update. The committee included lay representatives (x2) in addition to representation from nursing (x2), gynaecology (x3), general practice/primary care (x2) and a co-opted interventional radiologist. We feel this mix was the right balance to produce the guideline. We accept that there are value judgements with respect to the optimal composition of the committee and that some stakeholders might disagree with the final composition. Nevertheless, the guideline committee is constrained to work according to NICE methods and processes, making recommendations based on the best available evidence and being transparent in providing a rationale for those recommendations. The stakeholder consultation is a crucial part in scrutinising those recommendations (and rationale) and is open to all interested parties.

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British Society for Gynaecological Endoscopy	ER A	39	16 - 17	Under **Investigations for women with HMB** vaginoscopy as the standard technique, using miniature hysteroscopes (smaller than 3.5 mm) *As above in Comment 1, suggest 'smaller or equal to 3.5 mm' for precision and clarity.*	Thank you for your comment. We have changed the recommendation to say 'smaller or equal to 3.5 mm' as suggested.
British Society for Gynaecological Endoscopy	ER A	39	25	Under **Endometrial biopsy at the time of hysteroscopy** A6. Do not offer 'blind' endometrial biopsy to women with HMB. *A global endometrial sample (such as Pipelle biopsy) when a diffuse endometrial abnormality has been seen at hysteroscopy would establish the nature of the endometrium at significantly lower cost and than using a hysteroscopic tissue removal system and with a greater quantity of tissue than a directed biopsy using a small 5 french forcep.*	Thank you for your comment. The guideline committee recommends that endometrial biopsy should be taken in the context of hysteroscopy but not necessarily with a hysteroscopic technique, i.e. once the endometrium has been visualised, a global sampler such as Pipelle could be used. We have edited the wording in the evidence report to indicate this. We have also amended the recommendation on endometrial biopsy to state 'Only obtain an endometrial sample in the context of diagnostic hysteroscopy. Do not offer 'blind' endometrial biopsy to women with HMB.' for clarity.
British Society for Gynaecological Endoscopy	ER A	46	10 - 18	**Evidence reviews for diagnostic test accuracy in investigation for women presenting with heavy menstrual bleeding** The committee considered a blind biopsy to be painful and emphasised that blind biopsy may miss treatable pathology, thus should not be conducted in women presenting with HMB. An endometrial biopsy was only	Thank you for your comment. The guideline committee recommends that endometrial biopsy should be taken in the context of hysteroscopy but not necessarily with a hysteroscopic technique, i.e. once the endometrium has been visualised, a global sampler such as Pipelle could be used. We have edited the wording in the evidence report to indicate this. We have also amended the recommendation on

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				deemed necessary in women at high risk of endometrial hyperplasia or malignancy. According to the committee's knowledge and expertise, these include obese women, women with persistent intermenstrual bleeding, irregular bleeding or infrequent bleeding, women taking tamoxifen, and women in whom treatment has failed or was ineffective. In these circumstances a biopsy should be taken via hysteroscopic techniques in line with RCOG best practice guidelines (RCOG and BSGE 2011). *Following scrutiny of the RCOG BSGE 2011 Best Practice Guidelines there is nothing describing the hysteroscopic techniques referred to in lines 17 & 18 to be found. A description of these would be helpful given that the 'blind' techniques are painful, a comment with which I would concur, but not necessarily that they are too painful. The blind devices are cheap compared with the hysteroscopic techniques (tissue removal systems, Truclear and Myosure) with which I am familiar that provide a substantial amount of material. These are appropriate on occasions (endometrial polyps, small submucosal fibroids, diffuse polypoidal changes), but not always. (There is a new device available that can be passed down the hysteroscope sheath with a spring-handle action that morcellates tissue, but I haven't used it).*	endometrial biopsy to state 'Only obtain an endometrial sample in the context of diagnostic hysteroscopy. Do not offer 'blind' endometrial biopsy to women with HMB.' for clarity.
British Society for Gynaecologi	Economic Analysis	General	General	Why is LNG-IUS included in an economic review of diagnosis.	Thank you for your comment.

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cal Endoscopy				This is 1 of the most bizarre cost effectiveness analyses I have ever read. It doesn't really look at diagnosis at all in most instances. It fails to do a number of things: 1. Recognise that the quality of USS has improved considerably. 2. More than 1 pathology may coexist. Perhaps the Committee has not heard of PALM-COIEN which is now the accepted way of assessing the cause and classification of AUB and recognises that more than 1 pathology may and often does, coexist. 3. Hysteroscopy is more invasive than scanning even in the best hands. 4. There is no possibility that hysteroscopy that requires disposable equipment and is done in a secondary care setting can be better economic value than an ultrasound. The chance of many being done in primary care is minute. Very good for private practice though. 5. The incidence of endometrial cancer in a pre-menopausal woman without risk factors is extremely low. 6. The insertion of LNG-IUS does not require a hysteroscopy or a biopsy in most women. 7. A randomised study comparing USS and Hysteroscopy that investigates quality of life (Critchley et al) is considered as too old i.e. it does not support the possible preconceived prejudices	The study by Cooper (2014) sought to compare diagnostic strategies for HMB (see https://www.journalslibrary.nihr.ac.uk/hta/hta18240/#/abstract). Empirical treatment with LNG-IUS was considered as an alternative to diagnostic strategies as that reflected NICE guidance. More generally, it is important to consider treatment in an economic evaluation of diagnosis as the benefits of diagnosis are largely predicated on the outcomes of treatment. The guideline text has been amended to make it clearer that 2 empirical treatment strategies (LNG-IUS alone and hysterctomy alone) were included in the strategies evaluated in the Cooper (2014) study. The model allows a comparison of a wide variety of diagnostic treatment strategies, including empirical treatment as an alternative to strategies starting with a diagnostic test. All of the results presented in the analysis include strategies which start with a diagnostic test. 1. The economic model utilises the evidence of the clinical review of diagnostic accuracy undertaken for this guideline. Stakeholders have not identified studies missed by this review. The guideline committee recognises that the quality of technology for ultrasound scanning has developed and the detection of fibroids and adenomyosis through

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				of some of the Committee members). I accept that equipment has improved but there will still be problems with hysteroscopy in some women who find it unpleasant and invasive even if not particularly painful. Also, distending the uterus is often the most painful part of the procedure. Also, why is this considered a very low-quality study? 8. Why are the Indian Study of USS published in 2002and the Danish study published in 2001 included? Equipment has vastly improved, more so than for hysteroscopy. 9. Hysteroscopy can only detect sub-mucous fibroids and there is no conclusive evidence that those in other sites in the uterus are not involved in the aetiology of menstrual disorder. The assumption that only cavity lesions cause AUB is completely wrong. 10. Many polyps are asymptomatic and the evidence they lead to HMB is tenuous at best. 11. No one in their right mind would diagnose endometrial cancer or even hyperplasia without an endometrial biopsy and so much of the discussion of endometrial pathology is meaningless. 12. Page 31 1st 2 paragraphs. Can't quite see why LNG-IUS is in the discussion of diagnosis. 13. The recommendations based on Very Low quality evidence are too strong.	ultrasound has improved considerably over time. However, for submucosal fibroids and endometrial polyps, the accuracy of hysteroscopy is still superior also allowing for a targeted endometrial biopsy as well as a 'see-and-treat' service. 2. All models require simplifying assumptions. We followed the approach of a recently published UK HTA (see https://www.journalslibrary.nihr.ac.uk/hta/hta18240/#/abstract) which stated that a "single underlying aetiology was assumed to be causative and concurrent pathologies were not considered. This assumption is in keeping with most HMB cases and prevented unnecessary model complexity". This assumption is discussed in the guideline section "Underlying pathology and prevalence". 3. We accept that this is not explicitly addressed in the economic analysis. Due to the short duration of the test any impact on health related quality of life would be negligible. However, in the context of the guideline more generally it is recognised that this may be an important factor in a woman's choice. 4. It isn't exactly clear what is meant by this comment. According to the NHS Reference Costs used in the model, hysteroscopy is a more expensive test than ultrasound but the determination

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					of "economic value" is much more complex than the unit costs of the tests. So for example, including underlying pathology, the possibility of 'see and treat' with diagnostic hysteroscopy and the ability of the diagnostic test to direct the woman to appropriate treatment will all influence cost-effectiveness. 5. The model excluded endometrial disease as an underlying pathology in the model for this reason. "It was thought that the risk of endometrial disease was so low in the model population that it could reasonably be excluded". 6. The model includes strategies where LNG-IUS is inserted without a prior diagnostic test (empirical treatment). However, the model also includes other strategies where LNG-IUS might be the first-line treatment after a diagnostic test. 7. The study by Critchley et al. (2004) used techniques and practices that are outdated in current practice and the guideline committee agreed that the evidence from this study should not be used to make recommendations. The guideline committee recognises that some women find outpatient hysteroscopy unpleasant, invasive and painful, however, the recommendations aim to minimise the discomfort by emphasising that outpatient

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					hysteroscopy should be performed according to the current best practice guidelines. The evidence from the Critchley study was considered to be of very low quality because in the assessment of risk of bias the following concerns were raised. a) High risk of performance bias and detection bias because blinding of participants and personnel was not possible due to the nature of the interventions. All the outcomes of interest for the guideline review were subjective outcomes reported by the participants and since they could not be blinded there is a high risk of bias. b) High risk of attrition bias. Only around 70% of eligible participants were recruited to the trial and outcome data at 10 months and at 24 months was only available for 80% and 56% of the participants, respectively. c) Unclear risk of reporting bias. Statistical analysis was done selectively and for the outcomes of interest the article mainly reports descriptive data without statistical analysis of differences between groups. 8. We included studies published post-2000 but being aware of improvements in technology we conducted sensitivity analyses when high heterogeneity was detected in meta-analysis by excluding studies published before 2007. However, this did not change the results.

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					9. The committee agreed that outpatient hysteroscopy should be offered to women to identify causes of HMB when history suggests submucosal fibroids, polyps or endometrial pathology. In the committee's discussion of the evidence it is noted that "Because hysteroscopy is not able to detect abnormalities outside the uterine cavity, the committee agreed that pelvic ultrasound (TVUS and/or TAUS) should be offered to women whose history and examination suggest larger fibroids. In detecting adenomyosis the committee recommended the first-line investigation for suspected adenomyosis to be TVUS. The health economic analysis did not triage patients by history but sensitivity for the detection of subserosal fibroids in the analysis is 0%. Often an underlying cause is not identified for HMB and hysteroscopy will often "correctly identify" this from a negative result for other underlying pathology. 10. The guideline committee would agree that many polyps are asymptomatic and often do not cause HMB. The prevalence of underlying pathologies used in the health economic model and the source of the

					estimates is discussed in the health economics chapter under the heading "Underlying pathology and prevalence". 11. We are unsure what the comment is referring to here. The guideline does not make recommendations that endometrial cancer or hyperplasia be diagnosed without biopsy. The health economic analysis excluded endometrial pathology from the model population. However, this analysis followed the approach of a recently published UK HTA (Cooper 2014) which allowed for a false positive rate for endometrial disease for non-biopsy tests if that is what the comment is alluding to. 12. Empirical treatment with LNG-IUS was considered as an alternative to diagnostic strategies as that reflected NICE guidance both in the HTA being reviewed and in the health economic analysis developed for the guideline. The guideline text has been revised to make it clearer that empirical treatment strategies were considered as alternative to diagnostic strategies in the Cooper (2014) study. "One cost-utility analysis (Cooper 2014) undertaken in the UK included 13 different strategies: transvaginal ultrasound scan, saline infusion sonography, global endometrial biopsy and

					outpatient hysteroscopy used alone, or in combination. LNG-IUS alone and hysterectomy alone were also included as empiric treatment strategies." 13. It is not entirely clear which recommendations this comment relates to. In the committee's discussion of the evidence it is noted that the populations in the included studies were not always identical to the population of interest in this guideline (premenopausal women with HMB). The committee had agreed in the review protocol that one third of the women included in the studies could be other than women with HMB, for example, women with pelvic pain without HMB. Therefore, most studies in these reviews included a proportion of women that were not directly the population of interest. This contributed to the downgrading of the quality of the evidence, however, the committee agreed that the diagnostic test accuracy would not be expected to differ in a population that was not directly of interest and thus found it appropriate to make 'strong' recommendations in order to facilitate detecting any underlying pathology and appropriate treatment.

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British Society for Gynaecological Endoscopy	App A	7	Glossary	Blind Biopsy Biopsy taken without visual guidance or strong evidence of localised disease. *The term ' Biopsy taken without visual guidance' is simple to understand. However, 'Biopsy taken without strong evidence of localised disease' is less clear. What if the disease is not localised, but there is a diffuse endometrial change? This could have been identified at hysteroscopy, is it then appropriate to perform a 'blind' or global endometrial biopsy using such devices as an endometrial sampler (Pipelle)?*	Thank you for your comment. We have amended the definition of 'blind biopsy' in the glossary to 'biopsy taken without initial visualisation of the endomterium' for clarity. As the comment suggests, when a diffuse endometrial change has been identified via hysteroscopy, an endometrial biopsy using a global device could be used. This would not be considered a 'blind' biopsy since visualisation of the endometrium was done. We have also amended the recommendation to say 'Obtain an endometrial sample only in the context of diagnostic hysteroscopy. Do not offer ‘blind’ endometrial biopsy to women with HMB.' for clarity.
British Society of Interventional Radiology	Short	7	General	1.3.9 & 1.3.10: Delete the use of "2-dimensional pelvic ultrasound". Either use the term trans abdominal or trans-vaginal. As with modern Ultrasound we are able to perform 3D and 4D imaging this term is outdated. Please state the evidence used to state that US is better then MRI when considering that the use of US is entirely operator dependent where-as MRI is not.	Thank you for your comment. The guideline committee has amended the recommendation by taking out the word '2-dimensional' as it can become outdated as indicated in the comment. We agree that the accuracy of pelvic ultrasound depends on the skills and expertise of the scanner. The evidence underlying this recommendation is presented in detail in the Diagnosis evidence report.
British Society of Interventional Radiology	Short	7	General	1.3.9 & 1.3.10: Delete the use of "2-dimensional pelvic ultrasound". Either use the term trans abdominal or trans-vaginal. As with modern Ultrasound we are able to perform 3D and 4D imaging this term is outdated.	Thank you for your comment. The guideline committee has amended the recommendation by taking out the word '2-dimensional' as it can become outdated as indicated in the comment. We agree that the accuracy of pelvic ultrasound depends on the skills and expertise of the scanner. The evidence

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				Please state the evidence used to state that US is better then MRI when considering that the use of US is entirely operator dependent where-as MRI is not.	underlying this recommendation is presented in detail in the Diagnosis evidence report.
British Society of Interventional Radiology	Short	11	General	1.5.4: Uterine artery embolisation should be added as an option if you are considering hysterectomy. UAE works for both small symptomatic fibroids and adenomyosis. It does not exclude hysterectomy in the future but may prevent it and all the morbidity associated. It is stated in the subsequent section - therefore makes no sense to exclude in this.	Thank you for your comment. We did not find evidence for the effectiveness, acceptability and safety of UAE on treatment of fibroids less than 3 cm in diameter or adenomyosis. The guideline committee agreed that since its use for small fibroids or adenomyosis is not widespread in clinical practice, and in the absence of clinical evidence, UAE should not be recommended for fibroids under 3 cm in diameter or adenomyosis. In the committees discussion of the evidence they noted: "No eligible evidence was found on the use of UAE for the management of adenomyosis. However, the committee were aware of the interventional procedural guidance on UAE for treating adenomyosis (IPG473, NICE 2013). This report concluded that UAE is efficacious for symptom relief in the short term and medium term for a substantial proportion of women, with no major safety concerns. However it was also noted that symptoms may return and that further procedures may be needed. In the absence of evidence for long term effectiveness the committee did not feel it

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					could recommend UAE for the treatment of adenomyosis."
British Society of Interventional Radiology	Short	11	General	1.5.4: Uterine artery embolisation should be added as an option if you are considering hysterectomy. UAE works for both small symptomatic fibroids and adenomyosis. It does not exclude hysterectomy in the future but may prevent it and all the morbidity associated. It is stated in the subsequent section - therefore makes no sense to exclude in this.	Thank you for your comment. We did not find evidence for the effectiveness, acceptability and safety of UAE on treatment of fibroids less than 3 cm in diameter or adenomyosis. The guideline committee agreed that since its use for small fibroids or adenomyosis is not widespread in clinical practice, and in the absence of clinical evidence, UAE should not be recommended for fibroids under 3 cm in diameter or adenomyosis. In the committees discussion of the evidence they noted: "No eligible evidence was found on the use of UAE for the management of adenomyosis. However, the committee were aware of the interventional procedural guidance on UAE for treating adenomyosis (IPG473, NICE 2013). This report concluded that UAE is efficacious for symptom relief in the short term and medium term for a substantial proportion of women, with no major safety concerns. However it was also noted that symptoms may return and that further procedures may be needed. In the absence of evidence for long term effectiveness the committee did not feel it could recommend UAE for the treatment of adenomyosis."

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British Society of Interventional Radiology	General	General	General	BSIR (representing all its IR members) has serious concerns regarding this document and the lack of integration of known, tried and tested interventional treatments which are cost effective for female patients. We are concerned that the routine use of diagnostic ultrasound has been removed as a first line examination in HMP. It is cheap and easy and helps diagnose conditions within the uterine wall and outside the uterus. It has to date a zero mortality. The statement that all first line diagnosis should be hysteroscopy is not proven. It has a significant cost and is associated with a significant complications and mortality. If this is to be recommended then patients should be informed of these matters. UFE should be considered for fibroids < 3cm and in adenomyosis. Patients should be informed of the total options. MRgFUS is not even mentioned as an option. Endometrial ablation is mentioned with very little data to support and has clear issues with regard the potential for self referral.	Thank you for your comment. The guideline does not suggest that hysteroscopy should be the first-line diagnostic investigation for all women with HMB but for women with HMB for whom history and/or examination suggest uterine cavity abnormalities or endometrial pathology. For women with suspected large fibroids or suspected adenomyosis, ultrasound scan should be the first-line diagnostic investigation. Women with HMB with a high risk of endometrial pathology should be offered an endometrial biopsy that is obtained in the context of hysteroscopy to ensure that the biopsy is targeted and therefore can effectively identify endometrial pathology. We are not aware of evidence that diagnostic hysteroscopy is associated with mortality and if done according to best practice guidelines, should have low rates of complications. Part of best practice is to inform the woman about the procedure including its risks and benefits. We did not find any evidence from randomised controlled trials on the effectiveness and safety of uterine artery embolisation on fibroids less than 3 cm in diameter or adenomyosis or MRgFUS on fibroids. The guideline committee also agreed they are not widely performed in practice. In the absence of trial evidence, and without widespread use in clinical practice, the guideline committee did not find it appropriate to recommend the use of UAE

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				Joint clinics and referral to IR clinics should be mandatory to allow patients to have fully informed decisions regarding their treatment.	for fibroids smaller than 3 cm in diameter or adenomyosis, or MRgFUS on fibroids. On the other hand we did find evidence from over 40 randomised controlled trials on the effectiveness and safety of different endometrial ablation techniques. The evidence is presented in the Management evidence report document.
City Health Care Partnership	Short	11	1	Option currently reads: "Cyclical oral progestogens" – could we consider changing this to "Cyclical or continuous oral progestogens **or** continuous intramuscular/ subcutaneous progestogens (including Medroxyprogesterone Acetate)"? Reason for request: • There is no proven benefit as far as I know for a cyclical approach to treatment • Continuous intramuscular/ subcutaneous Medroxyprogesterone Acetate which lowers estradiol levels is likely to be of more benefit in the case of small fibroids compared to a cyclical progestogen Cyclical Norethisterone is likely to be particularly less desirable in the case of fibroids due to conversion to estradiol	Thank you for your comment. In our evidence review and analysis, we found evidence that cyclical oral progestogen can be effective in treating HMB. However, we did not find any evidence on the effectiveness of continuous progestogens and have therefore included a research recommendation on the effectiveness of the progestogen-only pill, injectable progestogens, or progestogen implants in alleviating HMB. The guideline committee is, however, aware that in clinical practice continuous progestogen is used to treat HMB and is aware that in its licensed use as a contraceptive it may suppress menstruation and therefore could benefit a woman with HMB. We have added a recommendation about this. In our evidence review we did not compare the effectiveness of different progestogens, therefore, we do not recommend a specific progestogen.
City Health Care Partnership	Short	12	17	Option currently reads: "Cyclical oral progestogens" – could we consider changing this to "Cyclical or continuous oral progestogens **or** continuous intramuscular/	Thank you for your comment. In our evidence review and analysis, we found evidence that cyclical oral progestogen can be effective in treating

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				subcutaneous progestogens (including Medroxyprogesterone Acetate)"? Reason for request: • There is no proven benefit as far as I know for a cyclical approach to treatment • Continuous intramuscular/ subcutaneous Medroxyprogesterone Acetate which lowers estradiol levels is likely to be of more benefit in the case of small fibroids compared to a cyclical progestogen Cyclical Norethisterone is likely to be particularly less desirable in the case of fibroids due to conversion to estradiol	HMB. However, we did not find any evidence on the effectiveness of continuous progestogens and have therefore included a research recommendation on the effectiveness of the progestogen-only pill, injectable progestogens, and progestogen implants in alleviating HMB. The guideline committee is, however, aware that in clinical practice continuous progestogen is used to treat HMB and is aware that in its licensed use as a contraceptive it may suppress menstruation and therefore could benefit a woman with HMB. We have added a recommendation about this.
Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health	Short	General	General	The CEU has major concerns about the wholesale move to recommend hysteroscopy as first line for management of heavy menstrual bleeding. The previous recommendation for an ultrasound scan followed by endometrial biopsy was simple to organise, highly acceptable to women and cost effective. This has been extensively followed in primary care and community sexual and reproductive health clinics saving many women the need to attend secondary services for an operative procedure. The CEU would question the evidence to support women now needing hysteroscopy over management based on ultrasound and endometrial biopsy.	Thank you for your comment. The guideline does not recommend that hysteroscopy should be offered to all women with HMB but for women with HMB for whom history and examination suggest uterine cavity abnormalities or endometrial pathology. Women whose history and/or examination do not suggest structural or histological abnormality can go on to receive treatment without diagnostic investigations. Women with suspected large fibroids or adenomyosis would be offered an ultrasound scan. As you say, current practice is to an offer ultrasound scan and an endometrial biopsy. The evidence reviewed for this guideline suggested that

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					hysteroscopy allows for more accurate detection or exclusion of uterine cavity abnormalities than pelvic ultrasound. In addition, many women undergo painful endometrial biopsy unnecessarily and 'blind' biopsies might miss pathology. We recommend that endometrial biopsy should be taken only in the context of hysteroscopy and only when there is an increased risk for endometrial pathology or when there is visual proof of suspected abnormality. The guideline committee believes that the recommendations will allow women to be offered the most accurate and cost-effective diagnostic investigations which will help to identify the most appropriate management. For women with submucosal fibroids, hysteroscopy would also allow for a 'see and treat' service where fibroids would be removed immediately once identified. This could speed up effective treatment for women and result in cost savings.
Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health	Short	4	10	Symptoms of intra-cavity abnormality – this is not well defined. Does it essentially mean 'intermenstrual bleeding'. It would be more helpful if it was more specific.	Thank you for your comment. Persistent intermenstrual bleeding together with HMB are considered to be the main symptoms of uterine cavity abnormalities. We have amended the recommendations to say 'persistent intermenstrual bleeding'. We have also changed 'intracavitary abnormality' to 'uterine cavity abnormality' for clarity and consistency with terminology used in clinical practice.

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Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health	Short	20	2	Primary Care is currently at breaking point in terms of workload. To expect a significant number of GPs and practice nurses to train in hysteroscopy to meet the demand following NICE recommendations is totally unrealistic.	Thank you for your comment. Whilst current practice is varied, we do appreciate that some change to service organisation and staff training will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. However, NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made.
Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health	Short	20	4	It is very difficult to believe that arranging hysteroscopy for all women will result in any cost savings.	Thank you for your comment. The guideline does not recommend that hysteroscopy should be the offered to all women with HMB but for women with HMB for whom history and examination suggest uterine cavity abnormalities or high risk of endometrial pathology. Women whose history and/or examination do not suggest abnormalities could go on to receive treatment without diagnostic investigations. Women with suspected large fibroids or adenomyosis would be offered an ultrasound scan. The guideline committee hopes that the recommendations will allow women to be offered the most accurate and cost-effective diagnostic investigations depending on the findings of the

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					history and examination. Offering the best investigation will consequently allow for the most appropriate treatment options to be considered. In current practice, ultrasound scan and a 'blind' biopsy are the most common investigations. In the guideline committee's view, currently many women undergo painful endometrial biopsy unnecessarily and the accuracy of ultrasound can be low resulting in false diagnosis, missed diagnosis and further referral to hysteroscopy. The new recommendations aim to avoid these which consequently can result in cost savings. For women with submucosal fibroids, hysteroscopy would also allow for a 'see and treat' service where fibroids would be removed immediately once identified. This could speed up effective treatment for women and result in cost savings, providing that safety of the service is assured.
FEmISA	Short	General	General	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]	Thank you for your comment. The change to recommendation 1.2.4 was discussed in the consultation documentation (see https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline, page 35). "Postcoital bleeding has been taken out because it is not a usual symptom of uterine cavity abnormality, histological abnormality or adenomyosis." The

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				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. <u>Whether menstrual blood loss is a problem should be determined not by measuring blood loss but by the woman herself. [2007]</u>"* 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]"*	other symptoms have been removed from this recommendation but there is a cross-reference to an earlier recommendation on history taking where the symptoms are covered: '1.2.1 Take a history from the woman that covers: • the nature of the bleeding • related symptoms such as persistent intermenstrual bleeding, pelvic pain and/or pressure symptoms that might suggest uterine cavity abnormality, histological abnormality, adenomyosis or fibroids' The rationale for deleting this recommendation was given in https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline (see page 27). Deleting this recommendation does not imply that it is for the healthcare professional to determine whether the symptoms are problematic. Rather it reflects that PBAC are no longer used in routine clinical practice in the NHS making the recommendation obsolete/academic. The guideline committee does not believe that this change in terminology (replacing 'structural abnormality' with 'uterine cavity abnormality') will have implications for the diagnosis of other causes of HMB as the terms have a similar meaning but uterine cavity abnormality is considered to be more

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				This has been removed and needs to be reinstated as it will delay proper diagnosis and treatment.	precise. Endometriosis is outside of the scope of this guideline. The guidelines have been revised to ensure women are offered a choice of effective treatment options which are listed in recommendation 1.5.10. This may include immediate referral to secondary care if that is the woman's choice, which would seem likely if the symptoms are significant (see recommendation 1.5.7), but she could also opt for alternative treatments and may value remaining in primary care for these. In particular, the use of ulipristal is new since the 2007 guideline and this could be started in primary care as a first-line treatment. The committee did not agree that proper diagnosis would be delayed as primary care is able to organise an ultrasound scan which is the best initial diagnostic test where fibroids are suspected.
FEmISA	Short	Training - Missing	General	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]	Thank you for your comment. The deletion of these recommendations was discussed in the consultation documentation (see https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline, starting page 33). Whilst many of these recommendations describe good practice they could be said to apply across all specialities. Furthermore, NICE no longer makes

				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.*	general recommendations on training, which is the responsibility of the relevant professional bodies.

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				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/*	
FEmISA	Short	Training - Missing	General	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	Thank you for your comment. NICE no longer makes recommendations on the education and training of healthcare professionals, which is the responsibility of relevant professional bodies, for example: https://www.rcog.org.uk/en/careers-training/ https://www.rcog.org.uk/en/cpd-revalidation/cpd-guide/ https://www.rcog.org.uk/en/courses-exams-events/ http://www.gmc-uk.org/education/continuing_professional_development/26758.asp.

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FEmISA	Short	Maintenance - missing	General	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**	Thank you for your comment. The maintenance of the skills of healthcare professionals is not part of NICE's remit and NICE no longer makes recommendations on the education and training of health care professionals, which is the responsibility of relevant professional bodies, for example: https://www.rcog.org.uk/en/careers-training/ https://www.rcog.org.uk/en/cpd-revalidation/cpd-guide/ https://www.rcog.org.uk/en/courses-exams-events/ http://www.gmc-uk.org/education/continuing_professional_development/26758.asp. It is not within the remit of NICE guidelines to make recommendations on the publication of individual performance/outcome data for gynaecologists.

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				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.	
FEmISA	Short	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	Thank you for your comment. This section was not covered by the partial update of the guideline. Some amendments were made to change terminology and adenomyosis was added since it was not included in the 2007 guideline. The guideline does not suggest that a diagnosis of the causes of HMB could be made solely based on history. Instead history should guide whether or not examination and further investigations are needed. Many women with HMB will find effective relief from pharmacological treatments without the need to go through investigations such as an ultrasound scan or hysteroscopy. However, if the history suggests an abnormality, examination and investigations should take place to guide the choice for subsequent treatment.

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				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.	
FEmISA	Short	6	8 - 14	The 2007 version needs to be put back - 1.2.14 Imaging should be undertaken in the following circumstances: • 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	Thank you for your comment. For clarity, the developer's response is presented under the same headings as in the comment. **<u>The 2007 version needs to be put back</u>** The new guideline recommendations have resulted from a rigorous review of the best available evidence addressing clinical and cost-effectiveness of various investigations. While the format and sequence of the recommendations are not necessarily identical to the 2007 guideline, the updated indications and respective roles for ultrasound scan and hysteroscopy have been presented in various sections of the guideline. For instance, the new guideline continues to recommend ultrasound (imaging) where the uterus is palpable abdominally and where a history or examination suggests a pelvic mass. **<u>New guidelines</u>** The review of the best available evidence regarding the respective roles of hysteroscopy and ultrasound scan, their clinical and cost-effectiveness, concluded that hysteroscopy was the primary investigation of

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				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."***	choice in women with suspected uterine cavity lesions such as polyps, submucosal fibroids or endometrial pathology. Hysteroscopy was superior to ultrasound scan in this group of women. In other women, empirical treatment can and often is started prior to investigations and this is reflected in the guideline recommendations. The guideline also recommends an ultrasound scan as the primary investigation in other groups (see comment above). In addition, the guideline acknowledges that MRI can be useful in selected women. For instance, the guideline recommends that in the context of suspected 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." Telescopic examination of the uterine cavity (hysteroscopy) is not a new intervention and has been used in day-to-day gynaecological practice since the 1970s with even earlier reports (see http://emedicine.medscape.com/article/267021-overview#a7). Around 100,000 diagnostic hysteroscopy procedures are undertaken in NHS Trusts each year (NHS Reference Costs 2015/16).

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				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.***	This is a minimally invasive procedure that is well established and universally considered to be safe, a fact endorsed by professional bodies and supported by various large studies. See, for example, https://www.rcog.org.uk/globalassets/documents/guidelines/gtg59hysteroscopy.pdf http://www.nhs.uk/conditions/Hysteroscopy/Pages/Introduction.aspx https://www.acog.org/Patients/FAQs/Hysteroscopy http://emedicine.medscape.com/article/1848258-overview#a9 https://www.ncbi.nlm.nih.gov/pubmed/10908775 http://www.sciencedirect.com/science/article/pii/S0301211502001069 Hysteroscopy can be performed for diagnostic or therapeutic purposes. It can be performed as an outpatient or inpatient procedure; under local, regional or general anaesthesia; using cervical dilatation or not; using single channel or multiple channel equipment; using various pressures to distend the uterine cavity; and the instruments have evolved technologically over the years. As such, the efficacy and reported side effects of "hysteroscopy" are very much dependent on these factors among other considerations. Hence the literature and various reports should be

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				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*	read and interpreted carefully, and within the spirit of the considerations referred to above. Nevertheless, there are many published studies of the efficacy of operative hysteroscopy as well as studies of diagnostic test accuracy of hysteroscopy, such as those included in the evidence review produced for this guideline: Abd Elkhalek 2016 (diagnostic) Cicinelli 1995 (diagnostic) Fakhar and Mahmud 2010 (diagnostic) Krampl 2001 (diagnostic) Mukhopadhyay 2007 (diagnostic) Soguktas 2012 (diagnostic) Taylor 2001 (diagnostic) Vercellini 1997 (diagnostic) http://www.sciencedirect.com/science/article/pii/S014067369904101X (operative) http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2508.1998.00165.x/full (operative) http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.1997.tb11540.x/full (operative) **Pain for women** The guideline does not propose hysteroscopy as the first-line investigation for women with “possible large fibroids” or with “suspected adenomyosis”. The diagnosis of endometriosis is not within the scope of this guideline.

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				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*	In the interpretation of the evidence it is noted that hysteroscopy is largely acceptable to women if it is performed according to best practice guidelines and therefore the following recommendation was included to promote best practice and minimise any discomfort or pain experienced by women. "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 technique, using miniature hysteroscopes (smaller than 3.5 mm) • service organisation that enables 'see-and-treat' in a single setting if feasible." The guideline nevertheless recognises that hysteroscopy may not be acceptable to all women and includes 2 recommendations which address this explicitly. 1.3.8 If a woman declines outpatient hysteroscopy, offer hysteroscopy under general or regional anaesthesia. 1.3.9 For women who decline hysteroscopy, consider pelvic ultrasound, explaining the

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				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	limitations of this technique for detecting uterine cavity causes of HMB. The woman's satisfaction and experience was an important part of the guideline committee's deliberations and their discussion of the evidence with respect to this can be found on pages 45-46 of the relevant evidence review https://www.nice.org.uk/guidance/gid-ng10012/documents/evidence-review. **Safety** As with any intervention there are risks, but we do not recognise the rate of mortality due to hysteroscopy referred to in the comment and we could not find evidence for it in the references provided by FEmISA. A study of 13,600 hysteroscopic procedures reported a total of 38 complications (0.28%) (see https://ac.els-cdn.com/S0029784400008656/1-s2.0-S0029784400008656-main.pdf?_tid=7256c180-a9bc-11e7-8e92-00000aacb362&acdnat=1507201430_72c997cf6aabb65a7de0a5d040c339cd) with no reported mortality. Diagnostic hysteroscopy had a lower complication rate (0.13%) than operative hysteroscopy. A total of 5 cases of fluid overload were recorded (rate 0.20%) of which none occurred

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				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.
					with diagnostic procedures. The authors concluded "Diagnostic hysteroscopic procedures had very low complication rates, so are safe procedures with which to evaluate uterine pathology."
					
					Uterine perforation is recognised as the most frequent complication (albeit still rare). The most common site for this is the uterine fundus in which case conservative management is appropriate as usually little bleeding occurs (see http://emedicine.medscape.com/article/1848258-overview#showall); Furthermore, "Midline uterine perforation rarely leads to significant morbidity unless a laser or electrosurgical device is used" (see https://insights.ovid.com/pubmed?pmid=21606772)
					.
					
					We are unable to locate the Agostini A 2002a study cited reporting on the incidence of fluid overload using hysteroscopy. However, Agostini did publish papers in 2002 relating to hysteroscopy complications seemingly based on the same patient cohort. These studies all related to operative hysteroscopy and the population was not limited to women with HMB.
					See
					https://www.ncbi.nlm.nih.gov/pubmed/11937131
					postoperative infection

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				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.** **<u>Cost – Hysteroscopy is not cost Effective</u>** 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**	https://www.ncbi.nlm.nih.gov/pubmed/12101319 uterine perforation Similarly we were unable to locate the Overton 1997 study reporting the incidence of fluid overload with hysteroscopy. However as noted above, the Jansen study reported an incidence of fluid overload of 0.2% and another article cites an incidence of fluid overload of 0.1% to 0.2% for operative hysteroscopy (see http://www.aquilex.co.uk/resources/2013-US-AAGL-FM-Guidelines.pdf). Once more, these are rare complications in the context of diagnostic hysteroscopy, and with modern equipment. Treatment of polyps was outside the scope of the guideline. **<u>Diagnostic Efficacy</u>** The guideline focuses on targeted diagnostic strategies and interventions depending on the suspected pathology. This is to acknowledge the fact that heavy menstrual bleeding has a variety of causes, each best detected by a specific diagnostic modality. We recognise that hysteroscopy will not detect subserosal fibroids but is superior at identifying uterine cavity lesions. Ultrasound has its clear indications and detects a different subset of causes of HMB. Pelvic congestion and

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				even in outpatients is likely to require a whole day off work and require a family member too escort them..	endometriosis are outside the scope of this guideline and HMB is not the main presenting symptom of these conditions. Many women with HMB are found to have no identifiable pathology and therefore, regardless of the test used, many women will not have an underlying pathology diagnosed. However, management is often the same or similar even if no pathology is identified. **Cost - Hyteroscopy is not cost-effective** Cost-effectiveness takes into account benefits as well as the costs and the joint consideration of the trade-off between costs and benefits is considered in the economic analysis presented for this guideline (see https://www.nice.org.uk/guidance/GID-NG10012/documents/addendum-appendix-7). The economic analysis for this guideline was undertaken in line with NICE methods which are described in "Developing NICE guidelines: the manual" (see https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf). Department of Health NHS Reference Costs are used in preference to the NHS Tariff as it thought they are likely to be a more accurate representation of the opportunity cost, especially as the Tariff may sometimes be set to provide certain incentives to providers. Furthermore, we would consider the cost of a transvaginal ultrasound as more relevant for the

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					economic analysis and therefore we do not consider a diagnostic hysteroscopy to be 850% more costly than an ultrasound investigation. The unit costs used in the health economic model were provided in the health economics appendix (see https://www.nice.org.uk/guidance/GID-NG10012/documents/addendum-appendix-7, page 32).
FEmISA	Short	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.	Thank you for your comment. Many women with HMB will receive effective treatment and relief from pharmacological agents without the need to go through investigations. The cause of HMB is not always identifiable and diagnostic investigations might be inconclusive. If the woman's history and/or physical examination do not suggest an abnormality, such as presence of fibroids or adenomyosis, there is no need for the woman to undergo diagnostic investigations unnecessarily. The guideline recommends that referral to specialist care should be considered if treatment is unsuccessful.
FEmISA	Short	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	Thank you for your comment. The rationale for taking oral analgesia at home is to minimise any pain and discomfort from

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				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.**	hysteroscopy. We did not review the evidence of oral analgesia and the recommendation is based on RCOG best practice guideline which was included in order to improve the experience of women having hysteroscopy especially as the committee were aware that previous surveys among British Society for Gynaecological Endoscopy (BSGE) members suggested poor provision of best practice. The health economic analysis includes a "failure rate" of diagnostic tests.
FEmISA	Short	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.	Thank you for your comment. The guideline recommends an ultrasound scan as the first-line diagnostic investigation for women with suspected adenomyosis or possible large fibroids. Ultrasound should also be offered to women if physical examination is difficult or inconclusive. As noted in the comment, care for women with suspected endometriosis would follow the NICE guideline on Endometriosis (NG73).
FEmISA	Short	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*	Thank you for your comment. The guideline recommends ulipristal acetate (a progesterone receptor modulator) to be offered as a treatment option to women with fibroids 3 cm or more in diameter. In our recommendations/algorithm these women would not be offered an endometrial biopsy, and, therefore, this was not considered to be relevant to

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				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.	the recommendations relating to endometrial biopsy or the use of progesterone receptor modulators.
FEmISA	Short	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	Thank you for your comment. The recommendations in the Interventional procedural guidance 473 are based on observational evidence from 7 case series and 2 case reports. There is no trial data or long-term effectiveness data available. While the available observational evidence shows that UAE can be effective for symptom relief in the short term and medium term with no major safety concerns, IPG473 notes that symptoms may return and that further procedures may be needed. In the absence of evidence for long-term effectiveness and without widespread use of UAE for adenomyosis in practice, the guideline committee judged that it could not recommend UAE for the treatment of adenomyosis.
FEmISA	Short	8	General	**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]	Thank you for your comment. The section of the 2007 guideline on "Education and Information Provision" was not being updated and therefore was outside the scope of this guideline partial update. Recommendation 1.3.1 in the 2007 guideline was deleted because it is now covered by

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				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*	the NICE guideline on "Patient Experience in Adult NHS Services" (CG138). NICE is still providing information for the public with every guideline. It has however moved to a more bespoke approach, which allows the provision of the most relevant information for the topic and a renewed focus on promoting and enabling shared decision-making. This move is in line with feedback gathered from users of the NICE website.

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				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:*	

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				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."*	

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				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.***	
FEmISA	Short	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.	Thank you for your comment. In line with the guideline published in 2007, the updated guidance recommends that MRI should not be used as a first-line investigation for HMB. However, the guideline does recommend that it can be used as a second-line investigation for suspected adenomyosis if a woman declines transvaginal ultrasound or it is not suitable for her when deemed clinically appropriate. The updated recommendations on investigations for women with

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					HMB aim to guide the choice of investigation depending on the findings of history and examination in order to offer the best, most accurate and cost-effective investigation for women.
FEmISA	Short	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	Thank you for your comment. It is considered normal good practice to discuss all treatment options with the woman, including the benefits, risks and consequences. The guideline committee considers it crucial that the woman is able to make an informed choice. The discussion about retaining the woman's fertility and/or uterus is part of this discussion which many women find very important. Many treatment options for HMB affect fertility, including pharmacological and surgical treatments. It would not be good practice to omit these topics from a discussion with the woman. We are aware of studies reporting the risks and complications of myomectomy, for example: https://www.ncbi.nlm.nih.gov/pubmed/16508820. The treatments for fibroids 3 cm or more in diameter include all the treatments listed in the comment, except MRgFUS. The Interventional procedural guidance 413 on MRgFUS for uterine fibroids is based on evidence from 1 non-randomised comparative study, 6 case series and 2

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				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.	case reports. There is no evidence from randomised controlled trials. The committee judged that in the absence of robust evidence on its effectiveness and safety, and without widespread use in clinical practice, MRgFUS should not be recommended as a treatment for fibroids.

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FEmISA	Short	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**	Thank you for your comment. Patient information and the provision of multidisciplinary clinics were not part of the scope of this partial guideline update. Therefore, evidence on patient information and multi-disciplinary clinics was not reviewed. NICE's remit is to provide guidelines to the NHS but does not cover training organised by the Royal medical colleges.

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				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**	

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				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.** **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**	

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				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.	
FEmISA	Short	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*	Thank you for your comment. The Cochrane systematic review by Bhave Chittawar et al. (2014) was not included in our evidence review because we did not compare different myomectomy techniques. The Cochrane systematic review by Gupta et al. (2014) was included in our evidence review. In our evidence review, we found two RCTs that compared the effectiveness of myomectomy to UAE (Mara et al., 2008 and Manyonda et al., 2012) and two RCTs that compared UAE to myomectomy or hysterectomy (Jun et al. 2012 and the REST trial). The evidence for this is presented in the Management chapter. As you say, no evidence on mortality was found although it is likely that the studies would have reported deaths if they had occurred in the study population. However, the available evidence on quality of life and adverse events (such as infection, need for blood transfusion or unscheduled readmission within 4-6 weeks) showed no difference between UAE and

				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	myomectomy. The guideline committee strongly thinks that the benefits and risks of the different treatment options should be discussed with the woman in order to enable her to make an informed choice; please see recommendation 1.4.2.

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				Explain to women that the evidence on myomectomy and fertility is "*low and needs further investigation*" – see 2 meta-analyses above.	
FEmISA	Short	11	17 - 20	The size, location, number and type of fibroids will only be known if the women had a previous MRI scan.	Thank you for your comment. Pelvic ultrasound is the first-line imaging modality for suspected fibroids and is usually sufficient to determine the size, location, number and type of fibroids. However, the guideline recommends that if further information about the position, size, number and vascularity of fibroids is needed prior to scheduling UAE or myomectomy, then MRI should be considered.
FEmISA	Short	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.	Thank you for your comment. Submucosal fibroids fit best under the category of "no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis" as they are classed as a uterine cavity pathology. Treatment of submucosal fibroids is sometimes all that is required to treat HMB and any associated IMB or irregular bleeding (even with the presence of smaller fibroids less than 3 cm, and hence under the same heading). If the submucosal fibroid is so large, or fibroids lying behind it are so large, as to fall in the second category where an ultrasound scan would be the primary investigation (i.e. the woman will not have a hysteroscopy as well, and they will

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					not have 2 procedures as is the concern expressed in the comment). The guideline recommends to 'consider' hysteroscopic removal of submucosal fibroids. Other treatment options listed in the section should also be discussed and considered and might be appropriate for some women with submucosal fibroids. The risks and benefits of all treatment options should be discussed with the woman, as outlined in recommendation 1.4.2: 'Provide information about all possible treatment options (see section 1.5) and discuss these with the woman. Discussions should cover: • the benefits and risks of the various options • suitable treatments if she is trying to conceive • whether she wants to retain her fertility and/or her uterus. [2017]'.
FEmISA	Short	**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	Thank you for your comment. We did not find evidence from randomised controlled trials on the effectiveness, acceptability and safety of MRgFUS on treatment of fibroids. We are aware of one recent pilot randomised controlled trial (Jacoby et al., 2016) but due to its small size (the guideline review protocol outlines that trials with less than 10 participants in one arm should not be included) it was not included in our evidence

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				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	review. The guideline committee agreed that since its use is not widespread in clinical practice, and in the absence of robust clinical evidence, it was not able to recommend it as a treatment for HMB. The recommendation on ulipristal acetate was part of the Addendum to Clinical Guideline 44, Heavy menstrual bleeding: assessment and management Clinical Guideline Addendum 44.1, published in 2016 and not part of this 2017 partial guideline update. The recommendations state a maximum of 4 courses of treatment. Jacoby VL, Kohi MP, Poder L, Jacoby A, Lager J, Schembri M, Rieke V, Grady D, Vittinghoff E, Coakley FV. PROMISe trial: a pilot, randomized, placebo-controlled trial of magnetic resonance guided focused ultrasound for uterine fibroids. Fertil Steril. 2016 Mar;105(3):773-780. doi: 10.1016/j.fertnstert.2015.11.014. Epub 2015 Dec 1.
FEmISA	Short	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.	Thank you for your comment. “Consider second-generation endometrial ablation as a treatment option for women with HMB and fibroids of 3 cm or more in diameter who meet the criteria specified in the manufacturers’ instructions. [2017]”

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					We recognise the concern expressed in the comment with respect to the recommendation above but useful context is provided to the recommendation in the committee's discussion of the evidence. This explains why second-generation endometrial ablation can be considered where the manufacturer's criteria are met: "The size and shape of the uterine cavity are the main determinants of the feasibility and effectiveness of second generation endometrial ablation procedures. Fibroids of 3 cm or more in diameter lead to substantial uterine enlargement and distortion and so may be associated with poorer clinical outcomes or contraindicate the use of ablation procedures. However, the use of second generation endometrial ablation can be considered if such fibroids do not distort, nor enlarge, the uterine cavity, in line with the specific device's manufacturer's restrictions. The committee agreed that there were limitations to the wording of "manufacturers' instructions", nonetheless due to differing cavity dimensions set by the manufacturers to achieve therapeutic effectiveness and the limitations in the different techniques and devices, it was deemed too simplistic to write a recommendation only taking into consideration the size and shape of the endometrial cavity. The committee also recognised that the wording of the recommendation may be perceived as vague,

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					however they believed that the wording of "manufacturers' instructions" was pragmatic and generic enough to the specificities of each separate ablative technique and device." There was randomised controlled trial evidence included in our evidence review on fibroids up to 5 cm (Jain 2016). In addition there are studies that have considered the safety of the procedure (see https://www.ncbi.nlm.nih.gov/pubmed/12386350).
FEmISA	Short	14	1 - 4	1.5.19 Only remove ovaries with hysterectomy with the express wish and 2 informed consent of the woman, after discussion of all associated risks 3 and benefits. [2007, amended 2017] 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	Thank you for your comment. Recommendations on Removal of ovaries (oophorectomy) with hysterectomy (Section 1.9 of the 2007 guideline) were not part of this partial guideline update. However, a number of changes were made on editorial grounds or to address information now considered inaccurate. A rationale for the changes was provided in a table in the consultation version of the guideline (see https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline, page 33). In particular recommendation 1.9.1 in the 2007 guideline states that removal of healthy ovaries should not be undertaken whereas recommendation 1.9.2 states that they should be removed only with

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				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	the express wish and consent of the woman. So recommendation 1.9.1 implies that healthy ovaries should never be removed whereas recommendation 1.9.2 suggests that there are occasions where they could be removed with the "express wish and consent of the woman". The revised recommendations are intended to correct this anomaly but not to facilitate the removal of healthy ovaries. Indeed additional wording has been added to the old recommendation 1.9.2 "after discussion of all associated risks and benefits" to ensure that women are "fully informed and able to make decisions about their own care".

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				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.	

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FEmISA	Short	**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.	Thank you for your comment. The research question was generated from the paucity of data identified through systematic searches of the evidence to inform clinical practice regarding the diagnostic work up of women with HMB. There are a variety of tests available but the necessity of routine testing or the type or sequence of testing in HMB is unclear. Accurate and timely diagnosis of underlying pathologies may optimise clinical outcomes by directing the more appropriate treatments. However, unnecessary testing not only wastes scant health care resources but can also cause harms (e.g. inconvenience, pain, and embarrassment). Thus evaluating how best to use investigations within the clinical process for women with HMB is in the interests of women and their welfare. The committee felt that the alternative research question proposed by FEmISAlacks focus and clarity. The evidence shows that outpatient tests are associated with a low complication rate and so an assessment of safety would not be feasible within a randomised controlled trial with few events and would require an extremely large and impractical cohort study. We agree that the assessment of acceptability of testing should be embedded in the

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					research question about effectiveness and cost-effectiveness recommended in the draft guideline. Hysteroscopy and ultrasound were the two tests identified along with a third trial arm of empirical treatment (without testing) because these were the tests identified from the cost-effectiveness analysis and a previous one commissioned by the National Institute of Health Research. MRI was not included in these analyses because it is an expensive imaging modality and less readily accessible to clinicians and patients and is not currently used in routine practice for investigating HMB. When imaging is chosen by clinicians, this is invariably ultrasound which is convenient, readily available, within the skill sets of many practitioners and provides similar information to MRI. It is for these reasons that the use of MRI in current practice is restricted to the investigation of uterine masses, namely fibroids and to ascertain the appropriateness of, and response to, uterine artery embolisation. The recommended research question is looking at routine testing strategies applicable to all women presenting with HMB and not a subset suspected of having fibroids or adenomyosis. Specific research questions restricted to the optimal use of MRI may be of interest but we do not consider this to be as great a priority as the recommended research question which reflects current practice dilemmas, is feasible

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					and is applicable to the general population of women in primary and secondary care with HMB. There are several publications, including randomised controlled trials and systematic quantitative reviews evaluating the effectiveness, acceptability and pain associated with hysteroscopy (see also the response relating to evaluation of safety) including the evaluation of analgesia and anaesthesia. Furthermore, we are aware of a large RCT evaluating pain and acceptability of current outpatient hysteroscopy practice (see https://clinicaltrials.gov/ct2/show/NCT01972945) and an RCOG evidence-based guideline is in the process of being updated to include any new data relating to diagnostic procedures but also therapeutic interventions (see https://www.rcog.org.uk/globalassets/documents/guidelines/gtg59hysteroscopy.pdf). We would expect that the recommended trial would include some evaluation of acceptability, pain and complications.
FEmISA	Short	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	Thank you for your comment. We are aware of some studies that look at risks and complications of myomectomy, for example https://www.ncbi.nlm.nih.gov/pubmed/16508820. In our evidence review, we found two randomised controlled trials that compared the effectiveness of myomectomy to UAE (Mara et al., 2008 and

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				complication and side effects such as adhesions, reintervention rates – long-term and infertility.	Manyonda et al., 2012). The evidence for this is presented in the Management chapter. There was no difference in health-related quality of life at 1 year post-procedure, no difference in satisfaction with treatment (measured if symptom relief had been obtained) at 2 years post-procedure, no difference in need for blood transfusion, no difference in risk of pneumonia, sepsis or need for antibiotics, no difference in risk of pulmonary embolism within 1 year and no difference in risk of unscheduled readmission within 4-6 weeks. Duration of hospital stay was shorter in women who received UAE and there was an increased risk of urinary tract infection among women who received myomectomy. The committee would welcome more evidence on the effectiveness and safety of myomectomy, however, because some evidence is available, this was not considered a priority for research recommendations.
FEmISA	Short	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	Thank you for your comment. This was included as a research recommendation because the guideline committee thought it important that the effectiveness and safety of the procedure was studied in a randomised controlled trial. In practice, hysteroscopic removal of submucosal fibroids and endometrial polyps is carried out in many units and observational evidence shows that it is safe and effective. Acceptability to women would be one of the outcomes of interest, alongside for example quality of life, complications, long-term effects, and

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				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.**	woman's satisfaction. More information and details about the research recommendation can be found in the Appendix C of the Management evidence report document.
FEmISA	Short	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,	Thank you for your comment. The rationale for deletions and amendments to these recommendations were explained on pages 32 to 37 of https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline. Therefore, the rationale of deletions and amendments are explained in more detail below. Recommendation 1.8.1 in the 2007 guideline The committee does not anticipate that hysterectomy will be provided as a first-line treatment other than in exceptional circumstances where this reflects the woman's choice, she has severe symptoms and does not wish to preserve her uterus/fertility for example. The guideline is clear that women's preferences are important when agreeing treatment (see recommendation: "When agreeing the treatment options for HMB with the woman, take into account the woman's preferences") and therefore the committee did not want to include a recommendation that did not

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				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	allow hysterectomy as a first-line treatment in any circumstances. Recommendation 1.8.2 in the 2007 guideline This has been retained with a very minor editorial change: Have a full discussion with all women who are considering hysterectomy about the implications of surgery before a decision is made. The discussion should include: • sexual feelings • impact on fertility • bladder function • need for further treatment • treatment complications • her expectations • alternative surgery • psychological impact. Recommendation 1.8.3 in the 2007 guideline This has been retained with a very minor editorial change: Inform women about the increased risk of serious complications (such as intraoperative haemorrhage or damage to other abdominal organs) associated

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				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]	with hysterectomy when uterine fibroids are present. Recommendation 1.8.4 in the 2007 guideline This has been retained with a very minor editorial change: Inform women about the risk of possible loss of ovarian function and its consequences, even if their ovaries are retained during hysterectomy. Recommendation 1.8.5 in the 2007 guideline Whilst this has been deleted, as the committee did not review the route of hysterectomy and it was outside the scope of the guideline, there is a new recommendation for management which is consistent with the content of recommendation 1.8.5 in the 2007 guideline. When agreeing the treatment options for HMB with the woman, take into account: • the woman's preferences • any comorbidities • the presence or absence of polyps, fibroids (including size, number and location), endometrial pathology or adenomyosis • other symptoms such as pressure and pain. Recommendation 1.8.6 in the 2007 guideline

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					This has been amended with the explanation as follows in https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline "The comparison between different routes of hysterectomy was out of the scope of the protocol. The committee agreed the old recommendation is no longer valid, as the laparoscopic route is usually preferable. However they agreed to place the emphasis on women's choice." Recommendation 1.8.7 in the 2007 guideline This has been deleted with the explanation as follows in https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline "This recommendation has been deleted because it is not current practice. The topic of routes of hysterectomy has been flagged with the NICE surveillance review team." Recommendation 1.8.8 in the 2007 guideline This has been amended with the explanation as follows in https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline "The committee did not review the route of hysterectomy, but agreed that the recommendation

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					wording was out of date and made changes to reflect this."
FEmISA	General	General	General	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	Thank you for your comment. The committee does not anticipate that hysterectomy will be provided as a first-line treatment other than in exceptional circumstances where this reflects the woman's choice, she has severe symptoms and does not wish to preserve her uterus/fertility, for example. The guideline is clear that women's preferences are important when agreeing treatment (see recommendation: "When agreeing the treatment options for HMB with the woman, take into account the woman's preferences"). Recommendations on Removal of ovaries (oophorectomy) with hysterectomy (Section 1.9 of the 2007 guideline) were not part of this partial guideline update. However, a number of changes were made on editorial grounds or to address information now considered inaccurate. A rationale for the changes was provided in a table in the consultation version of the guideline (see https://www.nice.org.uk/guidance/gid-ng10012/documents/draft-guideline, page 33). In particular recommendation 1.9.1 in the 2007 guideline states that removal of healthy ovaries

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				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.	should not be undertaken whereas recommendation 1.9.2 states that they should be removed only with the express wish and consent of the woman. So recommendation 1.9.1 implies that healthy ovaries should never be removed whereas recommendation 1.9.2 suggests that there are occasions where they could be removed with the "express wish and consent of the women". The revised recommendations are intended to correct this anomaly but not to facilitate the removal of healthy ovaries. Indeed additional wording has been added to the old recommendation 1.9.2 "after discussion of all associated risks and benefits" to ensure that women are "fully informed and able to make decisions about their own care" Hysterectomy is one of many treatment alternatives that can be considered and the recommendations make it clear that women's preferences are an important part of agreeing treatment options. Although it is not made clear in this comment, we think the higher mortality and morbidity alluded to by FEmISA relates to a mistaken interpretation of the epidemiological literature which is discussed in responses to other comments from FEmISA. We believe our guideline is consistent with NHS England statements on shared decision making. Recommendations state, for example,

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					"Explain to women with HMB who are offered outpatient hysteroscopy what the procedure involves and discuss the possible alternatives." "If a woman declines outpatient hysteroscopy, consider hysteroscopy under anaesthesia." "For women who decline hysteroscopy, consider 2-dimensional pelvic ultrasound, explaining the limitations of this technique for detecting intracavitary causes of HMB" "If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques." "Provide information about HMB and its management to women. Follow the principles in the NICE guideline on patient experience in adult NHS services in relation to communication, information and shared decision-making." "Provide information about all possible treatment options (see section 1.5) and discuss these with the woman. Discussions should cover: • the benefits and risks of the various options • suitable treatments if she is trying to conceive

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					• whether she wants to retain her fertility and/or her uterus." "When agreeing the treatment options for HMB with the woman, take into account: • the woman's preferences" "If a woman with HMB declines LNG-IUS or it is not suitable, consider a choice of pharmacological treatments" "Only remove ovaries with hysterectomy with the express wish and informed consent of the woman, after discussion of all associated risks and benefits." In the committee discussion of the evidence and rationale and impact the following is written for example: "… committee recognised that not every woman would agree to undergo an outpatient hysteroscopy and emphasised that patient choice was important in deciding the diagnostic pathway." "Whilst the recommendations enable women to have surgery first line if that reflects their preferences, this is likely to be a small subset of women with more significant symptoms or pathology."

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					"The committee emphasised the importance of talking to the woman about her needs and preferences when deciding on treatments for HMB. This includes any plans for pregnancy and whether she wants to retain her uterus or fertility." "The recommendations allow access to surgical intervention to be expedited where this is aligned with the overall clinical picture and the women's preferences. However, the committee noted that these women often present with more significant symptoms and pathology and will often ultimately proceed to surgical intervention after being shown to be refractory to pharmacological treatment alternatives." "In general the published evidence and the model developed for this guideline can be considered as supportive of offering women a range of treatment alternatives to reflect their own preferences and individual clinical circumstances."
FEmISA	General	General	General	The outcomes of these recommendations are likely to be – 1. **Increased mortality and morbidity from hysteroscopy increase as first line diagnostic test**	Thank you for your comment. We believe the 0.3% mortality rate for diagnostic hysteroscopy cited by FEmISA is mistaken. This would be an extremely high mortality rate for a minimally invasive diagnostic procedure, especially

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

one undertaken in a non-elderly population. We also think the cited serious complication rate of 3.4% is incorrect.

A set of 13,600 hysteroscopic procedures reported a total of 38 complications (0.28%) (see https://ac.els-cdn.com/S0029784400008656/1-s2.0-S0029784400008656-main.pdf?_tid=7256c180-a9bc-11e7-8e92-00000aacb362&acdnat=1507201430_72c997cf6aabb65a7dc0a5d040c339cd) with no reported mortality. Diagnostic hysteroscopy had a lower complication rate (0.13%) than operative hysteroscopy. A total of 5 cases of fluid overload were recorded (rate 0.20%) of which none occurred with diagnostic procedures. The authors concluded "Diagnostic hysteroscopic procedures had very low complication rates, so are safe procedures with which to evaluate intrauterine pathology."

Uterine perforation is recognised as the most frequent complication. The most common site for this is the uterine fundus in which case conservative management is appropriate as usually little bleeding occurs (see http://emedicine.medscape.com/article/1848258-overview#showall); "Midline uterine perforation rarely leads to significant morbidity unless a laser or electrosurgical device is used" (see

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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, 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 Marsh
Current					
Abdominal	31,086	**176**	0.6 %	**111,910**	4.6 %
Vaginal	7,236	**6**	0.10 %	**26,050**	7.10 %

https://insights.ovid.com/pubmed?pmid=21606772)
.

We were unable to locate the Agostini A 2002a study cited reporting on the incidence of fluid overload using hysteroscopy. However, Agostini did publish papers in 2002 relating to hysteroscopy complications seemingly based on the same patient cohort. These studies all related to operative hysteroscopy and the population was not limited to women with HMB.

https://www.ncbi.nlm.nih.gov/pubmed/11937131 postoperative infection
https://www.ncbi.nlm.nih.gov/pubmed/12101319 uterine perforation

Similarly we were unable to locate the Overton 1997 study reporting the incidence of fluid overload with hysteroscopy.

However as noted above the Jansen study reported an incidence of fluid overload of 0.2% and another article cited an incidence of fluid overload of 0.1% to 0.2% for operative hysteroscopy. (See http://www.aquilex.co.uk/resources/2013-US-AAGL-FM-Guidelines.pdf)

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				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.**	Pelvic ultrasound is recommended as the first-line investigation if the woman's uterus is palpable abdominally, history or examination suggests a pelvic mass or if examination is inconclusive. If the woman has small subserosal fibroids then management would be similar as for a woman with no identified pathology. The guideline committee does not anticipate that the number of hysterectomies will increase as a result of their recommendations. Nor does the committee anticipate that hysterectomy will be provided as a first-line treatment other than in exceptional circumstances where this reflects the woman's choice, she has severe symptoms and does not wish to preserve her uterus/fertility, for example. NHS Digital (formerly HES) have provided statistics on the number of finished consultant episodes (FCEs) for a main or secondary procedures for myomectomy for females under 40 years of age in England; 2013/14 FCE = 1,685; 2014/15 FCE = 1,573; 2015/16 FCE = 1,626. This data is for "activity in English NHS Hospitals and English NHS commissioned activity in the independent sector". (See http://content.digital.nhs.uk/article/2021/Website-Search?q=myomectomy&go=Go&area=both, accessed 5 October 2017).

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				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.	UAE is a recommended treatment option/choice for women with fibroids of 3cm or more in diameter. It was not included in the economic evaluation because it was not possible to include any studies on UAE in the network meta-analysis. The included studies in the health economic literature review came to differing conclusions with respect to the cost-effectiveness of UAE. It is true that UAE has a lower procedure cost than hysterectomy but calculations of cost savings are complicated by rates of secondary intervention. A recent Cochrane review did not report a significantly lower complication rate than myomectomy "We found no clear evidence of a difference between UAE and surgery in the risk of major complications, but UAE was associated with a higher rate of minor complications and an increased likelihood of requiring surgical intervention within two to five years of the initial procedure". (See https://www.ncbi.nlm.nih.gov/pubmed/25541260).
FEmISA	General	General	General	**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**	Thank you for your comment. The population of women with HMB and fibroids is a very heterogeneous group. The 3 cm cut-off is arbitrary to a large extent and is not considered to represent an absolute cut-off in determining surgical treatments. For any surgical treatment modality,

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				comparison studies with myomectomy and UAE are required.	including endometrial ablation, UAE, myomectomy or hysterectomy a number of factors have to be considered. In addition to the size of the largest fibroid, the location and number of fibroids, the size of the uterus, the shape of the endometrial cavity, the presence of caesarean section scars, comorbidities etc. are all important when considering alternative treatments. The presence of a single fibroid greater than 3 cm is not a contraindication to endometrial ablation if other parameters are suitable. **Hysteroscopic resection of submucosal fibroids is a well-established technique, see e.g. http://www.bmj.com/content/309/6960/979.**
FEmISA	ER B	General	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	Thank you for the list of references. In our systematic evidence review for clinical studies we looked for highest quality evidence from systematic reviews of randomised controlled trials or individual randomised controlled trials of sufficient size (minimum 10 participants in one intervention arm) on the effectiveness and safety of different treatment interventions, including magnetic resonance-guided focused ultrasound (MRgFUS), on treating HMB caused by fibroids, adenomyosis or no identified pathology. More details can be found in the review protocol in the

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				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.	Management evidence review document Appendix A. We have considered all of the references cited in the comment. Please see after each reference below if we have included the paper in our review and when applicable the reason for not including the paper in our review. Please note that some of the references listed have been published after our literature search was conducted in November 2016 would therefore not appear in our excluded studies list. More information about our literature search strategy can be found in the Management evidence report Appendix E. 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. This paper was not included in our evidence review because it is not a randomised controlled trial (RCT).

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				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	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. This paper was not included in our evidence review because it is a case report and not an RCT. 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. This paper was not included in our evidence review because 1) it is an observational study and 2) it is on the administration of GnRHa prior to MRgFUS and not on the effectiveness of MRgFUS as such.

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				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.	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. This paper was not included in our evidence review because it is not an RCT. 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. This paper was not included in our evidence review because it is not an RCT but a retrospective observational study.

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				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.	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. This paper was not included in our evidence review because it is not an RCT but a case report. 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] This paper was not included in our evidence review because it is not an RCT but a retrospective observational study.

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				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	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. This paper was not included in our evidence review because it is not an RCT but a retrospective observational study. 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. This paper was not included in our evidence review because it is a conference abstract. 10. Clinical Consideration of Treatment to Ablate Uterine Fibroids with Magnetic Resonance

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				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.	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. This paper was not included in our evidence review because it is not an RCT. 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. This paper was not included in our evidence review because it is not an RCT. 12. Nonsurgical Alternatives for Uterine Fibroids. Zupi E, Centini G, Sabbioni L, Lazzeri L, Argay IM, Petraglia F.

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				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	Best Pract Res Clin Obstet Gynaecol. 2016 Jul;34:122-31. doi: 10.1016/j.bpobgyn.2015.11.013. Epub 2015 Nov 25. This paper was not included in our evidence review because it is not an RCT. 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. This paper was not included in our evidence review because there were less than 10 participants in one intervention arm. 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.

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				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.	Int J Womens Health. 2015 Nov 13;7:901-12. doi: 10.2147/IJWH.S55564. eCollection 2015. Review. This paper was not included in our evidence review because it is not an RCT. 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. This paper was not included in our evidence review because it is not an RCT. 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. This paper was not included in our evidence review because it is not an RCT.

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				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 survey times after MR-guided focused ultrasound surgery in uterine fibroids: first report in a Mexican mestizo population. Carrasco-Choque AL, Lara YF, Vivas-Bonilla I, Romero-Trejo C, Villa AR, Roldan-Valadez E. Eur Radiol. 2015 Oct;25(10):2905-12. doi: 10.1007/s00330-015-3707-2. Epub 2015 Mar 26. PMID: 25809744 [PubMed - indexed for MEDLINE] Similar articles 23. Magnetic resonance-guided focused ultrasound surgery (MRgFUS) of uterine fibroids in Singapore. Han NL, Ong CL. Ann Acad Med Singapore. 2014 Nov;43(11):550-8. PMID: 25523859 [PubMed - indexed for MEDLINE] Free Article 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. This paper was not included in our evidence review because it is not an RCT but a retrospective observational study. 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. This paper was not included in our evidence review because it is not an RCT.

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				24. Cost comparison between uterine-sparing fibroid treatments one year following treatment. Borah BJ, Carls GS, Moore BJ, Gibson TB, Moriarty JP, Stewart EA. J Ther Ultrasound. 2014 Mar 31;2:7. doi: 10.1186/2050-5736-2-7. eCollection 2014. PMID: 25512868 [PubMed] Free PMC Article Similar articles 25. Women seeking second opinion for symptomatic uterine leiomyoma: role of comprehensive fibroid center. Tan N, McClure TD, Tarnay C, Johnson MT, Lu DS, Raman SS. J Ther Ultrasound. 2014 Apr 15;2:3. doi: 10.1186/2050-5736-2-3. eCollection 2014. PMID: 25512867 [PubMed] Free PMC Article Similar articles 26. MRI predictors of clinical success in MR-guided focused ultrasound (MRgFUS) treatments of uterine fibroids: results from a single centre. Mindjuk I, Trumm CG, Herzog P, Stahl R, Matzko M. Eur Radiol. 2015 May;25(5):1317-28. doi: 10.1007/s00330-014-3538-6. Epub 2014 Dec 16.	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. This paper was not included in our evidence review because it is not an RCT. 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. This paper was not included in our evidence review because it is not an RCT. 21. Scaled signal intensity of uterine fibroids based on T2-weighted MR images: a potential objective method to determine the suitability for

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				PMID: 25510445 [PubMed - indexed for MEDLINE] Similar articles 27. Safety and five-year re-intervention following magnetic resonance-guided focused ultrasound (MRgFUS) for uterine fibroids. Quinn SD, Vedelago J, Gedroyc W, Regan L. Eur J Obstet Gynecol Reprod Biol. 2014 Nov;182:247-51. doi: 10.1016/j.ejogrb.2014.09.039. Epub 2014 Oct 6. PMID: 25445107 [PubMed - indexed for MEDLINE] Similar articles 28. Alternative therapies in management of leiomyomas. Patel A, Malik M, Britten J, Cox J, Catherino WH. Fertil Steril. 2014 Sep;102(3):649-55. doi: 10.1016/j.fertnstert.2014.07.008. Epub 2014 Aug 5. Review. PMID: 25106764 [PubMed - indexed for MEDLINE] Similar articles 29. Review of MRI positioning devices for guiding focused ultrasound systems.	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. This paper was not included in our evidence review because it is not an RCT but a retrospective observational study. 22. Perfusion volume correlates, percentage of involution, and clinical efficacy at diverse follow-up survey times after MR-guided focused ultrasound surgery in uterine fibroids: first report in a Mexican mestizo population. Carrasco-Choque AL, Lara YF, Vivas-Bonilla I, Romero-Trejo C, Villa AR, Roldan-Valadez E. Eur Radiol. 2015 Oct;25(10):2905-12. doi: 10.1007/s00330-015-3707-2. Epub 2015 Mar 26. This paper was not included in our evidence review because it is not an RCT but a retrospective observational study. 23. Magnetic resonance-guided focused ultrasound surgery (MRgFUS) of uterine fibroids in Singapore.

				Yiallouras C, Damianou C. Int J Med Robot. 2015 Jun;11(2):247-55. doi: 10.1002/rcs.1601. Epub 2014 Jul 7. Review. PMID: 25045075 [PubMed - indexed for MEDLINE] Similar articles 30. Cost-effectiveness of uterine-preserving procedures for the treatment of uterine fibroid symptoms in the USA. Cain-Nielsen AH, Moriarty JP, Stewart EA, Borah BJ. J Comp Eff Res. 2014 Sep;3(5):503-14. doi: 10.2217/cer.14.32. Epub 2014 May 30. PMID: 24878319 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 31. Intracranial applications of magnetic resonance-guided focused ultrasound. Lipsman N, Mainprize TG, Schwartz ML, Hynynen K, Lozano AM. Neurotherapeutics. 2014 Jul;11(3):593-605. doi: 10.1007/s13311-014-0281-2. Review. PMID: 24850310 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles	Han NL, Ong CL. Ann Acad Med Singapore. 2014 Nov;43(11):550-8. This paper was not included in our evidence review because it is not an RCT. 24. Cost comparison between uterine-sparing fibroid treatments one year following treatment. Borah BJ, Carls GS, Moore BJ, Gibson TB, Moriarty JP, Stewart EA. J Ther Ultrasound. 2014 Mar 31;2:7. doi: 10.1186/2050-5736-2-7. eCollection 2014. This study was not included in our health economic analysis because it was a costing study and not a full economic evaluation. 25. Women seeking second opinion for symptomatic uterine leiomyoma: role of comprehensive fibroid center. Tan N, McClure TD, Tarnay C, Johnson MT, Lu DS, Raman SS. J Ther Ultrasound. 2014 Apr 15;2:3. doi: 10.1186/2050-5736-2-3. eCollection 2014.

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				32. Reproductive impact of MRI-guided focused ultrasound surgery for fibroids: a systematic review of the evidence. Clark NA, Mumford SL, Segars JH. Curr Opin Obstet Gynecol. 2014 Jun;26(3):151-61. doi: 10.1097/GCO.0000000000000070. Review. PMID: 24751998 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 33. High-Intensity Focused Ultrasound Ablation of Uterine Fibroids - Potential Impact on Fertility and Pregnancy Outcome. Bohlmann MK, Hoellen F, Hunold P, David M. Geburtshilfe Frauenheilkd. 2014 Feb;74(2):139-145. PMID: 24741124 [PubMed] Free PMC Article Similar articles 34. Early evaluation of magnetic resonance imaging guided focused ultrasound sonication in the treatment of uterine fibroids. Himabindu Y, Sriharibabu M, Nyapathy V, Mishra A. Indian J Med Res. 2014 Feb;139(2):267-72.	This paper was not included in our evidence review because it is not an RCT but a retrospective observational study. 26. MRI predictors of clinical success in MR-guided focused ultrasound (MRgFUS) treatments of uterine fibroids: results from a single centre. Mindjuk I, Trumm CG, Herzog P, Stahl R, Matzko M. Eur Radiol. 2015 May;25(5):1317-28. doi: 10.1007/s00330-014-3538-6. Epub 2014 Dec 16. This paper was not included in our evidence review because it is not an RCT. 27. Safety and five-year re-intervention following magnetic resonance-guided focused ultrasound (MRgFUS) for uterine fibroids. Quinn SD, Vedelago J, Gedroyc W, Regan L. Eur J Obstet Gynecol Reprod Biol. 2014 Nov;182:247-51. doi: 10.1016/j.ejogrb.2014.09.039. Epub 2014 Oct 6. This paper was not included in our evidence review because it is not an RCT but an observational study.

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				PMID: 24718402 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 35. Uterine fibroids: current perspectives. Khan AT, Shehmar M, Gupta JK. Int J Womens Health. 2014 Jan 29;6:95-114. doi: 10.2147/IJWH.S51083. eCollection 2014. Review. PMID: 24511243 [PubMed] Free PMC Article Similar articles 36. MR-guided focused ultrasound surgery, present and future. Schlesinger D, Benedict S, Diederich C, Gedroyc W, Klibanov A, Larner J. Med Phys. 2013 Aug;40(8):080901. doi: 10.1118/1.4811136. Review. PMID: 23927296 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 37. Magnetic resonance-guided focused ultrasound myomectomy: safety, efficacy, subsequent fertility and quality-of-life improvements, a systematic review.	28. Alternative therapies in management of leiomyomas. Patel A, Malik M, Britten J, Cox J, Catherino WH. Fertil Steril. 2014 Sep;102(3):649-55. doi: 10.1016/j.fertnstert.2014.07.008. Epub 2014 Aug 5. Review. This paper was not included in our evidence review because it is not an RCT but a narrative review. 29. Review of MRI positioning devices for guiding focused ultrasound systems. Yiallouras C, Damianou C. Int J Med Robot. 2015 Jun;11(2):247-55. doi: 10.1002/rcs.1601. Epub 2014 Jul 7. Review. This paper was not included in our evidence review because it is not an RCT but a narrative review. 30. Cost-effectiveness of uterine-preserving procedures for the treatment of uterine fibroid symptoms in the USA. Cain-Nielsen AH, Moriarty JP, Stewart EA, Borah BJ. J Comp Eff Res. 2014 Sep;3(5):503-14. doi: 10.2217/cer.14.32. Epub 2014 May 30.

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				Gizzo S, Saccardi C, Patrelli TS, Ancona E, Noventa M, Fagherazzi S, Mozzanega B, D'Antona D, Nardelli GB. Reprod Sci. 2014 Apr;21(4):465-76. doi: 10.1177/1933719113497289. Epub 2013 Jul 18. Review. PMID: 23868442 [PubMed - indexed for MEDLINE] Similar articles 38. [Prospective study on magnetic resonance-guided focused ultrasound surgery for symptomatic uterine fibroid: short-term follow up]. Fan R, Zhu L, Gong XM, Xue HD, Shi HF, Jin ZY, Chen GJ. Zhonghua Fu Chan Ke Za Zhi. 2013 Mar;48(3):183-7. Chinese. PMID: 23849940 [PubMed - indexed for MEDLINE] Similar articles 39. Technical eligibility for treatment of magnetic resonance-guided focused ultrasound surgery. Fröling V, Kröncke TJ, Schreiter NF, Scheurig-Muenkler C, Collettini F, Hamm B, Beck A. Cardiovasc Intervent Radiol. 2014 Apr;37(2):445-50. doi: 10.1007/s00270-013-0678-z. Epub 2013 Jul 10.	Thank you for notifying us of this study. This was not picked up by our literature search and we have added it to the list of included health economic studies. 31. Intracranial applications of magnetic resonance-guided focused ultrasound. Lipsman N, Mainprize TG, Schwartz ML, Hynynen K, Lozano AM. Neurotherapeutics. 2014 Jul;11(3):593-605. doi: 10.1007/s13311-014-0281-2. Review. This paper was not included in our evidence review because it is on the intracranial application of MRgFUS. 32. Reproductive impact of MRI-guided focused ultrasound surgery for fibroids: a systematic review of the evidence. Clark NA, Mumford SL, Segars JH. Curr Opin Obstet Gynecol. 2014 Jun;26(3):151-61. doi: 10.1097/GCO.0000000000000070. Review. This paper was not included in our evidence review because it is not an RCT but a review of the effect

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				PMID: 23839005 [PubMed - indexed for MEDLINE] Similar articles 40. Analysis and reduction of thermal dose errors in MRgFUS treatment. Zucconi F, Colombo PE, Pasetto S, Lascialfari A, Ticca C, Torresin A. Phys Med. 2014 Feb;30(1):111-6. doi: 10.1016/j.ejmp.2013.04.003. Epub 2013 Jun 5. PMID: 23746616 [PubMed - indexed for MEDLINE] Similar articles 41. Magnetic resonance imaging-guided focused ultrasound surgery for symptomatic uterine fibroids: estimation of treatment efficacy using thermal dose calculations. Yoon SW, Cha SH, Ji YG, Kim HC, Lee MH, Cho JH. Eur J Obstet Gynecol Reprod Biol. 2013 Jul;169(2):304-8. doi: 10.1016/j.ejogrb.2013.02.023. Epub 2013 Mar 22. PMID: 23523412 [PubMed - indexed for MEDLINE] Similar articles	of MRgFUS on fertility and reproductive outcomes (not an outcome of interest in our review). 33. High-Intensity Focused Ultrasound Ablation of Uterine Fibroids - Potential Impact on Fertility and Pregnancy Outcome. Bohlmann MK, Hoellen F, Hunold P, David M. Geburtshilfe Frauenheilkd. 2014 Feb;74(2):139-145. This paper was not included in our evidence review because it is not an RCT but a review of the effect of MRgFUS on fertility and reproductive outcomes (not an outcome of interest in our review). 34. Early evaluation of magnetic resonance imaging guided focused ultrasound sonication in the treatment of uterine fibroids. Himabindu Y, Sriharibabu M, Nyapathy V, Mishra A. Indian J Med Res. 2014 Feb;139(2):267-72. This paper was not included in our evidence review because it is not an RCT but an observational study. 35. Uterine fibroids: current perspectives.

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				42. MR-guided high-intensity focused ultrasound: current status of an emerging technology. Napoli A, Anzidei M, Ciolina F, Marotta E, Cavallo Marincola B, Brachetti G, Di Mare L, Cartocci G, Boni F, Noce V, Bertaccini L, Catalano C. Cardiovasc Intervent Radiol. 2013 Oct;36(5):1190-203. doi: 10.1007/s00270-013-0592-4. Epub 2013 Mar 9. Review. PMID: 23474917 [PubMed - indexed for MEDLINE] Similar articles 43. [MR-guided focused ultrasound. Current and future applications]. Trumm CG, Napoli A, Peller M, Clevert DA, Stahl R, Reiser M, Matzko M. Radiologe. 2013 Mar;53(3):200-8. doi: 10.1007/s00117-012-2417-x. German. PMID: 23456041 [PubMed - indexed for MEDLINE] Similar articles 44. Magnetic Resonance-guided Focused Ultrasound Treatment for Uterine Fibroids: First Study in Indian Women.	Khan AT, Shehmar M, Gupta JK. Int J Womens Health. 2014 Jan 29;6:95-114. doi: 10.2147/IJWH.S51083. eCollection 2014. Review. This paper was not included in our evidence review because it is not an RCT. 36. MR-guided focused ultrasound surgery, present and future. Schlesinger D, Benedict S, Diederich C, Gedroyc W, Klibanov A, Larner J. Med Phys. 2013 Aug;40(8):080901. doi: 10.1118/1.4811136. Review. This paper was not included in our evidence review because it is not an RCT. 37. Magnetic resonance-guided focused ultrasound myomectomy: safety, efficacy, subsequent fertility and quality-of-life improvements, a systematic review. Gizzo S, Saccardi C, Patrelli TS, Ancona E, Noventa M, Fagherazzi S, Mozzanega B, D'Antona D, Nardelli GB. Reprod Sci. 2014 Apr;21(4):465-76. doi: 10.1177/1933719113497289. Epub 2013 Jul 18. Review.

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				Desai SB, Patil AA, Nikam R, Desai AS, Bachhav V. J Clin Imaging Sci. 2012;2:74. doi: 10.4103/2156-7514.104307. Epub 2012 Dec 4. PMID: 23393630 [PubMed] Free PMC Article Similar articles 45. Safety and treatment volumes achieved following new developments of the magnetic resonance-guided focused ultrasound system in the treatment of uterine fibroids: a cohort study. Quinn SD, Vedelago J, Regan L, Gedroyc WM. J Ther Ultrasound. 2013 Oct 1;1:20. doi: 10.1186/2050-5736-1-20. eCollection 2013. PMID: 25512863 [PubMed] Free PMC Article Similar articles 46. Clinical predictors of successful magnetic resonance-guided focused ultrasound (MRgFUS) for uterine leiomyoma. Gorny KR, Borah BJ, Weaver AL, Brown D, Woodrum DA, Stewart EA, Hesley GK. J Ther Ultrasound. 2013 Sep 2;1:15. doi: 10.1186/2050-5736-1-15. eCollection 2013. PMID: 25512860 [PubMed] Free PMC Article Similar articles	This paper was not included in our evidence review because it is not an RCT but a systematic review. None of the included studies were RCTs but observational studies. 38. [Prospective study on magnetic resonance-guided focused ultrasound surgery for symptomatic uterine fibroid: short-term follow up]. Fan R, Zhu L, Gong XM, Xue HD, Shi HF, Jin ZY, Chen GJ. Zhonghua Fu Chan Ke Za Zhi. 2013 Mar;48(3):183-7. Chinese. This paper was not included in our evidence review because it is not an RCT but an observational study. The full text is in Chinese and we include articles only if they are published in English. 39. Technical eligibility for treatment of magnetic resonance-guided focused ultrasound surgery. Fröling V, Kröncke TJ, Schreiter NF, Scheurig-Muenkler C, Collettini F, Hamm B, Beck A. Cardiovasc Intervent Radiol. 2014 Apr;37(2):445-50. doi: 10.1007/s00270-013-0678-z. Epub 2013 Jul 10.

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				47. MR-guided focused ultrasound (MRgFUS) is effective for the distinct pattern of uterine fibroids seen in African-American women: data from phase III/IV, non-randomized, multicenter clinical trials. Machtinger R, Fennessy FM, Stewart EA, Missmer SA, Correia KF, Tempany CM. J Ther Ultrasound. 2013 Dec 2;1:23. doi: 10.1186/2050-5736-1-23. eCollection 2013. PMID: 25232480 [PubMed] Free PMC Article Similar articles 48. [Clinical outcome of magnetic-resonance-guided focused ultrasound surgery (MRgFUS) in the treatment of symptomatic uterine fibroids]. Kamp JE, David M, Scheurig-Muenkler C, Hengst S, Beck A. Rofo. 2013 Feb;185(2):136-43. doi: 10.1055/s-0032-1325512. Epub 2012 Nov 29. German. PMID: 23196835 [PubMed - indexed for MEDLINE] Similar articles 49. MR-guided focus ultrasound (MRgFUS) for symptomatic uterine fibroids: predictors of treatment success.	This paper was not included in our evidence review because it is not an RCT but a retrospective observational study on the technical eligibility of MRgFUS. 40. Analysis and reduction of thermal dose errors in MRgFUS treatment. Zucconi F, Colombo PE, Pasetto S, Lascialfari A, Ticca C, Torresin A. Phys Med. 2014 Feb;30(1):111-6. doi: 10.1016/j.ejmp.2013.04.003. Epub 2013 Jun 5. This paper was not included in our evidence review because it is not an RCT but an observational study on the errors in the temperature measurements when using MRgFUS and their effect on thermal dose. 41. Magnetic resonance imaging-guided focused ultrasound surgery for symptomatic uterine fibroids: estimation of treatment efficacy using thermal dose calculations. Yoon SW, Cha SH, Ji YG, Kim HC, Lee MH, Cho JH. Eur J Obstet Gynecol Reprod Biol. 2013 Jul;169(2):304-8. doi: 10.1016/j.ejogrb.2013.02.023. Epub 2013 Mar 22.

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				Machtinger R, Inbar Y, Cohen-Eylon S, Admon D, Alagem-Mizrachi A, Rabinovici J. Hum Reprod. 2012 Dec;27(12):3425-31. doi: 10.1093/humrep/des333. Epub 2012 Sep 26. PMID: 23019304 [PubMed - indexed for MEDLINE] Similar articles 50. Review of nonsurgical/minimally invasive treatments for uterine fibroids. van der Kooij SM, Ankum WM, Hehenkamp WJ. Curr Opin Obstet Gynecol. 2012 Dec;24(6):368-75. doi: 10.1097/GCO.0b013e328359f10a. Review. PMID: 23014141 [PubMed - indexed for MEDLINE] Similar articles 51. High-intensity focused ultrasound: principles, therapy guidance, simulations and applications. Jenne JW, Preusser T, Günther M. Z Med Phys. 2012 Dec;22(4):311-22. doi: 10.1016/j.zemedi.2012.07.001. Epub 2012 Aug 10. Review. PMID: 22884198 [PubMed - indexed for MEDLINE] Similar articles	This paper was not included in our evidence review because it is not an RCT but an observational study. 42. MR-guided high-intensity focused ultrasound: current status of an emerging technology. Napoli A, Anzidei M, Ciolina F, Marotta E, Cavallo Marincola B, Brachetti G, Di Mare L, Cartocci G, Boni F, Noce V, Bertaccini L, Catalano C. Cardiovasc Intervent Radiol. 2013 Oct;36(5):1190-203. doi: 10.1007/s00270-013-0592-4. Epub 2013 Mar 9. Review. This paper was not included in our evidence review because it is not an RCT. 43. [MR-guided focused ultrasound. Current and future applications]. Trumm CG, Napoli A, Peller M, Clevert DA, Stahl R, Reiser M, Matzko M. Radiologe. 2013 Mar;53(3):200-8. doi: 10.1007/s00117-012-2417-x. German. This paper was not included in our evidence review because it is not an RCT. The full text is in German

				52. Clinical 24 month experience of the first MRgFUS unit for treatment of uterine fibroids in Australia. Dobrotwir A, Pun E. J Med Imaging Radiat Oncol. 2012 Aug;56(4):409-16. doi: 10.1111/j.1754-9485.2012.02376.x. Epub 2012 Apr 24. PMID: 22883648 [PubMed - indexed for MEDLINE] Similar articles 53. MRgFUS treatment of uterine fibroid in a nulliparous woman with acute retention of urine. Nyapathy V, Polina L. J Radiol Case Rep. 2012 Feb;6(2):1-8. doi: 10.3941/jrcr.v6i2.809. Epub 2012 Feb 1. PMID: 22690280 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 54. MR-guided focused ultrasound for the treatment of uterine fibroids. Hesley GK, Gorny KR, Woodrum DA. Cardiovasc Intervent Radiol. 2013 Feb;36(1):5-13. doi: 10.1007/s00270-012-0367-3. Epub 2012 Mar 28. Review.	and we include articles only if they are published in English. 44. Magnetic Resonance-guided Focused Ultrasound Treatment for Uterine Fibroids: First Study in Indian Women. Desai SB, Patil AA, Nikam R, Desai AS, Bachhav V. J Clin Imaging Sci. 2012;2:74. doi: 10.4103/2156-7514.104307. Epub 2012 Dec 4. This paper was not included in our evidence review because it is not an RCT but an observational study. 45. Safety and treatment volumes achieved following new developments of the magnetic resonance-guided focused ultrasound system in the treatment of uterine fibroids: a cohort study. Quinn SD, Vedelago J, Regan L, Gedroyc WM. J Ther Ultrasound. 2013 Oct 1;1:20. doi: 10.1186/2050-5736-1-20. eCollection 2013. This paper was not included in our evidence review because it is not an RCT but an observational study.

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				PMID: 22453202 [PubMed - indexed for MEDLINE] Similar articles 55. [Principles and technique of magnetic resonance guided focused ultrasound surgery (MRgFUS) in the treatment of uterine fibroids]. Vázquez-Lamadrid J, Fernández-de Lara Y, Carrasco-Choque A, Romero-Trejo C, Cosme-Labarthe J, Roldan-Valadez E. Gac Med Mex. 2011 Jul-Aug;147(4):333-41. Review. Spanish. PMID: 21894231 [PubMed - indexed for MEDLINE] Similar articles 56. Mitigation of abdominal scars during MR-guided focused ultrasound treatment of uterine leiomyomas with the use of an energy-blocking scar patch. Yoon SW, Seong SJ, Jung SG, Lee SY, Jun HS, Lee JT. J Vasc Interv Radiol. 2011 Dec;22(12):1747-50. doi: 10.1016/j.jvir.2011.07.005. Epub 2011 Aug 16. PMID: 21840732 [PubMed - indexed for MEDLINE] Similar articles	46. Clinical predictors of successful magnetic resonance-guided focused ultrasound (MRgFUS) for uterine leiomyoma. Gorny KR, Borah BJ, Weaver AL, Brown D, Woodrum DA, Stewart EA, Hesley GK. J Ther Ultrasound. 2013 Sep 2;1:15. doi: 10.1186/2050-5736-1-15. eCollection 2013. This paper was not included in our evidence review because it is not an RCT but a retrospective observational study. 47. MR-guided focused ultrasound (MRgFUS) is effective for the distinct pattern of uterine fibroids seen in African-American women: data from phase III/IV, non-randomized, multicenter clinical trials. Machtinger R, Fennessy FM, Stewart EA, Missmer SA, Correia KF, Tempany CM. J Ther Ultrasound. 2013 Dec 2;1:23. doi: 10.1186/2050-5736-1-23. eCollection 2013. This paper was not included in our evidence review because it is not an RCT. 48. [Clinical outcome of magnetic-resonance-guided focused ultrasound surgery (MRgFUS) in the treatment of symptomatic uterine fibroids].

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				57. Uncomplicated term vaginal delivery following magnetic resonance-guided focused ultrasound surgery for uterine fibroids. Zaher S, Lyons D, Regan L. Biomed Imaging Interv J. 2010 Apr-Jun;6(2):e28. doi: 10.2349/biij.6.2.e28. Epub 2010 Apr 1. PMID: 21611041 [PubMed] Free PMC Article Similar articles 58. Magnetic resonance-guided focused ultrasound surgery (MRgFUS) treatment for uterine fibroids. Abdullah B, Subramaniam R, Omar S, Wragg P, Ramli N, Wui A, Lee C, Yusof Y. Biomed Imaging Interv J. 2010 Apr-Jun;6(2):e15. doi: 10.2349/biij.6.2.e15. Epub 2010 Apr 1. PMID: 21611036 [PubMed] Free PMC Article Similar articles 59. Uterine artery embolisation and magnetic resonance-guided focused ultrasound treatment of uterine fibroids. Sieroń D, Wiggermann P, Skupiński J, Kukawska-Sysio K, Lisek U, Koczy A. Pol J Radiol. 2011 Apr;76(2):37-9. PMID: 22802829 [PubMed] Free PMC Article Similar articles	Kamp JE, David M, Scheurig-Muenkler C, Hengst S, Beck A. Rofo. 2013 Feb;185(2):136-43. doi: 10.1055/s-0032-1325512. Epub 2012 Nov 29. German. This paper was not included in our evidence review because it is not an RCT. The full text is in German ad we include articles only if they are published in English. 49. MR-guided focus ultrasound (MRgFUS) for symptomatic uterine fibroids: predictors of treatment success. Machtinger R, Inbar Y, Cohen-Eylon S, Admon D, Alagem-Mizrachi A, Rabinovici J. Hum Reprod. 2012 Dec;27(12):3425-31. doi: 10.1093/humrep/des333. Epub 2012 Sep 26. This paper was not included in our evidence review because it is not an RCT but a non-comparative retrospective study. 50. Review of nonsurgical/minimally invasive treatments for uterine fibroids. van der Kooij SM, Ankum WM, Hehenkamp WJ.

				60. Successful in vitro fertilization pregnancy following magnetic resonance-guided focused ultrasound surgery for uterine fibroids. Zaher S, Lyons D, Regan L. J Obstet Gynaecol Res. 2011 Apr;37(4):370-3. doi: 10.1111/j.1447-0756.2010.01344.x. Epub 2011 Mar 9. PMID: 21392163 [PubMed - indexed for MEDLINE] Similar articles 61. High intensity focused ultrasound ablation: a new therapeutic option for solid tumors. Orsi F, Arnone P, Chen W, Zhang L. J Cancer Res Ther. 2010 Oct-Dec;6(4):414-20. doi: 10.4103/0973-1482.77064. Review. PMID: 21358073 [PubMed - indexed for MEDLINE] Free Article Similar articles 62. Spontaneous vaginal expulsion of uterine myoma after magnetic resonance-guided focused ultrasound surgery. Kim KA, Yoon SW, Yoon BS, Park CT, Kim SH, Lee JT.	Curr Opin Obstet Gynecol. 2012 Dec;24(6):368-75. doi: 10.1097/GCO.0b013e328359f10a. Review. This paper was not included in our evidence review because it is not an RCT but a narrative review with no new relevant RCTs in the reference list. 51. High-intensity focused ultrasound: principles, therapy guidance, simulations and applications. Jenne JW, Preusser T, Günther M. Z Med Phys. 2012 Dec;22(4):311-22. doi: 10.1016/j.zemedi.2012.07.001. Epub 2012 Aug 10. Review. This paper was not included in our evidence review because it is not an RCT but a narrative review of technology. 52. Clinical 24 month experience of the first MRgFUS unit for treatment of uterine fibroids in Australia. Dobrotwir A, Pun E. J Med Imaging Radiat Oncol. 2012 Aug;56(4):409-16. doi: 10.1111/j.1754-9485.2012.02376.x. Epub 2012 Apr 24.

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				J Minim Invasive Gynecol. 2011 Jan-Feb;18(1):131-4. doi: 10.1016/j.jmig.2010.09.015. PMID: 21195969 [PubMed - indexed for MEDLINE] Similar articles 63. [French first results using magnetic resonance-guided focused ultrasound for myoma treatment]. Marret H, Bleuzen A, Guérin A, Lauvin-Gaillard MA, Herbreteau D, Patat F, Tranquart F. Gynecol Obstet Fertil. 2011 Jan;39(1):12-20. doi: 10.1016/j.gyobfe.2010.08.038. Epub 2010 Dec 24. French. PMID: 21185759 [PubMed - indexed for MEDLINE] Similar articles 64. Contrast-Enhanced Dynamic MR Imaging of Uterine Fibroids as a Potential Predictor of Patient Eligibility for MR Guided Focused Ultrasound (MRgFUS) Treatment for Symptomatic Uterine Fibroids. Yoon SW, Lee C, Kim KA, Kim SH. Obstet Gynecol Int. 2010;2010. pii: 834275. doi: 10.1155/2010/834275. Epub 2010 Aug 16. PMID: 20847940 [PubMed] Free PMC Article Similar articles	This paper was not included in our evidence review because it is not an RCT. 53. MRgFUS treatment of uterine fibroid in a nulliparous woman with acute retention of urine. Nyapathy V, Polina L. J Radiol Case Rep. 2012 Feb;6(2):1-8. doi: 10.3941/jrcr.v6i2.809. Epub 2012 Feb 1. This paper was not included in our evidence review because it is not an RCT but a case report. 54. MR-guided focused ultrasound for the treatment of uterine fibroids. Hesley GK, Gorny KR, Woodrum DA. Cardiovasc Intervent Radiol. 2013 Feb;36(1):5-13. doi: 10.1007/s00270-012-0367-3. Epub 2012 Mar 28. Review. This paper was not included in our evidence review because it is not an RCT but a narrative review. 55. [Principles and technique of magnetic resonance guided focused ultrasound surgery (MRgFUS) in the treatment of uterine fibroids].

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				65. ExAblate magnetic resonance-guided focused ultrasound system in multiple body applications. Dick EA, Gedroyc WM. Expert Rev Med Devices. 2010 Sep;7(5):589-97. doi: 10.1586/erd.10.38. PMID: 20822382 [PubMed - indexed for MEDLINE] Similar articles 66. Successful magnetic resonance imaging-guided focused ultrasound surgery for recurrent uterine fibroid previously treated with uterine artery embolization. Yoon SW, Kim KA, Kim SH, Lee JT. Obstet Gynecol Int. 2010;2010. pii: 351273. doi: 10.1155/2010/351273. Epub 2010 Aug 16. PMID: 20814554 [PubMed] Free PMC Article Similar articles 67. Magnetic resonance-guided focused ultrasound surgery. Al Hilli MM, Stewart EA. Semin Reprod Med. 2010 May;28(3):242-9. doi: 10.1055/s-0030-1251481. Epub 2010 Apr 22. PMID: 20414847 [PubMed - indexed for MEDLINE] Similar articles	Vázquez-Lamadrid J, Fernández-de Lara Y, Carrasco-Choque A, Romero-Trejo C, Cosme-Labarthe J, Roldan-Valadez E. Gac Med Mex. 2011 Jul-Aug;147(4):333-41. Review. Spanish. This paper was not included in our evidence review because it is not an RCT but a narrative review of the technique. The full text is in Spanish and we include articles only if they are published in English. 56. Mitigation of abdominal scars during MR-guided focused ultrasound treatment of uterine leiomyomas with the use of an energy-blocking scar patch. Yoon SW, Seong SJ, Jung SG, Lee SY, Jun HS, Lee JT. J Vasc Interv Radiol. 2011 Dec;22(12):1747-50. doi: 10.1016/j.jvir.2011.07.005. Epub 2011 Aug 16. This paper was not included in our evidence review because it is not an RCT but a prospective, nonrandomised, single-arm study. 57. Uncomplicated term vaginal delivery following magnetic resonance-guided focused ultrasound surgery for uterine fibroids.

				68. Eligibility and accessibility of magnetic resonance-guided focused ultrasound (MRgFUS) for the treatment of uterine leiomyomas. Behera MA, Leong M, Johnson L, Brown H. Fertil Steril. 2010 Oct;94(5):1864-8. doi: 10.1016/j.fertnstert.2009.09.063. PMID: 19931074 [PubMed - indexed for MEDLINE] Similar articles 69. Magnetic resonance-guided focused ultrasound (MRgFUS) compared with abdominal hysterectomy for treatment of uterine leiomyomas. Taran FA, Tempany CM, Regan L, Inbar Y, Revel A, Stewart EA; MRgFUS Group. Ultrasound Obstet Gynecol. 2009 Nov;34(5):572-8. doi: 10.1002/uog.7435. PMID: 19852046 [PubMed - indexed for MEDLINE] Free Article Similar articles 70. Non-invasive magnetic resonance-guided focused ultrasound treatment of uterine fibroids in a large Japanese population: impact of the learning curve on patient outcome.	Zaher S, Lyons D, Regan L. Biomed Imaging Interv J. 2010 Apr-Jun;6(2):e28. doi: 10.2349/biij.6.2.e28. Epub 2010 Apr 1. This paper was not included in our evidence review because it is not an RCT but a case study. 58. Magnetic resonance-guided focused ultrasound surgery (MRgFUS) treatment for uterine fibroids. Abdullah B, Subramaniam R, Omar S, Wragg P, Ramli N, Wui A, Lee C, Yusof Y. Biomed Imaging Interv J. 2010 Apr-Jun;6(2):e15. doi: 10.2349/biij.6.2.e15. Epub 2010 Apr 1. This paper was not included in our evidence review because it is not an RCT but a description of how the technique is performed in one clinical unit. 59. Uterine artery embolisation and magnetic resonance-guided focused ultrasound treatment of uterine fibroids. Sieroń D, Wiggermann P, Skupiński J, Kukawska-Sysio K, Lisek U, Koczy A. Pol J Radiol. 2011 Apr;76(2):37-9.

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				Okada A, Morita Y, Fukunishi H, Takeichi K, Murakami T. Ultrasound Obstet Gynecol. 2009 Nov;34(5):579-83. doi: 10.1002/uog.7454. PMID: 19852042 [PubMed - indexed for MEDLINE] Free Article Similar articles 71. Clinical outcomes of magnetic resonance-guided focused ultrasound surgery for uterine myomas: 24-month follow-up. Funaki K, Fukunishi H, Sawada K. Ultrasound Obstet Gynecol. 2009 Nov;34(5):584-9. doi: 10.1002/uog.7455. PMID: 19852041 [PubMed - indexed for MEDLINE] Free Article Similar articles 72. MRgFUS: a sound approach to fibroid therapy. Gedroyc WM. Ultrasound Obstet Gynecol. 2009 Nov;34(5):494-6. doi: 10.1002/uog.7458. No abstract available. PMID: 19852039 [PubMed - indexed for MEDLINE] Free Article Similar articles	This paper was not included in our evidence review because it is not an RCT but a description of the benefits and risks of the techniques. 60. Successful in vitro fertilization pregnancy following magnetic resonance-guided focused ultrasound surgery for uterine fibroids. Zaher S, Lyons D, Regan L. J Obstet Gynaecol Res. 2011 Apr;37(4):370-3. doi: 10.1111/j.1447-0756.2010.01344.x. Epub 2011 Mar 9. This paper was not included in our evidence review because it is not an RCT but a case study of in-vitro fertilisation after MRgFUS treatment. 61. High intensity focused ultrasound ablation: a new therapeutic option for solid tumors. Orsi F, Arnone P, Chen W, Zhang L. J Cancer Res Ther. 2010 Oct-Dec;6(4):414-20. doi: 10.4103/0973-1482.77064. Review. This paper was not included in our evidence review because it is not an RCT but a review of high-intensity focused ultrasound ablation on cancer tumours.

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				73. A novel method to aid in the visualisation and treatment of uterine fibroids with MRgFUS in patients with abdominal scars. Zaher S, Gedroyc W, Lyons D, Regan L. Eur J Radiol. 2010 Nov;76(2):269-73. doi: 10.1016/j.ejrad.2009.07.004. Epub 2009 Aug 8. PMID: 19665856 [PubMed - indexed for MEDLINE] Similar articles 74. MRI-guided focused ultrasound surgery. Jolesz FA. Annu Rev Med. 2009;60:417-30. doi: 10.1146/annurev.med.60.041707.170303. Review. PMID: 19630579 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 75. Reduction by 98% in uterine myoma volume associated with significant symptom relief after peripheral treatment with magnetic resonance imaging-guided focused ultrasound surgery. de Melo FC, Diacoyannis L, Moll A, Tovar-Moll F. J Minim Invasive Gynecol. 2009 Jul-Aug;16(4):501-3. doi: 10.1016/j.jmig.2009.04.007.	62. Spontaneous vaginal expulsion of uterine myoma after magnetic resonance-guided focused ultrasound surgery. Kim KA, Yoon SW, Yoon BS, Park CT, Kim SH, Lee JT. J Minim Invasive Gynecol. 2011 Jan-Feb;18(1):131-4. doi: 10.1016/j.jmig.2010.09.015. This paper was not included in our evidence review because it is not an RCT but a case report. 63. [French first results using magnetic resonance-guided focused ultrasound for myoma treatment]. Marret H, Bleuzen A, Guérin A, Lauvin-Gaillard MA, Herbreteau D, Patat F, Tranquart F. Gynecol Obstet Fertil. 2011 Jan;39(1):12-20. doi: 10.1016/j.gyobfe.2010.08.038. Epub 2010 Dec 24. French. This paper was not included in our evidence review because it is not an RCT. The full text is in French and we include articles only if they are published in English. 64. Contrast-Enhanced Dynamic MR Imaging of Uterine Fibroids as a Potential Predictor of

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				PMID: 19573831 [PubMed - indexed for MEDLINE] Similar articles 76. MR-guided focused ultrasound: a potentially disruptive technology. Bradley WG Jr. J Am Coll Radiol. 2009 Jul;6(7):510-3. doi: 10.1016/j.jacr.2009.01.004. Review. PMID: 19560068 [PubMed - indexed for MEDLINE] Similar articles 77. Decreasing margins to the uterine serosa as a method for increasing the volume of fibroids ablated with magnetic resonance-guided focused ultrasound surgery. Morita Y, Takeuchi S, Hikida H, Ohashi H, Ito N. Eur J Obstet Gynecol Reprod Biol. 2009 Sep;146(1):92-5. doi: 10.1016/j.ejogrb.2009.05.004. Epub 2009 May 28. PMID: 19481328 [PubMed - indexed for MEDLINE] Similar articles 78. What factors currently limit magnetic resonance-guided focused ultrasound of leiomyomas? A survey	Patient Eligibility for MR Guided Focused Ultrasound (MRgFUS) Treatment for Symptomatic Uterine Fibroids. Yoon SW, Lee C, Kim KA, Kim SH. Obstet Gynecol Int. 2010;2010. pii: 834275. doi: 10.1155/2010/834275. Epub 2010 Aug 16. This paper was not included in our evidence review because it is not an RCT but a case study. 65. ExAblate magnetic resonance-guided focused ultrasound system in multiple body applications. Dick EA, Gedroyc WM. Expert Rev Med Devices. 2010 Sep;7(5):589-97. doi: 10.1586/erd.10.38. This paper was not included in our evidence review because it is not an RCT but a description of the technology. 66. Successful magnetic resonance imaging-guided focused ultrasound surgery for recurrent uterine fibroid previously treated with uterine artery embolization. Yoon SW, Kim KA, Kim SH, Lee JT.

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				conducted at the first international symposium devoted to clinical magnetic resonance-guided focused ultrasound. Taran FA, Hesley GK, Gorny KR, Stewart EA. Fertil Steril. 2010 Jun;94(1):331-4. doi: 10.1016/j.fertnstert.2009.02.083. Epub 2009 Apr 21. PMID: 19386300 [PubMed - indexed for MEDLINE] Similar articles 79. Initial evaluation of acoustic reflectors for the preservation of sensitive abdominal skin areas during MRgFUS treatment. Gorny KR, Chen S, Hangiandreou NJ, Hesley GK, Woodrum DA, Brown DL, Felmlee JP. Phys Med Biol. 2009 Apr 21;54(8):N125-33. doi: 10.1088/0031-9155/54/8/N02. Epub 2009 Mar 20. PMID: 19305044 [PubMed - indexed for MEDLINE] Similar articles 80. The utility of pelvic coil SNR testing in the quality assurance of a clinical MRgFUS system. Gorny KR, Hangiandreou NJ, Ward HA, Hesley GK, Brown DL, Felmlee JP. Phys Med Biol. 2009 Apr 7;54(7):N83-91. doi: 10.1088/0031-9155/54/7/N01. Epub 2009 Mar 5.	Obstet Gynecol Int. 2010;2010. pii: 351273. doi: 10.1155/2010/351273. Epub 2010 Aug 16. This paper was not included in our evidence review because it is not an RCT but a case study. 67. Magnetic resonance-guided focused ultrasound surgery. Al Hilli MM, Stewart EA. Semin Reprod Med. 2010 May;28(3):242-9. doi: 10.1055/s-0030-1251481. Epub 2010 Apr 22. This paper was not included in our evidence review because it is not an RCT but a narrative review. 68. Eligibility and accessibility of magnetic resonance-guided focused ultrasound (MRgFUS) for the treatment of uterine leiomyomas. Behera MA, Leong M, Johnson L, Brown H. Fertil Steril. 2010 Oct;94(5):1864-8. doi: 10.1016/j.fertnstert.2009.09.063. This paper was not included in our evidence review because it is not an RCT but a retrospective study.

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				PMID: 19265205 [PubMed - indexed for MEDLINE] Similar articles 81. Patient suitability for magnetic resonance guided focused ultrasound surgery of uterine fibroids. Zaher S, Gedroyc WM, Regan L. Eur J Obstet Gynecol Reprod Biol. 2009 Apr;143(2):98-102. doi: 10.1016/j.ejogrb.2008.12.011. Epub 2009 Jan 31. PMID: 19185968 [PubMed - indexed for MEDLINE] Similar articles 82. MRI-based thermal dosimetry and diffusion-weighted imaging of MRI-guided focused ultrasound thermal ablation of uterine fibroids. Pilatou MC, Stewart EA, Maier SE, Fennessy FM, Hynynen K, Tempany CM, McDannold N. J Magn Reson Imaging. 2009 Feb;29(2):404-11. doi: 10.1002/jmri.21688. PMID: 19161196 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 83. [New options in the diagnosis and management of uterine myoma].	69. Magnetic resonance-guided focused ultrasound (MRgFUS) compared with abdominal hysterectomy for treatment of uterine leiomyomas. Taran FA, Tempany CM, Regan L, Inbar Y, Revel A, Stewart EA; MRgFUS Group. Ultrasound Obstet Gynecol. 2009 Nov;34(5):572-8. doi: 10.1002/uog.7435. This paper was not included in our evidence review because it is a non-randomised trial. 70. Non-invasive magnetic resonance-guided focused ultrasound treatment of uterine fibroids in a large Japanese population: impact of the learning curve on patient outcome. Okada A, Morita Y, Fukunishi H, Takeichi K, Murakami T. Ultrasound Obstet Gynecol. 2009 Nov;34(5):579-83. doi: 10.1002/uog.7454. This paper was not included in our evidence review because it is not an RCT. 71. Clinical outcomes of magnetic resonance-guided focused ultrasound surgery for uterine myomas: 24-month follow-up.

				Hrgović Z, Kulas T, Habek D, Izetbegović S, Hrgović I. Med Arh. 2008;62(4):234-9. Review. Bosnian. PMID: 19145810 [PubMed - indexed for MEDLINE] Similar articles 84. Cost-effectiveness of magnetic resonance guided focused ultrasound for the treatment of uterine fibroids. O'Sullivan AK, Thompson D, Chu P, Lee DW, Stewart EA, Weinstein MC. Int J Technol Assess Health Care. 2009 Jan;25(1):14-25. doi: 10.1017/S0266462309090035. PMID: 19126247 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 85. Magnetic resonance-guided focused ultrasound for uterine fibroids. Roberts A. Semin Intervent Radiol. 2008 Dec;25(4):394-405. doi: 10.1055/s-0028-1102999. PMID: 21326581 [PubMed] Free PMC Article Similar articles	Funaki K, Fukunishi H, Sawada K. Ultrasound Obstet Gynecol. 2009 Nov;34(5):584-9. doi: 10.1002/uog.7455. This paper was not included in our evidence review because it is not an RCT. 72. MRgFUS: a sound approach to fibroid therapy. Gedroyc WM. Ultrasound Obstet Gynecol. 2009 Nov;34(5):494-6. doi: 10.1002/uog.7458. No abstract available. This paper was not included in our evidence review because it is not an RCT. 73. A novel method to aid in the visualisation and treatment of uterine fibroids with MRgFUS in patients with abdominal scars. Zaher S, Gedroyc W, Lyons D, Regan L. Eur J Radiol. 2010 Nov;76(2):269-73. doi: 10.1016/j.ejrad.2009.07.004. Epub 2009 Aug 8. This paper was not included in our evidence review because it is not an RCT.

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				86. The responsiveness of the uterine fibroid symptom and health-related quality of life questionnaire (UFS-QOL). Harding G, Coyne KS, Thompson CL, Spies JB. Health Qual Life Outcomes. 2008 Nov 12;6:99. doi: 10.1186/1477-7525-6-99. PMID: 19014505 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 87. Pregnancy outcome after magnetic resonance-guided focused ultrasound surgery (MRgFUS) for conservative treatment of uterine fibroids. Rabinovici J, David M, Fukunishi H, Morita Y, Gostout BS, Stewart EA; MRgFUS Study Group. Fertil Steril. 2010 Jan;93(1):199-209. doi: 10.1016/j.fertnstert.2008.10.001. Epub 2008 Nov 14. PMID: 19013566 [PubMed - indexed for MEDLINE] Similar articles 88. Pain palliation in patients with bone metastases using MR-guided focused ultrasound surgery: a multicenter study. Liberman B, Gianfelice D, Inbar Y, Beck A, Rabin T, Shabshin N, Chander G, Hengst S, Pfeffer R, Chechick A, Hanannel A, Dogadkin O, Catane R.	74. MRI-guided focused ultrasound surgery. Jolesz FA. Annu Rev Med. 2009;60:417-30. doi: 10.1146/annurev.med.60.041707.170303. Review. This paper was not included in our evidence review because it is not an RCT but a narrative review. 75. Reduction by 98% in uterine myoma volume associated with significant symptom relief after peripheral treatment with magnetic resonance imaging-guided focused ultrasound surgery. de Melo FC, Diacoyannis L, Moll A, Tovar-Moll F. J Minim Invasive Gynecol. 2009 Jul-Aug;16(4):501-3. doi: 10.1016/j.jmig.2009.04.007. This paper was not included in our evidence review because it is not an RCT. 76. MR-guided focused ultrasound: a potentially disruptive technology. Bradley WG Jr. J Am Coll Radiol. 2009 Jul;6(7):510-3. doi: 10.1016/j.jacr.2009.01.004. Review.

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				Ann Surg Oncol. 2009 Jan;16(1):140-6. doi: 10.1245/s10434-008-0011-2. Epub 2008 Nov 11. PMID: 19002530 [PubMed - indexed for MEDLINE] Similar articles 89. Real-time liver motion compensation for MRgFUS. Ross JC, Tranquebar R, Shanbhag D. Med Image Comput Comput Assist Interv. 2008;11(Pt 2):806-13. PMID: 18982679 [PubMed - indexed for MEDLINE] Similar articles 90. Evaluation of referenceless thermometry in MRI-guided focused ultrasound surgery of uterine fibroids. McDannold N, Tempany C, Jolesz F, Hynynen K. J Magn Reson Imaging. 2008 Oct;28(4):1026-32. doi: 10.1002/jmri.21506. PMID: 18821603 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 91. Successful use of magnetic resonance-guided focused ultrasound surgery to relieve symptoms in a patient with symptomatic focal adenomyosis.	This paper was not included in our evidence review because it is not an RCT. 77. Decreasing margins to the uterine serosa as a method for increasing the volume of fibroids ablated with magnetic resonance-guided focused ultrasound surgery. Morita Y, Takeuchi S, Hikida H, Ohashi H, Ito N. Eur J Obstet Gynecol Reprod Biol. 2009 Sep;146(1):92-5. doi: 10.1016/j.ejogrb.2009.05.004. Epub 2009 May 28. This paper was not included in our evidence review because it is not an RCT. 78. What factors currently limit magnetic resonance-guided focused ultrasound of leiomyomas? A survey conducted at the first international symposium devoted to clinical magnetic resonance-guided focused ultrasound. Taran FA, Hesley GK, Gorny KR, Stewart EA. Fertil Steril. 2010 Jun;94(1):331-4. doi: 10.1016/j.fertnstert.2009.02.083. Epub 2009 Apr 21.

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				Yoon SW, Kim KA, Cha SH, Kim YM, Lee C, Na YJ, Kim SJ. Fertil Steril. 2008 Nov;90(5):2018.e13-5. doi: 10.1016/j.fertnstert.2008.05.028. Epub 2008 Aug 9. PMID: 18692791 [PubMed - indexed for MEDLINE] Similar articles 92. Patient selection guidelines in MR-guided focused ultrasound surgery of uterine fibroids: a pictorial guide to relevant findings in screening pelvic MRI. Yoon SW, Lee C, Cha SH, Yu JS, Na YJ, Kim KA, Jung SG, Kim SJ. Eur Radiol. 2008 Dec;18(12):2997-3006. doi: 10.1007/s00330-008-1086-7. Epub 2008 Jul 11. PMID: 18618119 [PubMed - indexed for MEDLINE] Similar articles 93. A clinical review of focused ultrasound ablation with magnetic resonance guidance: an option for treating uterine fibroids. Hesley GK, Gorny KR, Henrichsen TL, Woodrum DA, Brown DL. Ultrasound Q. 2008 Jun;24(2):131-9. doi: 10.1097/RUQ.0b013e31817c5e0c. Review.	This paper was not included in our evidence review because it is not an RCT but a survey-based study among clinicians. 79. Initial evaluation of acoustic reflectors for the preservation of sensitive abdominal skin areas during MRgFUS treatment. Gorny KR, Chen S, Hangiandreou NJ, Hesley GK, Woodrum DA, Brown DL, Felmlee JP. Phys Med Biol. 2009 Apr 21;54(8):N125-33. doi: 10.1088/0031-9155/54/8/N02. Epub 2009 Mar 20. This paper was not included in our evidence review because it is not an RCT on the effectiveness of treating women with HMB. 80. The utility of pelvic coil SNR testing in the quality assurance of a clinical MRgFUS system. Gorny KR, Hangiandreou NJ, Ward HA, Hesley GK, Brown DL, Felmlee JP. Phys Med Biol. 2009 Apr 7;54(7):N83-91. doi: 10.1088/0031-9155/54/7/N01. Epub 2009 Mar 5. This paper was not included in our evidence review because it is not an RCT on the effectiveness of treating HMB.

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				PMID: 18528271 [PubMed - indexed for MEDLINE] Similar articles 94. Conventional myomectomy. Mukhopadhaya N, De Silva C, Manyonda IT. Best Pract Res Clin Obstet Gynaecol. 2008 Aug;22(4):677-705. doi: 10.1016/j.bpobgyn.2008.01.012. Epub 2008 Apr 18. Review. PMID: 18395493 [PubMed - indexed for MEDLINE] Similar articles 95. Cost-effectiveness of magnetic resonance-guided focused ultrasound surgery for treatment of uterine fibroids. Zowall H, Cairns JA, Brewer C, Lamping DL, Gedroyc WM, Regan L. BJOG. 2008 Apr;115(5):653-62. doi: 10.1111/j.1471-0528.2007.01657.x. PMID: 18333948 [PubMed - indexed for MEDLINE] Free PMC Article Similar articles 96. Management of symptomatic fibroids: conservative surgical treatment modalities other than abdominal or laparoscopic myomectomy.	81. Patient suitability for magnetic resonance guided focused ultrasound surgery of uterine fibroids. Zaher S, Gedroyc WM, Regan L. Eur J Obstet Gynecol Reprod Biol. 2009 Apr;143(2):98-102. doi: 10.1016/j.ejogrb.2008.12.011. Epub 2009 Jan 31. This paper was not included in our evidence review because it is not an RCT but a retrospective analysis. 82. MRI-based thermal dosimetry and diffusion-weighted imaging of MRI-guided focused ultrasound thermal ablation of uterine fibroids. Pilatou MC, Stewart EA, Maier SE, Fennessy FM, Hynynen K, Tempany CM, McDannold N. J Magn Reson Imaging. 2009 Feb;29(2):404-11. doi: 10.1002/jmri.21688. This paper was not included in our evidence review because it is not an RCT. 83. [New options in the diagnosis and management of uterine myoma].

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				Istre O. Best Pract Res Clin Obstet Gynaecol. 2008 Aug;22(4):735-47. doi: 10.1016/j.bpobgyn.2008.01.010. Epub 2008 Mar 7. Review. PMID: 18328788 [PubMed - indexed for MEDLINE] Similar articles 97. Non-invasive magnetic resonance imaging-guided focused ultrasound treatment for uterine fibroids - early experience. Morita Y, Ito N, Hikida H, Takeuchi S, Nakamura K, Ohashi H. Eur J Obstet Gynecol Reprod Biol. 2008 Aug;139(2):199-203. Epub 2007 Dec 21. PMID: 18160200 [PubMed - indexed for MEDLINE] Similar articles 98. Subjective effect of magnetic resonance-guided focused ultrasound surgery for uterine fibroids. Funaki K, Sawada K, Maeda F, Nagai S. J Obstet Gynaecol Res. 2007 Dec;33(6):834-9. PMID: 18001451 [PubMed - indexed for MEDLINE] Similar articles	Hrgović Z, Kulas T, Habek D, Izetbegović S, Hrgović I. Med Arh. 2008;62(4):234-9. Review. Bosnian. This paper was not included in our evidence review because it is not an RCT. The full text is in Bosnian and we include articles only if they are published in English. 84. Cost-effectiveness of magnetic resonance guided focused ultrasound for the treatment of uterine fibroids. O'Sullivan AK, Thompson D, Chu P, Lee DW, Stewart EA, Weinstein MC. Int J Technol Assess Health Care. 2009 Jan;25(1):14-25. doi: 10.1017/S0266462309090035. Thank you for notifying us of this study. This was not picked up by our literature search and we have added it to the list of included health economic studies. 85. Magnetic resonance-guided focused ultrasound for uterine fibroids. Roberts A.

				99. Clinical improvement and shrinkage of uterine fibroids after thermal ablation by magnetic resonance-guided focused ultrasound surgery. Rabinovici J, Inbar Y, Revel A, Zalel Y, Gomori JM, Itzchak Y, Schiff E, Yagel S. Ultrasound Obstet Gynecol. 2007 Oct;30(5):771-7. PMID: 17899577 [PubMed - indexed for MEDLINE] Free Article Similar articles 100. Mid-term outcome of magnetic resonance-guided focused ultrasound surgery for uterine myomas: from six to twelve months after volume reduction. Funaki K, Fukunishi H, Funaki T, Kawakami C. J Minim Invasive Gynecol. 2007 Sep-Oct;14(5):616-21. PMID: 17848324 [PubMed - indexed for MEDLINE] Similar articles 101. Features influencing patient selection for fibroid treatment with magnetic resonance-guided focused ultrasound. Arleo EK, Khilnani NM, Ng A, Min RJ. J Vasc Interv Radiol. 2007 May;18(5):681-5.	Semin Intervent Radiol. 2008 Dec;25(4):394-405. doi: 10.1055/s-0028-1102999. This paper was not included in our evidence review because it is not an RCT. 86. The responsiveness of the uterine fibroid symptom and health-related quality of life questionnaire (UFS-QOL). Harding G, Coyne KS, Thompson CL, Spies JB. Health Qual Life Outcomes. 2008 Nov 12;6:99. doi: 10.1186/1477-7525-6-99. This paper was not included in our evidence review because it is not an RCT but a post-hoc analysis of the responsiveness of the UFS-QOL questionnaire. 87. Pregnancy outcome after magnetic resonance-guided focused ultrasound surgery (MRgFUS) for conservative treatment of uterine fibroids. Rabinovici J, David M, Fukunishi H, Morita Y, Gostout BS, Stewart EA; MRgFUS Study Group. Fertil Steril. 2010 Jan;93(1):199-209. doi: 10.1016/j.fertnstert.2008.10.001. Epub 2008 Nov 14.

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				PMID: 17494853 [PubMed - indexed for MEDLINE] Similar articles 102. Magnetic resonance-guided focused ultrasound surgery for uterine fibroids: relationship between the therapeutic effects and signal intensity of preexisting T2-weighted magnetic resonance images. Funaki K, Fukunishi H, Funaki T, Sawada K, Kaji Y, Maruo T. Am J Obstet Gynecol. 2007 Feb;196(2):184.e1-6. PMID: 17306674 [PubMed - indexed for MEDLINE] Similar articles 103. Focused ultrasound surgery of intramural leiomyomas may facilitate fertility: a case report. Hanstede MM, Tempany CM, Stewart EA. Fertil Steril. 2007 Aug;88(2):497.e5-7. Epub 2007 Feb 8. PMID: 17292361 [PubMed - indexed for MEDLINE] Similar articles 104. MR-guided focused ultrasound surgery (MRgFUS) for the palliation of pain in patients with bone metastases--preliminary clinical experience.	This paper was not included in our evidence review because it is not an RCT and looks at pregnancy outcomes after MRgFUS treatment. 88. Pain palliation in patients with bone metastases using MR-guided focused ultrasound surgery: a multicenter study. Liberman B, Gianfelice D, Inbar Y, Beck A, Rabin T, Shabshin N, Chander G, Hengst S, Pfeffer R, Chechick A, Hanannel A, Dogadkin O, Catane R. Ann Surg Oncol. 2009 Jan;16(1):140-6. doi: 10.1245/s10434-008-0011-2. Epub 2008 Nov 11. This paper was not included in our evidence review because it is not an RCT and not on treatment of HMB. 89. Real-time liver motion compensation for MRgFUS. Ross JC, Tranquebar R, Shanbhag D. Med Image Comput Comput Assist Interv. 2008;11(Pt 2):806-13. This paper was not included in our evidence review because it is not an RCT.

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				Catane R, Beck A, Inbar Y, Rabin T, Shabshin N, Hengst S, Pfeffer RM, Hanannel A, Dogadkin O, Liberman B, Kopelman D. Ann Oncol. 2007 Jan;18(1):163-7. Epub 2006 Oct 9. PMID: 17030549 [PubMed - indexed for MEDLINE] Similar articles 105. Does the phase of menstrual cycle affect MR-guided focused ultrasound surgery of uterine leiomyomas? So MJ, Fennessy FM, Zou KH, McDannold N, Hynynen K, Jolesz FA, Stewart EA, Rybicki FJ, Tempany CM. Eur J Radiol. 2006 Aug;59(2):203-7. PMID: 16766153 [PubMed - indexed for MEDLINE] Similar articles 106. MR guided focused ultrasound: technical acceptance measures for a clinical system. Gorny KR, Hangiandreou NJ, Hesley GK, Gostout BS, McGee KP, Felmlee JP. Phys Med Biol. 2006 Jun 21;51(12):3155-73. Epub 2006 Jun 6.	90. Evaluation of referenceless thermometry in MRI-guided focused ultrasound surgery of uterine fibroids. McDannold N, Tempany C, Jolesz F, Hynynen K. J Magn Reson Imaging. 2008 Oct;28(4):1026-32. doi: 10.1002/jmri.21506. This paper was not included in our evidence review because it is not an RCT. 91. Successful use of magnetic resonance-guided focused ultrasound surgery to relieve symptoms in a patient with symptomatic focal adenomyosis. Yoon SW, Kim KA, Cha SH, Kim YM, Lee C, Na YJ, Kim SJ. Fertil Steril. 2008 Nov;90(5):2018.e13-5. doi: 10.1016/j.fertnstert.2008.05.028. Epub 2008 Aug 9. This paper was not included in our evidence review because it is not an RCT but a pictorial essay. 92. Patient selection guidelines in MR-guided focused ultrasound surgery of uterine fibroids: a pictorial guide to relevant findings in screening pelvic MRI.

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				PMID: 16757869 [PubMed - indexed for MEDLINE] Similar articles 107. Magnetic resonance guided focused ultrasound surgery of uterine fibroids--the tissue effects of GnRH agonist pre-treatment. Smart OC, Hindley JT, Regan L, Gedroyc WM. Eur J Radiol. 2006 Aug;59(2):163-7. Epub 2006 Jun 5. PMID: 16740371 [PubMed - indexed for MEDLINE] Similar articles 108. Clinical outcomes of focused ultrasound surgery for the treatment of uterine fibroids. Stewart EA, Rabinovici J, Tempany CM, Inbar Y, Regan L, Gostout B, Hesley G, Kim HS, Hengst S, Gedroyc WM. Fertil Steril. 2006 Jan;85(1):22-9. Erratum in: Fertil Steril. 2006 Apr;85(4):1072. Gastout, Bobbie [corrected to Gostout, Bobbie]; Gedroye, Wladyslaw M [corrected to Gedroyc, Wladyslaw M]. PMID: 16412721 [PubMed - indexed for MEDLINE] Similar articles	Yoon SW, Lee C, Cha SH, Yu JS, Na YJ, Kim KA, Jung SG, Kim SJ. Eur Radiol. 2008 Dec;18(12):2997-3006. doi: 10.1007/s00330-008-1086-7. Epub 2008 Jul 11. This paper was not included in our evidence review because it is not an RCT but a case study. 93. A clinical review of focused ultrasound ablation with magnetic resonance guidance: an option for treating uterine fibroids. Hesley GK, Gorny KR, Henrichsen TL, Woodrum DA, Brown DL. Ultrasound Q. 2008 Jun;24(2):131-9. doi: 10.1097/RUQ.0b013e31817c5e0c. Review. This paper was not included in our evidence review because it is not an RCT but an overview of clinical experience. 94. Conventional myomectomy. Mukhopadhaya N, De Silva C, Manyonda IT. Best Pract Res Clin Obstet Gynaecol. 2008 Aug;22(4):677-705. doi: 10.1016/j.bpobgyn.2008.01.012. Epub 2008 Apr 18. Review.

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				109. Pregnancy and live birth after focused ultrasound surgery for symptomatic focal adenomyosis: a case report. Rabinovici J, Inbar Y, Eylon SC, Schiff E, Hananel A, Freundlich D. Hum Reprod. 2006 May;21(5):1255-9. Epub 2006 Jan 12. PMID: 16410334 [PubMed - indexed for MEDLINE] Similar articles 110. MRI-guided focused ultrasound surgery of uterine leiomyomas. Fennessy FM, Tempany CM. Acad Radiol. 2005 Sep;12(9):1158-66. Review. PMID: 16099686 [PubMed - indexed for MEDLINE] Similar articles 111. [Magnetic resonance tomography guided focussed ultrasound surgery (MRgFUS) in tumor therapy--a new noninvasive therapy option]. Hengst SA, Ehrenstein T, Herzog H, Beck A, Utz-Billing I, David M, Felix R, Ricke J. Radiologe. 2004 Apr;44(4):339-46. Review. German.	This paper was not included in our evidence review because it is not an RCT. 95. Cost-effectiveness of magnetic resonance-guided focused ultrasound surgery for treatment of uterine fibroids. Zowall H, Cairns JA, Brewer C, Lamping DL, Gedroyc WM, Regan L. BJOG. 2008 Apr;115(5):653-62. doi: 10.1111/j.1471-0528.2007.01657.x. This paper was included in the health-economic analysis. 96. Management of symptomatic fibroids: conservative surgical treatment modalities other than abdominal or laparoscopic myomectomy. Istre O. Best Pract Res Clin Obstet Gynaecol. 2008 Aug;22(4):735-47. doi: 10.1016/j.bpobgyn.2008.01.010. Epub 2008 Mar 7. Review. This paper was not included in our evidence review because it is not an RCT.

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				PMID: 15057422 [PubMed - indexed for MEDLINE] Similar articles	97. Non-invasive magnetic resonance imaging-guided focused ultrasound treatment for uterine fibroids - early experience. Morita Y, Ito N, Hikida H, Takeuchi S, Nakamura K, Ohashi H. Eur J Obstet Gynecol Reprod Biol. 2008 Aug;139(2):199-203. Epub 2007 Dec 21. This paper was not included in our evidence review because it is not an RCT. 98. Subjective effect of magnetic resonance-guided focused ultrasound surgery for uterine fibroids. Funaki K, Sawada K, Maeda F, Nagai S. J Obstet Gynaecol Res. 2007 Dec;33(6):834-9. This paper was not included in our evidence review because it is not an RCT. 99. Clinical improvement and shrinkage of uterine fibroids after thermal ablation by magnetic resonance-guided focused ultrasound surgery. Rabinovici J, Inbar Y, Revel A, Zalel Y, Gomori JM, Itzchak Y, Schiff E, Yagel S Ultrasound Obstet Gynecol. 2007 Oct;30(5):771-7.

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					This paper was not included in our evidence review because it is not an RCT but a prospective observational study. 100. Mid-term outcome of magnetic resonance-guided focused ultrasound surgery for uterine myomas: from six to twelve months after volume reduction. Funaki K, Fukunishi H, Funaki T, Kawakami C. J Minim Invasive Gynecol. 2007 Sep-Oct;14(5):616-21. This paper was not included in our evidence review because it is not an RCT but a prospective observational study. 101. Features influencing patient selection for fibroid treatment with magnetic resonance-guided focused ultrasound. Arleo EK, Khilnani NM, Ng A, Min RJ. J Vasc Interv Radiol. 2007 May;18(5):681-5. This paper was not included in our evidence review because it is not an RCT.

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					102. Magnetic resonance-guided focused ultrasound surgery for uterine fibroids: relationship between the therapeutic effects and signal intensity of preexisting T2-weighted magnetic resonance images. Funaki K, Fukunishi H, Funaki T, Sawada K, Kaji Y, Maruo T. Am J Obstet Gynecol. 2007 Feb;196(2):184.e1-6. This paper was not included in our evidence review because it is not an RCT. 103. Focused ultrasound surgery of intramural leiomyomas may facilitate fertility: a case report. Hanstede MM, Tempany CM, Stewart EA. Fertil Steril. 2007 Aug;88(2):497.e5-7. Epub 2007 Feb 8. This paper was not included in our evidence review because it is not an RCT but a case report. 104. MR-guided focused ultrasound surgery (MRgFUS) for the palliation of pain in patients with bone metastases--preliminary clinical experience.

					Catane R, Beck A, Inbar Y, Rabin T, Shabshin N, Hengst S, Pfeffer RM, Hanannel A, Dogadkin O, Liberman B, Kopelman D. Ann Oncol. 2007 Jan;18(1):163-7. Epub 2006 Oct 9. This paper was not included in our evidence review because it is not an RCT. 105. Does the phase of menstrual cycle affect MR-guided focused ultrasound surgery of uterine leiomyomas? So MJ, Fennessy FM, Zou KH, McDannold N, Hynynen K, Jolesz FA, Stewart EA, Rybicki FJ, Tempany CM. Eur J Radiol. 2006 Aug;59(2):203-7. This paper was not included in our evidence review because it is not an RCT. 106. MR guided focused ultrasound: technical acceptance measures for a clinical system. Gorny KR, Hangiandreou NJ, Hesley GK, Gostout BS, McGee KP, Felmlee JP. Phys Med Biol. 2006 Jun 21;51(12):3155-73. Epub 2006 Jun 6.

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					This paper was not included in our evidence review because it is not an RCT. 107. Magnetic resonance guided focused ultrasound surgery of uterine fibroids--the tissue effects of GnRH agonist pre-treatment. Smart OC, Hindley JT, Regan L, Gedroyc WM. Eur J Radiol. 2006 Aug;59(2):163-7. Epub 2006 Jun 5. This paper was not included in our evidence review because it is not an RCT. 108. Clinical outcomes of focused ultrasound surgery for the treatment of uterine fibroids. Stewart EA, Rabinovici J, Tempany CM, Inbar Y, Regan L, Gostout B, Hesley G, Kim HS, Hengst S, Gedroyc WM. Fertil Steril. 2006 Jan;85(1):22-9. Erratum in: Fertil Steril. 2006 Apr;85(4):1072. Gastout, Bobbie [corrected to Gostout, Bobbie]; Gedroye, Wladyslaw M [corrected to Gedroyc, Wladyslaw M]. This paper was not included in our evidence review because it is not an RCT.

					109. Pregnancy and live birth after focused ultrasound surgery for symptomatic focal adenomyosis: a case report. Rabinovici J, Inbar Y, Eylon SC, Schiff E, Hananel A, Freundlich D. Hum Reprod. 2006 May;21(5):1255-9. Epub 2006 Jan 12. This paper was not included in our evidence review because it is not an RCT but a case report. 110. MRI-guided focused ultrasound surgery of uterine leiomyomas. Fennessy FM, Tempany CM. Acad Radiol. 2005 Sep;12(9):1158-66. Review. This paper was not included in our evidence review because it is not an RCT. 111. [Magnetic resonance tomography guided focussed ultrasound surgery (MRgFUS) in tumor therapy--a new noninvasive therapy option]. Hengst SA, Ehrenstein T, Herzog H, Beck A, Utz-Billing I, David M, Felix R, Ricke J. Radiologe. 2004 Apr;44(4):339-46. Review. German.

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					This paper was not included in our evidence review because it is not an RCT. The full text is in German and we include articles only if they are published in English.
FEmISA	Economic Model	General	General	**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	Thank you for your comment. The headings used in the comment have been reporoduced in the developer's response for clarity. **Treatment alternatives** UAE and MrgFUS were not included in the economic evaluation because it was not possible to include them in the network meta-analysis which was used in the model to estimate relative treatment effect. This is discussed in the health economics chapter. "The choice of treatments largely reflected those that were included within the NMA undertaken for this guideline. The exceptions were polypectomy and TCRF, which were included as they are potentially important first-line treatment options if diagnosis indicates polyps or SMFs. The model considered both first-line treatment and second-line treatment in those in whom first-line treatment was unsuccessful or discontinued." However, the guideline recommendations list UAE as one of the treatment options that can be considered as a treatment for fibroids of 3 cm or more in diameter, including as a first-line treatment.

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				Treatment Costs Missed myomectomy – Major, Laparoscopic or Endoscopic, Upper Genital Tract Procedures, with CC Score 2+ Major, Laparoscopic or Endoscopic, Upper Genital Tract Procedures, with CC Score 0-1 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**	**Test accuracy** In the updated guideline we use the term pelvic ultrasound (where either transabdominal or transvaginal ultrasound can be used) apart from possible adenomyosis where transvaginal is preferred. However, in the economic evaluation pelvic ultrasound is taken to be a transvaginal scan as according to the glossary in the NICE 2007 "the technique makes it possible to get closer to pelvic structures than transabdominal ultrasound". A recent UK HTA (Cooper 2014) used a transvaginal scan in their economic analysis which was justified as an adaptation of the 2007 NICE guideline. The only reference the NICE 2007 guideline makes to transabdominal ultrasound is in the glossary entry for transvaginal ultrasound (see quotation above). Recommendations, in the NICE 2007 guideline do not specify transabdominal or transvaginal but there is no indication that the previous guideline committee considered that transabdominal ultrasound should be used in preference to transvaginal ultrasound. For example, in Appendix A of the NICE 2007 guideline the costing of imaging procedures only includes the costs for transvaginal ultrasound. Pelvic ultrasound is recommended as the first-line diagnostic test for women where the uterus is palpable abdominally,

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				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.	history or examination suggests a pelvic mass or examination is inconclusive or difficult. MRI was not included in the model as it is not (commonly used) as a diagnostic test in women presenting with HMB other than when adenomyosis is suspected. The model reflects that endometrial biopsy will not diagnose subserosal fibroids (0% sensitivity) but can identify polyps and submucosal fibroids. Also, where endometrial biopsy does not indicate an underlying pathology it has good sensitivity for identifying that group with no identifiable pathology which are considered to represent a large group of those presenting with HMB (34% in the health economic model). Endometriosis is outside the scope of the guideline. Diagnosis of adenomyosis is controversial and whilst adenomyosis can be associated with HMB it is not the main presenting symptom. We adopted the approach of the Cooper (2014) study – "The omission can be justified because pain rather than HMB tends to be the presenting symptom of adenomyosis. Moreover, treatment is not affected by the suspicion of adenomyosis….it is unlikely that the exclusion of adenomyosis as a potential

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					aetiology of HMB would have any effect on the outcome of the economic evaluation." Some women classified as having "no identifiable pathology" may have adenomyosis but management would usually not differ if their pathology was identified. The model reflects that hysteroscopy will not diagnose subserosal fibroids (0% sensitivity). Adenomyosis is not included in the model but those identified as having no identifiable pathology through hysteroscopy would receive appropriate management if they had (unidentified) adenomyosis. Hysterectomy alone, without a prior diagnostic test, was included as an empirical treatment strategy which also reflected the approach of the Cooper (2014) study. Of the 12 analyses presented in the health economics chapter, only 2 considered empirical treatment with hysterectomy as one of the strategies and it was not found to be cost-effective in those analyses. **Diagnostic Consultation and Costs** See the rationale provided above for using transvaginal ultrasound costs in preference to transabdominal ultrasound and for why MRI was not included in the analysis.

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					The model assumes a failure rate for diagnostic tests after which it is assumed that a further confirmatory test would take place In line with the NICE guidelines methods manual (see https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf) this analysis was undertaken from an NHS and personal social services perspective. Costs incurred by women are not included under such a perspective. **Treatment Costs** Neither myomectomy nor ulipristal acetate was included in the economic analysis. **Operative Complications** UAE and MRgFUS are not included in the model. As noted elsewhere, diagnostic hysteroscopy is not thought to have significant morbidity or mortality. Lost pay/productivity are not included in analyses undertaken from an NHS and PSS perspective. **Treatment gain** These treatments are not included in the analysis which is reflected in Figure 12 of the consultation version of the health economics chapter. Figure 12

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					in the health economics chapter is based on the Excel Worksheet <Treatment Gain> in the spreadsheet model which allows the user to toggle treatment between 0/1 (ineffective/effective) for the various underlying pathologies in the model. Included on that sheet are a number of "legacy" treatments (including UAE, myomectomy and MRgFUS) that were not ultimately included in the model as there was no comparative effectiveness data on them in the network meta-analysis. These are marked "n/a" in that spreadsheet which means they are not included in the guideline version of the model. It is not an assessment as to whether they would be considered effective treatments or not for the underlying pathology. **Population and Health State Utility** It is standard practice in health economic models to make such assumptions, about a woman's age for example – for example in the HMB context see https://www.journalslibrary.nihr.ac.uk/hta/hta15190/#/abstract or https://www.journalslibrary.nihr.ac.uk/hta/hta18240/#/abstract. A rationale for choosing an age of 42 years at point of entry into the model is given in the "Setting and population" section. The guideline recommendations recognise that the treatment options/choices for younger women may differ for

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					example, because they are more likely to want to preserve their fertility. The health economic analysis assesses the health related quality of life benefits over 5 years reflecting the data in the network meta-analyses. This is stated under the heading of model structure in the health economics chapter "The timeframe of the model is 5 years reflecting the follow-up period of studies included in the NMA for long term health related quality of life." This is a commonly used time horizon for economic analyses of HMB, e.g. You 2006, You 2009, Clegg 2007, Lete 2011, Ganz 2015. However, when calculating the QALY loss from surgical mortality the model did consider the lifetime effect as restricting this to 5-years would clearly underestimate the QALY loss from mortality. Simplifying assumptions are made with respect to modelling operative and postoperative complications but we followed the approach of a previously published UK economic evaluation. The model assigns a large cost to complications arising from hysterectomy. Prolapse often occurs a very long time after surgery meaning that it largely would occur outside the timeframe of the model. **Complication Costs**

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					Whilst it is recognised that there is an increased risk of vaginal prolapse with hysterectomy the relationship is complicated with the precise risk determined by a number of factors such as number of vaginal births, difficulty and mode of birth. Furthermore, the onset of vaginal prolapse is usually a very long time after surgery. The economic evaluation does not explicitly model prolapse (or other specific adverse events) of hysterectomy but it does model postoperative complications of hysterectomy and assigns a high cost to such events. Costs to the women, her family and employer would not be included under an NHS and PSS perspective, which is the perspective stipulated in the NICE methods manual for interventions with health outcomes in an NHS settings. Litigation costs would not ordinarily be included either as it would imply that care was sub-optimal and/or not undertaken according to NICE guidelines. The rate of complications from hysteroscopy are low (0.28% in a study of 13,600 diagnostic and operative hysteroscopies) and those that do occur do not generally incur a high cost. In Cooper (2014) no serious complications were assumed to be associated with any of the ambulatory procedures (ultrasound, hysteroscopy and EBx) based on

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					evidence from systematic reviews of the available literature (references in Cooper HTA 21, 84, 95, 143). Mortality rates were assumed to be negligible for all the diagnostic tests (references in Cooper HTA 21, 84, 95, 143) http://emedicine.medscape.com/article/1848258-overview#a9 The most common site of perforation is the uterine fundus, which rarely leads to significant morbidity unless electrosurgical instrumentation is used. Injuries to this area can be managed conservatively because, generally, minimal bleeding occurs.
FEmISA	App B	General	General	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	Thank you for your comment. The Royal College of Obstetrics and Gynaecology (RCOG) is the host organisation for the National Guideline Alliance (NGA). The contract was awarded following a competitive tendering process. The independence of the NGA from RCOG is ensured by it being wholly funded by NICE and by provisions in the contract between NICE and RCOG regarding NGA's governance. This required the establishment of a consortium board, which is the decision-making body for the NGA. It has a wide membership and its purpose is to ensure that there is a robust framework in place for the

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				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. 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.	management of resources and deliverables and that controls and assurances against relevant risks are in place. Additionally, it ensures that outputs are developed in a fair and inclusive manner in line with NICE methodologies. The RCOG is not a majority member of the consortium board. It includes representatives from RCOG, the Royal College of Psychiatrists, the Royal College of Pathologists, the Royal College of Radiologists, the Royal College of Surgeons of England, the Royal College of Physicians, the Royal College of Paediatrics and Child Health, the Royal College of General Practitioners, the Royal College of Midwives, the Royal College of Nursing, the College of Social Work, and the British Psychological Society. We accept that there are value judgements with respect to the optimal composition of the committee and that some stakeholders might disagree with the final composition. Nevertheless, the guideline committee is constrained to work according to NICE methods and processes, making recommendations based on the best available evidence and being transparent in providing a rationale for those recommendations. The stakeholder consultation is a crucial part in scrutinising those recommendations (and rationale) and is open to all interested parties.

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					NICE guidelines are produced for the NHS and are based on the best available evidence and developed according to NICE methods. The guideline recognises the importance of women's treatment preferences (see recommendation: "When agreeing the treatment options for HMB with the woman, take into account the woman's preferences"). This guideline does not seek to promote hysterectomy where it would not be an appropriate treatment option and is produced for the NHS and not the private sector.
Gedeon Richter UK Ltd	Short	13	14 - 16	Preoperative anaemia is associated with adverse post-operative outcomes in women undergoing gynecological surgery[1]. Thus pretreatment should also be considered for those with anaemia/low haemoglobin prior to surgical intervention (and not just if uterine fibroids are causing an enlarged or distorted uterus as per current wording). Ulipristal acetate (UPA) 5mg is indicated for pre-operative and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.[2] The Aug 2016 HMB Guideline update noted the evidence for use of UPA in women with low Hb.[3,4,5] 1. Richards T, Musallam K, Nassif J, et al. Impact of Preoperative Anaemia and Blood Transf usion on Postoperative	Thank you for your comment. The guideline committee recognises the importance of assessing the anaemia status of the woman and its implications on treatment but considers this to be part of standard assessment prior to surgical interventions. We have amended the recommendation about pretreatment before surgery to include ulipristal acetate in addition to gonadotrophin-releasing hormone analogue: '1.5.16 Pretreatment with gonadotrophin-releasing hormone analogue or ulipristal acetate before hysterectomy and myomectomy should be considered if uterine fibroids are causing an enlarged or distorted uterus. [2007, amended 2017]'. However, because pretreatment was not part of the partial update of the guideline and no evidence was reviewed, we did not amend the recommendation further.

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				Outcomes in Gynaecological Surgery. PLoS One. 2015 Jul 6;10(7):e0130861. doi: 10.1371 2. Esmya 5mg ulipristal acetate SPC http://www.medicines.org.uk/emc/medicine/26068 3. NICE HMB Guideline Update Aug 2016 4. Donnez J, Tatarchuk TF, Bouchard P, et al. Ulipristal acetate versus placebo for fibroid treatment before surgery. N Engl J Med. 2012 Feb 2;366(5):409-20. doi: 10.1056/NEJMoa1103182. **Donnez J, Tomaszewski J, Vázquez F, et al. Ulipristal acetate versus leuprolide acetate for uterine fibroids. N Engl J Med. 2012 Feb 2;366(5):421-32. doi: 10.1056/NEJMoa1103180.**	
Gedeon Richter UK Ltd	App C	2		In line with 1.5.16 in the draft guideline (pg 13), please consider adding 'pretreatment' to the 'Consider surgery' tab on the treatment pathway	Thank you for your comment. We have added the recommendation regarding pretreatment before surgery to the algorithm.
Hologic UK Limited	Short	General	General	There is no reference within the current guidelines about techniques for removing polyps or fibroids and therefore no mention of hysteroscopic morcellation. We recommend that the current guidance (IPG522) needs to be updated to reflect the evidence that shows hysteroscopic morcellation is superior to electrosurgical resection[1, 2]. The evidence suggests that hysteroscopic morcellation should be considered first line treatment for the removal of polyps and fibroids, especially within an outpatient setting.	Thank you for your comment. The guideline committee recommends considering hysterosopic removal of uterine fibroids but did not specify the technique used in the absence of clinical evidence. The systematic reviews referenced (Shazly et al., 2016, and Li et al., 2016) did not include any studies that were eligible for our evidence review of randomised controlled trials on treatment for fibroids among women with HMB. Regarding updating the IPG522, we have referred your

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				1. Sherif A. M. Shazly, Shannon K. Laughlin-Tommaso, Daniel M. Breitkopf, MatthewR. Hopkins, Tatnai L. Burnett et al. Hysteroscopic Morcellation Versus Resection for the Treatment of Uterine Cavitary Lesions: A Systematic Review and Meta-analysis. *The Journal of Minimally Invasive Gynecology*. DOI http://dx.doi.org/10.1016/j.jmig.2016.04.013 Chunbo Li, Zhiyuan Dai, Yuping Gong, Bingying Xie, Bei Wang. A systematic review and meta-analysis of randomized controlled trials comparing hysteroscopic morcellation with resectoscopy for patients with endometrial lesions. *International Journal of Gynecology & Obstetrics*. DOI: 10.1002/ijgo.12012	comment to the NICE interventional procedures team.
Hologic UK Limited	Short	10	23 - 29	Recommendation 1.5.4: This recommendation would benefit from the addition/support of information currently within the appendices to provide clearer guidance on the use of endometrial ablation and the prevention of unnecessary delays in the patient receiving effective treatment. It is at a far too late stage that the patient is offered the treatment choice of second-generation endometrial ablation at recommendation 1.5.4. The recommendation and information in the appendices combined provide strong guidance, but the current draft recommendation 1.5.4 does not reflect the content of the appendices. If the patient can't tolerate hormonal treatment as first line treatment through LNG-IUS then there is a strong possibility that the patient won't be able to tolerate	Thank you for your comment. The guideline is for use in both primary care as well as secondary care. Primary care will be the first setting in which women with HMB will present. Most GPs / community gynaecologists can prescribe pharmacological treatments and fit LNG-IUS devices but do not perform endometrial ablation. Thus recommendations 1.5.2 and 1.5.3 are separated from 1.5.5 which refers to secondary care interventions which include endometrial ablation. We do not speculate upon the likelihood of women being able to tolerate different types of hormonal

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	Appendices	103	6 - 21	other hormonal medical management treatment options. It is our recommendation to offer second-generation endometrial ablation as a 'non-hormonal' treatment option for those patients who have finished child-bearing. Up to 60% of patient's discontinued LNG-IUS therapy within 5 years due to progestin related side effects, pelvic pain and unscheduled bleeding[1]. Furthermore the data states that at 2 years, 36% of patients had discontinued LNG-IUS therapy[2] and 42% of patients went on to have a hysterectomy, within 5 years[3]. At 5 years; more than 90% of patients avoided a hysterectomy[4] with a second-generation radiofrequency bipolar device and at 10 years; more than 83% of patients avoided a hysterectomy[5] with a second-generation radiofrequency bipolar device. We would suggest offering the treatment option of second-generation endometrial ablation at recommended guideline 1.5.3 rather than 1.5.4 to encourage patient choice with transparency. The following comments in the appendices expand on this further saying: "The committee discussed that in current clinical practice, women with HMB face difficulty in gaining access to surgery, often having tried and failed various treatment strategies over a prolonged period of time before even being considered for surgery. The committee agreed that for women who do not wish to have pharmacological treatment and who do not want to conserve their fertility, surgical options could be considered as a first-line treatment option. The evidence	interventions. Recommendation 1.5.3 refers to 'suitability' which is not synonymous with tolerability because it can include relative and absolute contraindications, patient preferences etc. Furthermore, the recommendation in question refers to 'pharmacological' treatments which are not limited to hormonal treatments but also include non-hormonal pharmacological treatments which may be an option for women who prefer not to take hormones. The committee felt that the use of the term 'non-hormonal' should be restricted to referring to 'non-hormonal' pharmacological treatments as this terminology is well understood by medical practitioners and should not be conflated with other non-pharmacological interventions such as surgery and uterine artery embolisation which are 'non-hormonal'. Endometrial ablation is indicated as stated in the comment in women who do not, or no longer, desire future fertility. However, endometrial ablation does not provide contraception in contrast to most recommended hormonal pharmacological treatments. Thus, pharmacological options should be considered as we state in recommendations 1.5.2 and 1.5.3 regardless of whether 'child-bearing' has finished.
	Appendices	103	34 - 38		
		103	43 - 51		
		104	1 - 4		

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				showed that, in women with HMB and no identified pathology or fibroids less than 3 cm in diameter, hysterectomy and second generation endometrial ablation were more effective than first generation endometrial ablation techniques on patient satisfaction. The committee decided that based on the evidence, hysterectomy or second generation surgical techniques should be used where surgery is deemed an appropriate first-line treatment option. The evidence further showed that hysterectomy was more effective than first and second generation endometrial ablation on health-related quality of life. However, the committee decided that not all women would want their uterus removed nor desire major surgery and thus hierarchy was not to be given to hysterectomy over second generation endometrial ablation." "The committee also discussed that referral to secondary care may be appropriate for women who decline initial pharmacological treatment. These women may benefit from a discussion on the risks and benefits of the different treatment options, including pharmacological and surgical options, with a specialist in order to find the most appropriate treatment strategy for the woman. Where symptoms are severe, the committee agreed that women may benefit from referral to secondary care for consideration of further investigations and to discuss treatment options further. Early referral of these women to specialists may result in a more appropriate management plan earlier on, avoiding prolonged suffering."	The evidence supports recommendation 1.5.2 to consider the LNG-IUS as first-line pharmacological treatment. Good quality RCTs have evaluated the LNG-IUS against hysterectomy and also against other pharmacological treatments. The discontinuation rates are well documented and reasons for discontinuation may not always relate to treatment failure. Indeed other pharmacological or surgical options can be considered if the LNG-IUS is not effective, desired or tolerated. Our network meta-analysis and other published good quality systematic quantitative reviews did not demonstrate any clear superiority of endometrial ablation over LNG-IUS, other pharmacological treatments or hysterectomy. Comparative studies of sufficient methodological quality are lacking to recommend endometrial ablation over LNG-IUS based upon effectiveness and avoidance of hysterectomy in women who have no future fertility desires. The option for women to proceed directly to surgical management in secondary care is explicitly stated in recommendation 1.5.5. "… the woman declines pharmacological treatment, or symptoms are severe" and is not solely predicated on the need to try pharmacological treatment first. The 'Rationale and impact' section expands further on this point ("The committee agreed that women who decline pharmacological treatment and ask for

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				"In women who do not respond to pharmacological treatment, the committee agreed that these women may benefit from referral to secondary care for consideration of further investigations and discuss treatment options further. Second line treatment options for women with HMB and no identified pathology, fibroids less than 3 cm in diameter, suspected or confirmed adenomyosis, in whom first-line treatment is unsuccessful were discussed by the committee. The evidence (especially on pharmacological treatments) often did not stipulate whether the treatment options were used as first or second line, thus given the paucity of evidence on second line treatment options the committee decided that there should be a choice of second line treatment options in the form of a different pharmacological therapeutic class or surgery. Management options should be discussed with the women, explaining the benefits and risks, and also taking into account her fertility intentions, desire to preserve her uterus, and individual factors such as co-morbidities." The current treatment pathway outlined within the recommendations of the primary guidelines can be confusing and may read so with patients. Considering the committee's responses within the above appendices have a clearer more defined pathway; we suggest that the above committee comments be captured in the main guideline, by moving these into the "rationale and impact" section of the main guidance.	surgery as a first treatment may be referred to secondary care for consideration of further investigations and surgical treatment."). Thus, we do not anticipate confusion requiring the need to move further text from the "Committee discussion" section.

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				1. Ghazizadeh Shirin, Panahi Zahra, Ghanbari Zinat et al. Comparative Efficacy of NovaSure, the Levonorgestrel-releasing Intrauterine System, and Hysteroscopic Endometrial Resection in the Treatment of Menorrhagia: Randomized Clinical Trial. *Journal of Gynecological Surgery*. 0.1089/gyn.2012.0041. 2. Gupta Janesh, Kai Joe, Middleton Lee et al, Levonorgestrel Intrauterine System versus Medical Therapy for Menorrhagia. *The New England Journal of Medicine*. n engl j med 368;2. 3. Ewies Ayman et al, Levonorgestrel-releasing Intrauterine System – The discontinuing story. *Gynecological Endocrinology*. October 2009;25(10): 668-663 4. JH Kleijn, R Engels, P Bourdrez, BWJ Mol, MY Bongers et al. Five-year follow up of a randomised controlled trial comparing NovaSure and ThermaChoice endometrial ablation. *BJOG An International Journal of Obstetrics and Gynaecology.* BJOG 2008;115:193–198 *5.* MC Herman, JPM Penninx, BW Mol, MY Bongers et al. Ten-year follow-up of a randomised controlled trial comparing bipolar endometrial ablatio1n with balloon ablation for	

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				heavy menstrual bleeding. *BJOG An International Journal of Obstetrics and Gynaecology.* BJOG 2013;120:966–970.	
Hologic UK Limited	Short	13	4 - 6	According to your recommendation 1.5.14; 'Second-generation endometrial ablation should be a treatment option for women with Heavy Menstrual Bleeding and fibroids of 3 cm or MORE in diameter.' Fibroids much larger than 3 cm may distort the uterine cavity and would then make the cavity inappropriate to use with any second-generation endometrial ablation modality. Data shows that if there are fibroids present that are more than 3cm in diameter; the ablation may be less effective[1]. In a clinical study, the author concluded that; in women with symptomatic fibroids and bleeding, myolysis combined with endometrial ablation reduces subsequent surgery rates compared with endometrial ablation alone[2]. Clinical trials that determine the safety and efficacy for global endometrial ablation devices excluded patients with intracavitary fibroids greater than 2cm in diameter[3,4] .We are concerned there may have been an error with 'more' being used rather than 'less 'and would like the committee board to reconsider this. 1. Elise Hachmann-Nielsen, and Martin Rudnicki. Clinical Outcome after Hydrothermal Ablation Treatment of Menorrhagia in Patients with and without Submucous Myomas. *The Journal of*	Thank you for your comment. Firstly, second-generation endometrial ablation is recommended as a treatment option for women with fibroids less than 3 cm in diameter (recommendation 1.5.5). However, as pointed out in the comment, recommendation 1.5.14 says 'Consider second-generation endometrial ablation as a treatment option for women with HMB and fibroids of 3 cm or more in diameter who meet the criteria specified in the manufacturers' instructions.' We recognise the concern expressed in the comment with respect to the recommendation above but useful context is provided to the recommendation in the committee's discussion of the evidence. This explains why second-generation endometrial ablation can be considered where the manufacturer's criteria are met: "The size and shape of the uterine cavity are the main determinants of the feasibility and effectiveness of second generation endometrial ablation procedures. Fibroids of 3 cm or more in diameter lead to substantial uterine enlargement and distortion and so may be associated with poorer clinical outcomes or contraindicate the use of

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				Minimally Invasive Gynecology. Vol 19, No 2, March/April 2012. 2. Goldfarb HA. Combining myoma coagulation with endometrial ablation/resection reduces subsequent surgery rates. *JSLS*. 1999;3:253-260. 3. Jay Cooper, Richard Gimpelson, Philippe Laberge, Donald Galen, Jose Gerardo Garza-Leal, Josef Scott, Nicholas Leyland et al. A Randomized, Multicenter Trial of Safety and Efficacy of the NovaSure System in the Treatment of Menorrhagia. *The Journal of Minimally Invasive Gynecology.* Am Assoc Gynecol Laparosc 9(4):418–428, 2002. 4. Antoni J. Duleba, Martha C. Heppard, Richard M. Soderstrom, and Duane E. Townsend et al. A Randomized Study Comparing Endometrial Cryoablation and Rollerball Electroablation for Treatment of Dysfunctional Uterine Bleeding. *The Journal of the American Association of Gynecologic Laparoscopists*. J Am Assoc Gynecol Laparosc 10(1):17–26, 2003	ablation procedures. However, the use of second generation endometrial ablation can be considered if such fibroids do not distort, nor enlarge, the uterine cavity, in line with the specific device's manufacturer's restrictions. The committee agreed that there were limitations to the wording of "manufacturers' instructions", nonetheless due to differing cavity dimensions set by the manufacturers to achieve therapeutic effectiveness and the limitations in the different techniques and devices, it was deemed too simplistic to write a recommendation only taking into consideration the size and shape of the endometrial cavity. The committee also recognised that the wording of the recommendation may be perceived as vague, however they believed that the wording of "manufacturers' instructions" was pragmatic and generic enough to the specificities of each separate ablative technique and device." There was randomised controlled trial evidence included in our evidence review on fibroids up to 5 cm (Jain 2016). In addition there are studies that have considered the safety of the procedure (see https://www.ncbi.nlm.nih.gov/pubmed/12386350)
Hologic UK Limited	Short	14	8 - 14	At recommendation 1.5.21 If dilatation is needed for non-hysteroscopic endometrial ablation ***confirm that there is***	Thank you for your comment. We have amended the recommendation to say 'ultrasound may be used'

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				no evidence of uterine perforation or false passage, by either: • hysteroscopy before inserting the ablation device, to establish the condition of the uterus, **or** • Ultrasound to ensure correct uterine placement of the ablation device; if the device uses a balloon, keep this inflated during the ultrasound scan. The suggestion of performing an ultrasound to ensure correct uterine placement of the ablation device is not done in routine practice and many clinicians are not trained to perform this. A second-generation radiofrequency bipolar device has a cavity integrity test that ensures that the uterine cavity has no perforations and the ablation is able to proceed. If ultrasound is recommended; it should be an option only if hysteroscopy isn't available. Please see suggested amendments in bold italics. The inclusion of 'or' allows for differentiation considering ultrasound is not performed within routine practice.	to be consistent with the guidance from the Medicines and Healthcare products Regulatory Agency.
Hologic UK Limited	Appendices	40	Evidence review B 6 - 9 10 - 11	The statements below regarding second-generation bipolar radiofrequency ablation are important to patients, and therefore we believe that these statements should to be moved from the appendix to become a primary recommendation or at the very least should be moved from appendix to the "rationale and impact" section within the	Thank you for your comment. Recommendations in NICE guidelines do not include a discussion of the evidence or provide a rationale for the recommendation. The 'Rationale and impact section' aims to provide a brief summary of the main arguments justifying the

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	Appendices Appendices	46 103	Evidence review B 9 - 15 Evidence review B 22 - 33	main guideline (especially the last sentence from the last comment below taken from p103). Clinical data furthermore states that second-generation bipolar radiofrequency ablation is superior to balloon endometrial ablation as an office procedure in amenorrhea rate, patient satisfaction and quality of life[1]. "Novasure was found to lead to significantly lower blood loss than most other treatments (LNG-IUS, thermal balloon ablation, microwave endometrial ablation, cavaterm ablation and first generation endometrial ablation). No significant differences were found between any of the other surgical techniques, though the results were generally very imprecise." "Novasure had the highest probability of being the best surgical treatment for reducing blood loss in women with no identifiable fibroids (90.7%) (Table 14)." "Novasure had significantly higher patient satisfaction than thermal balloon ablation, microwave endometrial ablation, hydrotherm endometrial ablation, and first generation endometrial ablation (Table 20). Hysterectomy also led to higher numbers of satisfied patients than first generation endometrial ablation. Novasure had the highest probability of being the best surgical treatment for improving patient satisfaction in women with no identifiable fibroids	recommendations in an easily understandable manner and does not include details of the evidence. The sections describing the available evidence and the committee's discussion of the evidence are available in the evidence report documents.

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				(48.7%), followed by endometrial laser intrauterine thermotherapy (24.8%) and hysterectomy (16.6%) (Table 20)." "The evidence from the NMA favoured radiofrequency endometrial ablation as a preferential second generation endometrial ablation technique for the outcomes of blood loss and satisfaction. The committee also recognised radiofrequency endometrial ablation's current position in clinical practice with a majority of the market share. However, division of the specific second generation endometrial ablation techniques was done ad-hoc and the NMA showed incoherence, indicating that the results should be interpreted with caution. The committee were also aware of ongoing research in the development of other second generation surgical techniques, thus decided not to exclude other second generation surgical techniques from the recommendation. However the committee agreed that when selecting a second generation technique, providers should select 1 that is expected to deliver outcomes at least equivalent to those from radiofrequency endometrial ablation." 1. Josien P.M. Penninx, Malou C. Herman, Roy F.P.M. Kruitwagen, Annette J.F. Ter Haar, Ben W. Mol, Marlies Y. Bongers. Bipolar versus balloon endometrial ablation in the office: a randomized controlled trial. *European*	

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				Journal of Obstetrics & Gynecology and Reproductive Biology. DOI: http://dx.doi.org/10.1016/j.ejogrb.2015.10.010	
Hysteroscopy Action	Short	6	22	*"Explain to women with HMB who are offered outpatient hysteroscopy what the procedure involves and discuss the possible alternatives."* Following the Montgomery Supreme Court ruling on informed consent it is essential that all women are fully informed of the risk of severe pain during outpatient hysteroscopy and given the genuine choice of hysteroscopy under sedation or General Anaesthesia using a modern, narrow hysteroscope. Patients should be informed that they may stop an outpatient procedure if it is too painful and have the procedure rescheduled with general anaesthetic in the near future. It is important that there is not a delay in obtaining a general anaesthetic appointment since 25% of endometrial cancer is detected in pre-menopausal women. 'An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. 'The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks	Thank you for your comment. The guideline committee recognises the concerns over analgesia for hysteroscopy. According to a survey conducted among British Society for Gynaecological Endoscopy (BSGE) members, outpatient hysteroscopy is, in current practice, unfortunately not always performed according to best practice guidelines and instead outdated techniques might be used (for example larger scopes, non-vaginoscopic technique and unnecessary endometrial biopsies). As a consequence many women endure pain and discomfort unnecessarily. The RCOG best practice guidelines for diagnostic outpatient hysteroscopy outline processes and procedures that aim to minimise discomfort and pain for the woman. We have emphasised this in the new recommendations. We have amended the recommendations to clarify that if the woman declines outpatient hysteroscopy, she should be offered hysteroscopy under general or regional anaesthesia. '1.3.7 Explain to women with HMB who are offered outpatient hysteroscopy what the procedure involves and discuss the possible alternatives. [2017]

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				involved in any recommended treatment, and of any reasonable alternative or variant treatments. 'The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'	1.3.8 If a woman declines outpatient hysteroscopy, offer hysteroscopy under general or regional anaesthesia. [2017] 1.3.9 For women who decline hysteroscopy, consider pelvic ultrasound, explaining the limitations of this technique for detecting uterine cavity causes of HMB. [2017]'
Hysteroscopy Action	Short	7	19	*"For women who decline hysteroscopy, consider 2-dimensional pelvic ultrasound,"* Please would you clarify that 'hysteroscopy' here refers to both outpatient and inpatient hysteroscopy with general anaesthetic.	Thank you for your comment. The guideline committee has amended the recommendations so that if a woman declines outpatient hysteroscopy, she should be offered (not 'considered' for) hysteroscopy under general or regional anaesthesia. After this a recommendation says 'For women who decline hysteroscopy, consider pelvic ultrasound, explaining the limitations of this technique for detecting uterine cavitary causes of HMB'. Therefore, the guideline recommends that a pelvic ultrasound is considered if the woman has declined both outpatient and inpatient hysteroscopy under anaesthesia.
Hysteroscopy Action	Short	15	8	*"advances in technology mean that the hysteroscopy is well tolerated in the outpatient setting, and it can potentially be performed outside the traditional hospital environment in a community*	Thank you for your comment. The guideline committee wants to emphasise that if performed according to best practice guidelines,

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				setting". This is a sweeping statement which does not consider the 25% hysteroscopy outpatients whom NHS audits report as experiencing severe pain. While there are certainly some individual clinics and hysteroscopists whose practice is well-tolerated, these tend to be specialist clinics and hysteroscopists who have performed hundreds, if not thousands of procedures. A grim snapshot of extremely painful and traumatic hysteroscopies, plus ways to optimise the patient experience is recorded in RCOG lecture Nov 2016 – Outpatient Hysteroscopy – Optimising the Patient Experience: http://mediasitesvr01.rcog.org.uk/Mediasite/Play/b78707f452bc44ce818b79b0c2159df61d We are concerned that there is not yet a national regulated standard of hysteroscopy skill which all NHS hysteroscopists are required to have reached.	diagnostic hysteroscopy should be accepted and tolerated by the majority of women. The guideline committee recognises that currently hysteroscopy services are not provided in every care setting in a manner that would ensure best practice, however, we are hoping that this new guidance will speed up the process of developing outpatient hysteroscopy services that are acceptable to women.
Hysteroscopy Action	Short	18	14	An example of good practice and a practical resource is Sheffield Teaching Hospitals' Outpatient Hysteroscopy Patient Information Leaflet prepared by Miss Mary Connor, FRCOG, in conjunction with patient representatives from Hysteroscopy Action. This leaflet assists both clinicians and patients in determining whether a patient may be able to tolerate a hysteroscopy in the outpatient clinic. https://publicdocuments.sth.nhs.uk/pil299.pdf	Thank you for your comment and for sharing this document with us. We will pass this information to our local practice collection team. More information on local practice can be found here https://www.nice.org.uk/localpractice/collection

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				It may be difficult to tolerate if you: • Have found a previous hysteroscopy very painful • Find cervical smears very difficult or painful • Faint due to period pain • Dislike the idea of having an injection into the cervix • Have had severe pain during a previous vaginal examination • Do not wish to have such an examination when awake	
Hysteroscopy Action	Short	18	23	'*Blind' endometrial biopsy is not recommended because it may not identify treatable lesions and it is painful for women.* This is an excellent recommendation since the prime aim of the guidance must be to detect cancer. Clearly, a targeted endometrial biopsy needs to be done in conjunction with hysteroscopy to detect or rule out cancer. Since the endometrial biopsy is painful for women, it is vital that effective analgesia is given during biopsy combined with outpatient hysteroscopy. Currently only ibuprofen or paracetamol is used and Hysteroscopy Action receives many reports that these drugs are ineffective against the acute pain of biopsy.	Thank you for your comment. The primary aim of the guideline is to give recommendations and standardise practice on the assessment and management of HMB. If cancer is suspected, we refer to NICE guideline on suspected cancer (see NG12, https://www.nice.org.uk/guidance/ng12) in the recommendations. The guideline committee thinks that currently many women with HMB undergo painful endometrial biopsy unnecessarily when history and examination and/or investigation indicates a low risk of endometrial pathology. According to a recent systematic review and meta-analysis, the prevalence of endometrial cancer among women with HMB is only 0.11% (95% CI 0.04 to 0.32%) showing that the risk is very low (Pennant et al., 2017). However,

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					among women with other symptoms alongside HMB, such as persistent intermenstrual or irregular bleeding, or infrequent bleeding in women who are obese or who have polycystic ovary syndrome, the risk might be high and an endometrial biopsy is warranted. We have tried to clarify the indications for taking an endometrial biopsy in the recommendations in order to target the women at high risk. In addition, when endometrial biopsy is indicated, it should be taken in the context of hysteroscopy to provide a visualisation of the endometrium. Hysteroscopy in turn should be done according to the best practice guidelines including advising women to take oral pain relief prior to the procedure. When endometrial biopsy is indicated, it should be taken in the context of hysteroscopy which in turn should be done according to the best practice guidelines including advising women to take oral pain relief prior to the procedure. Pennant ME, Mehta R, Moody P, Hackett G, Prentice A, Sharp SJ, Lakshman R. Premenopausal abnormal uterine bleeding and risk of endometrial cancer. BJOG. 2017 Feb;124(3):404-411. doi: 10.1111/1471-0528.14385. Epub 2016 Oct 20.

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Hysteroscopy Action	Short	18	24	The recommendation *"No evidence was found about hysteroscopic removal of submucosal fibroids, but the committee agreed that it is an effective treatment that is acceptable to women"* is also inaccurate if it refers to OUTPATIENT hysteroscopy. Once again, hysteroscopic removal of submucosal fibroids will be acceptable to some but not all women. The Campaign Against Painful Hysteroscopy's 2016 booklet of patients' stories includes evidence to the contrary. https://lookaside.fbsbx.com/file/CAPH2016SeptBooklet.pdf?token=AWzDgudxtw2WsViN-s8ftfGw1MOhxDK0JkwRaJ1C2oFvHEg5kBEno9z7RdGzy-8W6qgDPj4B3s3BgjFLVwvccIVMzwOaWRmF2ggusB6hfpFsd66cjL34Bx_ybslrOEujhwMfGSz4STFlySkkyRXyUH1R The evidence of recent audits of NHS hysteroscopy procedures shows that severe pain is affecting hundreds of women. • A patient satisfaction audit by Royal Derby Hospital in 2015 found that **35% of patients reported a pain score during the procedure of 7/10 or more.**	Thank you for your comment. We are aware of reports by women of considerable discomfort and pain during outpatient hysteroscopy. Unfortunately, in current practice outpatient hysteroscopy services are not up to standard in all units and this is reflected in the experiences that some women have reported. We believe that if all units arranged their hysteroscopy services in line with best practice guidelines on outpatient hysteroscopy it would greatly improve women's satisfaction and acceptability of the procedure. However, the guideline committee recognises that even if performed according to best practice guidance to minimise discomfort for women, outpatient hysteroscopy will not acceptable to all women and therefore includes a recommendation to address this. 1.3.9 For women who decline hysteroscopy, consider pelvic ultrasound, explaining the limitations of this technique for detecting uterine cavity causes of HMB. [2017]

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				• A 2017 review of polypectomy in the outpatient hysteroscopy clinic published by The British Society of Gynaecological Endoscopy (BSGE) Annual Scientific Meeting found that **25% of women reported the procedure with a high pain score.** • In 2015, a 6 month review of data at West Cumberland Hospital outpatient hysteroscopy found that **25% of patients reported pain during the procedure as severe.** • In 2014 a 6 month patient satisfaction review by Frimley Health NHS Foundation Trust found that **24% of patients reported a pain score of 8/10 or more.** • In 2014 results from the patient satisfaction surveys at Pinderfields Hospital outpatients hysteroscopy showed **19% of patients reported having experienced severe pain during the procedure.**	
Hysteroscopy Action	Rationale & Impact	18	14	We are concerned by the statement, *"it [Outpatient Hysteroscopy] is acceptable to women if done according*	Thank you for your comment.

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				to best practice guidelines." This is not accurate. The recommendation may imply that outpatient hysteroscopy is acceptable to all women, and that all women should undergo trial by outpatient hysteroscopy before being permitted to choose sedation or General Anaesthesia. While outpatient hysteroscopy is acceptable to many women, recent NHS audits show up to 25% patients experiencing severe pain during Outpatient Hysteroscopy. In the interests of equality, diversity and early diagnosis of cancer it is important that those patients unable upfront to attempt outpatient hysteroscopy are given the option of sedation or general anaesthesia with the hysteroscopist using a modern, narrow hysteroscope, rather than old equipment more likely to cause perforation. Professor Sir Bruce Keogh, MD, DSc, FRCS, FRCP, National Medical Director writes: "It is important to appreciate that hysteroscopy can be an uncomfortable and painful procedure to some women and some may require the use of anaesthesia to be able to undergo a hysteroscopy. Similar to other invasive medical procedures, it is essential that patients are given sufficient and accurate information so they can make an informed decision about what is best for them. The decision should be based on women's wishes and clinical assessment." From letter to Nicky Morgan MP and her constituent, a member of Hysteroscopy Action,	The guideline committee recognises the concerns over analgesia for hysteroscopy. The recommendations did not mean to imply that a woman should undergo a failed outpatient hysteroscopy before anaesthesia is considered. We have amended the recommendations to clarify that if the woman declines outpatient hysteroscopy, she should be offered hysteroscopy under general or regional anaesthesia. '1.3.7 Explain to women with HMB who are offered outpatient hysteroscopy what the procedure involves and discuss the possible alternatives. [2017] 1.3.8 If a woman declines outpatient hysteroscopy, offer hysteroscopy under general or regional anaesthesia. [2017]' We fully agree that diagnostic hysteroscopy (outpatient or inpatient) should be done with techniques that minimise discomfort, pain and complications. We have emphasised this in the recommendations.

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				who has given permission for this statement to be submitted to NICE.	
IND	Short	9	15 1.4.6	Effective Contraception with ablation – I am concerned that use of the word effective needs to be defined. The public would consider contraceptive condoms and pills as effective whereas typical use data suggests 7-8% failure rate pa. Would NICE consider defining effective contraception as COIL, implant or injection? This is being sought with the MHRA aswell I understand by the Faculty of Sexual and Reproductive Health	Thank you for your comment. This recommendation was from 2007 and was outside the scope for the partial update of the guideline.
INSIGHTEC	Short	9	General	The section on informing patients and on treatment options is incomplete and fails to advocate multi-disciplinary approach with gynaecologists and interventional radiologists to fully, objectively and properly explain all the treatment options to patients..	Thank you for your comment. The section about information for women about HMB was outside the scope of the 2017 partial update and therefore was not amended.
INSIGHTEC	Short	12	General	MRgFUS is not included as a treatment option for fibroids of 3cm or more in diameter. This is not equitable as patients should be offered the choice of a non-invasive uterine sparing treatment alternative. In 2002, the ExAblate® system received a CE mark for the treatment of uterine fibroids, and in 2004 the technology was given marketing approval by the FDA. It is currently reimbursed in the USA and Europe. In the UK, MRgFUS has Interventional procedures guidance [IPG413] supporting its use for treating fibroids. In Canada, the Ontario Health Technology Advisory Committee (OHTAC) and Canadian Coordinating Office for HTA provided a positive recommendation for the use of	Thank you for your comment. We did not find evidence from randomised controlled trials on the effectiveness, acceptability and safety of MRgFUS on treatment of fibroids. We are aware of one recent pilot randomised controlled trial (1) but due to its small size (the guideline review protocol outlines that trials with less than 10 participants in one arm should not be included) it was not included in our evidence review. The NICE IPG413 is based on evidence from one non-randomised comparative study, 6 case series and 2 case reports. The guideline committee agreed that since its use is not widespread in clinical

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				MRgFUS for the treatment of uterine fibroids based on clinical effectiveness, patient safety, cost-effectiveness and resource use data. To date, there have been 13, 384 UF treatments performed globally across 45 treatment centres	practice, and in the absence of robust clinical evidence, it was not able to recommend it as a treatment for HMB. 1. Jacoby VL, Kohi MP, Poder L, Jacoby A, Lager J, Schembri M, Rieke V, Grady D, Vittinghoff E, Coakley FV. PROMISe trial: a pilot, randomized, placebo-controlled trial of magnetic resonance guided focused ultrasound for uterine fibroids. Fertil Steril. 2016 Mar;105(3):773-780. doi: 10.1016/j.fertnstert.2015.11.014. Epub 2015 Dec 1.
INSIGHTE C	ER B	9	General	MRgFUS is listed as a comparator but it does not seem as though a systematic review has been performed to identify MRgFUS literature as no studies are listed/tabulated other than the Zowall 2008 economic study. No clinical papers on MRgFUS are included in the 521 pages of Evidence Tables - **https://www.nice.org.uk/guidance/GID-NG10012/documents/addendum-appendix-4** The following clinical studies are relevant to the review and guideline and should be included: • Stewart EA, Rabinovici J, Tempany CM, et al. Clinical outcomes of focused ultrasound surgery for the treatment of uterine fibroids. Fertil Steril. 2006;85(1):22-9. • Froeling V, Meckelburg K, Scheurig-Muenkler C, et al. Midterm results after uterine artery embolization versus MR-guided high-intensity	Thank you for your comment. We looked for randomised controlled trial evidence on the effectiveness of MRgFUS but did not find any relevant evidence. The guideline committee did not consider the available observational evidence to be sufficient to recommend MRgFUS as a treatment, especially as its use is not widespread in clinical practice. In our systematic evidence review we looked for highest quality evidence from systematic reviews of randomised controlled trials or individual randomised controlled trials of sufficient size (minimum 10 participants in one intervention arm) on the effectiveness and safety of different treatment interventions, including magnetic resonance-guided focused ultrasound (MRgFUS), on treating HMB caused by fibroids, adenomyosis

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				focused ultrasound treatment for symptomatic uterine fibroids. Cardiovasc Intervent Radiol. 2013a;36(6):1508-13. • Froeling V, Meckelburg K, Schreiter NF, et al. Outcome of uterine artery embolization versus MR-guided high-intensity focused ultrasound treatment for uterine fibroids: long-term results. Eur J Radiol. 2013b;82(12):2265-9. • Kim HS,Baik JH,Pham LD and Jacobs MA. MR-guided high-intensity focused ultrasound treatment for symptomatic uterine leiomyomata: long-term outcomes. Acad Radiol. 2011;18(8):970-6. • Yoon SW, Seong SJ, Jung SG, et al. Mitigation of abdominal scars during MR-guided focused ultrasound treatment of uterine leiomyomas with the use of an energy-blocking scar patch. J Vasc Interv Radiol. 2011;22(12):1747-50. • Zaher S,Gedroyc WM and Regan L. Patient suitability for magnetic resonance guided focused ultrasound surgery of uterine fibroids. Eur J Obstet Gynecol Reprod Biol. 2009;143(2):98-102. • Hindley J, Gedroyc WM, Regan L, et al. MRI guidance of focused ultrasound therapy of uterine fibroids: early results. AJR Am J Roentgenol. 2004;183(6):1713-9. Other than the Zowall 2008 study, there are several economic publications that are relevant to the review and guideline and should be included:	or no identified pathology. More details can be found in the review protocol in the Management evidence review document Appendix A. We have considered all of the references cited in the comment. Please see after each reference below if we have included the paper in our review and when applicable the reason for not including the paper in our review. • Stewart EA, Rabinovici J, Tempany CM, et al. Clinical outcomes of focused ultrasound surgery for the treatment of uterine fibroids. Fertil Steril. 2006;85(1):22-9. This study was not included in our review because it is a non-comparative study. • Froeling V, Meckelburg K, Scheurig-Muenkler C, et al. Midterm results after uterine artery embolization versus MR-guided high-intensity focused ultrasound treatment for symptomatic uterine fibroids. Cardiovasc Intervent Radiol. 2013a;36(6):1508-13. This study was not included in our review because it is a retrospective observational study.

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				• Babashov D,Palimaka S,Blackhouse G and O'Reilly D. Magnetic Resonance-Guided High-Intensity Focused Ultrasound (MRgHIFU) for Treatment of Symptomatic Uterine Fibroids: An Economic Analysis (Structured abstract). HTA Database: Health Quality Ontario, 2015. • Cain-Nielsen AH,Moriarty JP,Stewart EA and Borah BJ. Cost-effectiveness of uterine-preserving procedures for the treatment of uterine fibroid symptoms in the USA. J Comp Eff Res. 2014;3(5):503-14. • O'Sullivan AK, Thompson D, Chu P, et al. Cost-effectiveness of magnetic resonance guided focused ultrasound for the treatment of uterine fibroids. Int J Technol Assess Health Care. 2009;25(1):14-25. • Borah BJ, Carls GS, Moore BJ, et al. Cost comparison between uterine-sparing fibroid treatments one year following treatment. J Ther Ultrasound. 2014;2:7. Kong CY, Meng L, Omer ZB, et al. MRI-guided focused ultrasound surgery for uterine fibroid treatment: a cost-effectiveness analysis. AJR Am J Roentgenol. 2014;203(2):361-71.	• Froeling V, Meckelburg K, Schreiter NF, et al. Outcome of uterine artery embolization versus MR-guided high-intensity focused ultrasound treatment for uterine fibroids: long-term results. Eur J Radiol. 2013b;82(12):2265-9. This study was not included in our review because it is a retrospective observational study. • Kim HS,Baik JH,Pham LD and Jacobs MA. MR-guided high-intensity focused ultrasound treatment for symptomatic uterine leiomyomata: long-term outcomes. Acad Radiol. 2011;18(8):970-6. This study was not included in our review because it is an observational study. • Yoon SW, Seong SJ, Jung SG, et al. Mitigation of abdominal scars during MR-guided focused ultrasound treatment of uterine leiomyomas with the use of an energy-blocking scar patch. J Vasc Interv Radiol. 2011;22(12):1747-50. This study was not included in our review because it a non-comparative study. • Zaher S,Gedroyc WM and Regan L. Patient suitability for magnetic resonance guided focused

					ultrasound surgery of uterine fibroids. Eur J Obstet Gynecol Reprod Biol. 2009;143(2):98-102. This study was not included in our review because it is a retrospective observational study. • Hindley J, Gedroyc WM, Regan L, et al. MRI guidance of focused ultrasound therapy of uterine fibroids: early results. AJR Am J Roentgenol. 2004;183(6):1713-9. This study was not included in our review because it is a non-comparative study. The health economic references: • Babashov D,Palimaka S,Blackhouse G and O'Reilly D. Magnetic Resonance-Guided High-Intensity Focused Ultrasound (MRgHIFU) for Treatment of Symptomatic Uterine Fibroids: An Economic Analysis (Structured abstract). HTA Database: Health Quality Ontario, 2015. Thank you for notifying us of this study. This was not picked up by our literature search and we have added it to the list of included health economic studies.

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					• Cain-Nielsen AH,Moriarty JP,Stewart EA and Borah BJ. Cost-effectiveness of uterine-preserving procedures for the treatment of uterine fibroid symptoms in the USA. J Comp Eff Res. 2014;3(5):503-14. Thank you for notifying us of this study. This was not picked up by our literature search and we have added it to the list of included health economic studies. • O'Sullivan AK, Thompson D, Chu P, et al. Cost-effectiveness of magnetic resonance guided focused ultrasound for the treatment of uterine fibroids. Int J Technol Assess Health Care. 2009;25(1):14-25. Thank you for notifying us of this study. This was not picked up by our literature search and we have added it to the list of included health economic studies. • Borah BJ, Carls GS, Moore BJ, et al. Cost comparison between uterine-sparing fibroid treatments one year following treatment. J Ther Ultrasound. 2014;2:7. This study was not included in our health economic analysis because it was a costing study and not a full economic evaluation.

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					• Kong CY, Meng L, Omer ZB, et al. MRI-guided focused ultrasound surgery for uterine fibroid treatment: a cost-effectiveness analysis. AJR Am J Roentgenol. 2014;203(2):361-71. Thank you for notifying us of this study. This was not picked up by our literature search and we have added it to the list of included health economic studies.
Medtronic Ltd	Short	6	1.3.3	As the draft guidelines recommend outpatient hysteroscopy for polyps it would also be helpful to include polypectomies in the treatment section of the care pathway to ensure clarity for the reader (the care pathway currently only refers to fibroids)	Thank you for your comment. Treatment for polyps is outside the scope of this guideline because polyps are usually not the cause for HMB.
Medtronic Ltd	Short	6	1.3.4	The statement regarding the vaginoscopic approach and hysteroscopes less than 3.5 mm in diameter appears to be referring to the RCOG Green-top Guideline No. 59 where this recommendation is in reference to diagnostic procedures. The 3.5 mm diameter limit would exclude the majority of devices that are utilised for operative hysteroscopy including those used in see and treat settings via the vaginoscopic approach. Please revise the wording in this section to note that the recommendation for hysteroscopes less than 3.5 mm is in relation to purely diagnostic settings and consider using a statement similar to the one in the RCOG Green-top Guideline No. 59 “Units offering both hysteroscopic	Thank you for your comment. The guideline committee has amended the recommendation to clarify that miniature hysteroscopes (smaller or equal to 3.5 mm) should be used for diagnostic hysteroscopy. We recognise that for treatment purposes a bigger hysteroscope is needed.

				diagnosis and treatment in the outpatient setting should consider the versatility of respective hysteroscopes and relative resource implications when planning the composition of endoscopic equipment". It is of note that the UK OPT (Cooper N.J.M. et al Outpatient versus inpatient uterine polyp treatment for abnormal uterine bleeding. randomised controlled non-inferiority study BMJ 2015; 350:h1398) in which hysteroscopes were used that exceeded 3.5mm in diameter; established that outpatient polypectomy was non inferior to inpatient polypectomy in alleviating AUB and the overall safety feasibility and acceptability of the procedure. We have also included below a number of testimonials from clinicians that support the above statements: Miss Mary Connor FRCOG, Consultant Gynaecologist, Sheffield Teaching Hospitals Foundation Trust. The choice of which hysteroscope to use for the initial hysteroscopic investigation should be up to the clinician depending upon the information available at the time, with a </= 3.5 mm sheathed one as first option if there is no indication that an endometrial polyp or submucosal fibroid is present. However, if a scan has been performed and an endometrial polyp or a small (<3 cm) submucosal fibroid is suggested, then use of a larger diameter treatment scope should be considered as part of the initial hysteroscopic	

				investigation. Opening two separate hysteroscopes when it is obvious that the larger one is likely to be needed is not good use of resources and should be avoided if possible. However, this will happen at times if the smaller one is used first and a polyp or small submucosal fibroid is identified, and immediate treatment is indicated and an option. Miss Vicky Cording MRCOG, Consultant Obstetrician and Gynaecologist, Lead Gynaecologist for Outpatient Hysteroscopic Service, St Helens and Knowsley Teaching Hospitals Foundation Trust. As lead for an expanding outpatient hysteroscopy service, I often use hysteroscopes with a diameter up to and including 6mm to provide an effective see and treat service after initial diagnostics with smaller diameter scopes. I have not found any issues with tolerability of these higher diameter scopes and rarely need to provide injectable anaesthetic and/or cervical dilatation to enable their use. The larger diameter scopes do not preclude a vaginoscopic approach and indeed the Truclear 5C scope (Medtronic) enables effective atraumatic dilatation of the cervix vaginoscopically with the scope itself. Using these operative scopes in the outpatient setting has prevented the need for patients to be listed for a procedure under general anaesthetic at a later date, significantly improving the patient pathway.	

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				Miss Claire Stewart MRCOG MBChB St Helens and Knowsley Teaching Hospitals Foundation Trust. I support the use of larger diameter hysteroscopes, such as operative hysteroscopes, in the outpatient setting with a vaginoscopic approach. In my practice I often use operative hysteroscopes up to 6mm diameter via vaginoscopic approach with good success. My patients often find this approach more comfortable and eliminates the difficulties and discomfort that can be experienced with a speculum in situ. Its use is case by case, however I am finding myself using this method more often especially in our population of patients with very high BMI. Mr Martin Powell MB ChB DM FRCS MRCOG, Clinical Lead Gynaecology, Community Clinics & Private Patients, Circle Nottingham Patients are able to tolerate the vaginoscopic insertion of a 5mm diameter instrument in over 50% of cases requiring removal of intra uterine polyps. If necessary the availability of Nitrous oxide facilitates a greater number of insertions without the need for a speculum	
Medtronic Ltd	Short	6	1.3.7 1.3.8	We feel that some clarification may be required within the guidelines regarding the committee intentions in relation to the technique employed to conduct endometrial biopsies. There appears to be some inconsistency between the guidelines and the statement in the evidence review with	Thank you for your comment. We have amended the recommendation on endometrial biopsy to say 'Only obtain an endometrial sample in the context of diagnostic hysteroscopy. Do not offer ‘blind’ endometrial biopsy to women with HMB.' for

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				the guidelines advising biopsy at the time of hysteroscopy and the evidence review stating biopsy should be conducted by hysteroscopic technique.	clarity. We have also edited the wording in the evidence report to indicate that biopsy should be taken at the time of hysteroscopy instead of saying that biopsy should be taken using a hysteroscopic technique.
Primary Care Women's Health Forum	Short	General	General	The recommendation to use hysteroscopy as first line investigation rather than pelvic USscan and endometrial biopsy when indicated is unaffordable in the current climate, unachievable because of insufficient trained clinicians (in primary or secondary care), and at odds with the recommendations of the NHS FYFV which aims to provide more care in the community. This recommendation fails to appreciate the significant numbers of women who present to and are managed in primary care successfully by medical (inc LNG-IUS) treatments with appropriate USScanning and pipelle biopsy with referral for more invasive investigations by patient choice, failed treatments or clinical concerns. These recommendations are challenging to implement for commissioners – unaffordable, and providers – lack of trained clinicians and women who would experience more invasive investigations than required at times and with longer waits.	Thank you for your comment. Whilst current practice is varied, we do appreciate that some change to service will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. However, NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the recommendations made were justified. The evidence reviewed for this guideline suggested that hysteroscopy allows for more accurate detection or exclusion of uterine cavity causes of HMB than pelvic ultrasound. In addition, we believe currently many women undergo painful endometrial biopsy unnecessarily and 'blind' biopsies might miss pathology. We recommend that women whose history and/or examination suggests uterine cavity abnormality or endometrial pathology

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					should be offered an outpatient diagnostic hysteroscopy and endometrial biopsy should be taken only in the context of hysteroscopy when there is an increased risk for endometrial pathology or when there is visual proof of suspected abnormality. The guideline is for use in both primary care as well as secondary care. Primary care will be the first setting in which women with HMB will present. Most GPs / community gynaecologists can prescribe pharmacological treatments and fit LNG-IUS devices. Women whose history and/or examination does not suggest an abnormality can go on to receive LNG-IUS or other pharmacological treatment without having to go through an investigation that can be invasive and painful. If treatment fails it might be an indication of an abnormality, thus, investigations should take place. A pelvic ultrasound scan continues to be recommended as the first-line investigation in women where: • their uterus is palpable abdominally • history or examination suggests a pelvic mass • examination is inconclusive or difficult, for example in women who are obese.

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Primary Care Women's Health Forum	Short	18	22	'Blind' endometrial biopsy is less painful and less invasive than hysteroscopy and is tolerated in the majority of women. This combined with TV USscanning is more acceptable, and cost effective for the majority of women who do not have a history of IMB or do not have endometrial clinical risk factors – need more adding to improve the safety of this guideline. Ie. DM, ERT etc as commented previously.	Thank you for your comment. The guideline committee thinks that currently many women undergo painful endometrial biopsies unnecessarily. We recommend that endometrial biopsies should be taken only when there is an increased risk for endometrial pathology or there is visual proof of suspected abnormality. The new guidance recommends that endometrial biopsy should be taken only in the context of diagnostic hysteroscopy to maximise the effectiveness of biopsies in detecting endometrial pathology. Diagnostic hysteroscopy should be offered to women who have symptoms to suggest a uterine cavity abnormality, such as persistent intermenstrual bleeding alongside HMB and endometrial biopsy in the context of diagnostic hysteroscopy should be considered for women who have a high risk of endometrial pathology. The guideline committee wants to emphasise that when performed according to current best practice guidelines (including appropriate information provision for the woman, advising the woman to take analgesia beforehand, and using miniature hysteroscopes) outpatient hysteroscopy should be well tolerated and accepted by most women.

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					The list of risk factors for endometrial pathology provided is not an exhaustive list but an example of the most important factors to consider in women with HMB. Women using hormone replacement therapy would not be in the scope of this guideline since they would not be premenopausal women with HMB. In general, the risk of endometrial cancer is very low in premenopausal women with HMB (Pennant et al., 2017). However, there are some factors that warrant further investigations via endometrial biopsy. Persistent intermenstrual bleeding, irregular bleeding, and infrequent bleeding in women who have polycystic ovary syndrome or are obese were considered the 'red flags' for endometrial pathology in women with HMB. In addition, women taking tamoxifen and women with failed treatment for HMB were considered to be at high risk for endometrial pathology warranting an investigation via biopsy. Pennant ME, Mehta R, Moody P, Hackett G, Prentice A, Sharp SJ, Lakshman R. Premenopausal abnormal uterine bleeding and risk of endometrial cancer. BJOG. 2017 Feb;124 (3):404-411. doi: 10.1111/1471-0528.14385. Epub 2016 Oct 20.
Primary Care Women's	Short	4	10	Intracavity abnormality is correct but as this document is for patients, all healthcare professionals as well as specialists this needs clarifying. i.e Does this imply a history of IMB as well as HMB	Thank you for your comment. We have changed 'intracavitary abnormality' to 'uterine cavity abnormality' for clarity. Yes, persistent intermenstrual bleeding together with HMB are

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Health Forum					considered to be the main symptoms of uterine cavity abnormalities.
Primary Care Women's Health Forum	Short	5	13	Recognising this guidance is not for cervical concerns there is an overlap and a speculum examination is indicated for investigation of HMB if there is IMB or PCB. Many women do not really appreciate the difference during history taking.	Thank you for your comment. The guideline addresses HMB. There is an emphasis on appropriate history taking and elucidation of the pattern of bleeding. The guideline also acknowledges that IMB frequently coexists with HMB, and in the case of persistent IMB, the guideline recommends further investigation. A speculum is an integral part of physical examination in women and recommendation 1.2.5 addresses physical examination prior to initiating investigations. In addition, there is a separate recommendation that refers to NICE's full guideline on the management of suspected cancer (cervical included).
Primary Care Women's Health Forum	Short	6	2	Ensure cervical screening is up to date and consider screening for STIs – chlamydia/GC/PID can cause HMB +/- painful periods	Thank you for your comment. The committee considered that STIs are rarely the cause of HMB, however, the committee agrees that when taking a history it is important to consider related symptoms and co-morbidities.
Primary Care Women's Health Forum	Short	6	27	The recommendation for hysteroscopy + directed endometrial biopsy for women as first line investigation is unaffordable and unachievable with current expertise and resources. TV USScan and blind pipelle in selected women (those not at high risk of endometrial pathology)	Thank you for your comment. Whilst current practice is varied, we do appreciate that some change to service organisation and staff training will be required as a result of the

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				would successfully manage the majority with those of higher risk, failing treatment or opting for more invasive investigations requiring hysteroscopic assessment.	recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. However, NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made. The new guideline continues to recommend ultrasound as the initial investigation where the uterus is palpable abdominally and where a history or examination suggests a pelvic mass.
Primary Care Women's Health Forum	Short	7	9	There are additional risk factors to include : DM, women using estrogen only HRT or long history of cyclical HRT. There should be additional recommendations about taking directed biopsies from women using anticoagulant medications (warfarin or DOACs)	Thank you for your comment. The list of risk factors provided is not an exhaustive list of all the risk factors for endometrial pathology but an example of the most important factors to consider in women with HMB. In addition, women using hormone replacement therapy would not be in the scope of this guideline since they would not be premenopausal women with HMB. In general, the risk of endometrial cancer is very low in premenopausal women with HMB (Pennant et al., 2017). However, there are some factors that warrant further investigations via endometrial biopsy. Persistent intermenstrual bleeding, irregular

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					bleeding, and infrequent bleeding in women who have polycystic ovary syndrome or are obese were considered the 'red flags' for endometrial pathology in women with HMB. In addition, women taking tamoxifen and women with failed treatment for HMB were considered at high risk for endometrial pathology warranting an investigation via biopsy. Pennant ME, Mehta R, Moody P, Hackett G, Prentice A, Sharp SJ, Lakshman R. Premenopausal abnormal uterine bleeding and risk of endometrial cancer. BJOG. 2017 Feb;124 (3):404-411. doi: 10.1111/1471-0528.14385. Epub 2016 Oct 20.
Primary Care Women's Health Forum	Short	7	12	Clarify that transvaginal USscanning is preferred option especially in obese women where endometrial pathology is harder to visualise if using transabdominal scanning.	Thank you for your comment. The guideline committee did not want to specify the mode of pelvic ultrasound scan because transvaginal and transabdominal ultrasound scans are not mutually exclusive and in some cases both can be used to complement each other. In practice, clinicians will likely offer transvaginal ultrasound scan for obese women for clearer vision, as suggested.
Primary Care Women's Health Forum	Short	10	10	Women's preferences including a desire to retain her fertility options	Thank you for your comment. We agree that the woman's preferences include whether or not she desires to retain her fertility. Recommendation 1.4.2 emphasises the importance of discussing this with the woman.
Primary Care Women's	Short	10	24	Can use medication in conjunction	Thank you for your comment. The guideline committee agrees that pharmacological treatments can be used in conjunction with other treatments.

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Health Forum					The recommendations do not imply that treatments cannot be used in combination when that is deemed appropriate.
Primary Care Women's Health Forum	Short	10	29	Including option of continuous use of CHC	Thank you for your comment. In our evidence review and analysis, we found evidence that cyclical oral progestogen can be effective in treating HMB. However, we did not find any evidence on the effectiveness of continuous progestogens and have therefore included a research recommendation on the effectiveness of the progestogen-only pill, injectable progestogens, and progestogen implants in alleviating HMB. The guideline committee is, however, aware that in clinical practice the progestogen-only contraceptive pill is used to treat HMB and is aware that in its licensed use as a contraceptive it may suppress menstruation and therefore could benefit a woman with HMB. We have added a recommendation about this.
Primary Care Women's Health Forum	Short	11	1	Why cyclical. Continuous use is more effective. Please also clarify that MPA is safer (less thrombotic risk) and also has reduced oestrogenic properties and therefore is likely to be more effective in women with fibroids. Also no mention of use of im progestogen treatment which demonstrates reduction in HMB over the longer term use	Thank you for your comment. In our evidence review and analysis, we found evidence that cyclical oral progestogen can be effective in treating HMB. However, we did not find any evidence on the effectiveness of continuous progestogens and have therefore included a research recommendation on the effectiveness of the progestogen-only pill, injectable progestogens, or progestogen implants in alleviating HMB. The guideline committee is, however, aware that in clinical practice continuous progestogen is used to treat HMB and is aware that

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					in its licensed use as a contraceptive it may suppress menstruation and therefore could benefit a woman with HMB. We have added a recommendation about this. In our evidence review we did not compare the effectiveness of different progestogens, therefore, we do not recommend a specific progestogen.
Primary Care Women's Health Forum	Short	11	22	Need to use the terms 'specialist care' rather than secondary care because this might be a local community provider – for future proofing	Thank you for your comment, we have changed the wording as suggested.
Primary Care Women's Health Forum	Short	12	17 - 18	Continuous use of CHC or progestogens – and keep order as on page 10/11	Thank you for your comment. In our evidence review and analysis, we found evidence that cyclical oral progestogen can be effective in treating HMB. However, we did not find any evidence on the effectiveness of continuous progestogens and have therefore included a research recommendation on the effectiveness of the progestogen-only pill, injectable progestogens, and progestogen implants in alleviating HMB. The guideline committee is, however, aware that in clinical practice continuous progestogen is used to treat HMB and is aware that in its licensed use as a contraceptive it may suppress menstruation and therefore could benefit a woman with HMB. We have added a recommendation about this. We have also amended the order of combined hormonal contraception and cyclical oral

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					progestogens as suggested to be consistent with the style of the previous recommendation.
Primary Care Women's Health Forum	Short	15	10	Diagnostic and treatment hysteroscopy services can effectively be delivered in the out of hospital settings by appropriately and adequately trained clinicians – ref Herts gynae service, St Albans, and Westwood Park DTC in Bradford	Thank you for your comment. We will pass this information to our local practice collection team. More information on local practice can be found here https://www.nice.org.uk/localpractice/collection
Primary Care Women's Health Forum	Short	19	4	Clarify that TV USScanning is more reliable in women who are obese as this provides more detailed view of the endometrium	Thank you for your comment. The guideline committee did not want to specify the mode of pelvic ultrasound scan because transvaginal and transabdominal ultrasound scans are not mutually exclusive and in some cases both can be used to complement each other. In practice, clinicians will likely offer transvaginal ultrasound scan for obese women for clearer vision, as suggested. We discuss this more in the 'The committee's discussion of the evidence' section in the Diagnosis evidence report document.
Primary Care Women's Health Forum	Short	20	3 - 5	Primary care clinicians can be trained to perform diagnostic and treatment hysteroscopy procedures but there is significant costs to training and also competition for training places alongside O&G trainees. In the current climate of increasing workload for primary care this may not be feasible.	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made.

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					Whilst current practice is varied, we do appreciate that some changes to service will be required to ensure that hysteroscopy services are organised according to best practice (including a service organisation that enables 'see and treat' in a single setting where feasible). We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term, which is why the recommendation acknowledges that a service organisation that enables 'see and treat' in a single setting may not always be feasible.
Primary Care Women's Health Forum	Short	20	3 - 5	The recommendation for hysteroscopy for all would benefit a small minority of women but cause cost pressures, inconvenience and increased risk for women.	Thank you for your comment. The guideline does not recommend that hysteroscopy should be offered to all women with HMB but for women with HMB for whom history and examination suggest uterine cavity abnormalities. Women whose history and/or examination does not suggest structural or histological abnormality could go on to receive treatment without diagnostic investigations. Women with suspected large fibroids or adenomyosis would be offered an ultrasound scan. The guideline committee hopes that the recommendations will allow women to be offered the most accurate and cost-effective diagnostic investigations depending on the findings of the history and examination.

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					Offering the best investigation will consequently allow for the most appropriate treatment options to be considered. For women with submucosal fibroids, hysteroscopy would also allow for a 'see and treat' service where fibroids would be removed immediately once identified. This could speed up effective treatment for women and result in cost savings, providing that safety of the service is assured.
Primary Care Women's Health Forum	Short	21 22	13, 20 3	Remove secondary care and use the working specialist provider	Thank you for your comment. We have replaced 'secondary care' with 'specialist care' as suggested.
Primary Care Women's Health Forum	Appendix 3	2	General	Reverse the order of the surgery options: Endometrial ablation first Hysterectomy second	Thank you for your comment. We have changed the order of the surgery options in the algorithm.
RCGP	Short	General	General	The updated recommendation is timely but the reliance on hysteroscopy as the diagnoses of preference as outlined in this draft guidance is unachievable with current financial and training resources. As this is such a common concern for primary care the updated recommendations to support the use of clinical judgement to advise better on who can be managed without investigations is well received, although there are additional risk factors to be added to the list.	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. Many women will be started on treatment without investigation (see recommendation 1.3.1). The committee believes the evidence on clinical and cost-effectiveness justifies a different diagnostic approach according to the suspected underlying

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				Access to hysteroscopy is insufficient currently so without significant financial input to train clinicians (primary care secondary care) and the additional costs required to commission these services, the use of US scanning and endometrial biopsy will continue. These recommendations will be challenging to implement for commissioners because of the extra funding required, to providers because of insufficient clinical access and to women who will experience longer waiting times for more invasive investigations than the majority require. There are many examples of primary care led gynaecology services which are proven to be cost effective and provide local services which do not rely on costly invasive hysteroscopic investigations.	pathology. Ultrasound remains the first-line investigation for women with possible larger fibroids. Whilst current practice is varied, we do appreciate that some change to service will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term.
RCGP	Short	General	General	This guideline medicalises HMB. There is nothing about primary child onset HMB and dysmenorrhoea in which therapy if required would be tranexamic acid and NSAI and maybe CHC. It becomes a fibroid guideline later on. Can it have a section on normal early onset HMB and dysmenorrhoea and new later onset HMB as the guideline then becomes more relevant to GPs.	Thank you for your comment. The guideline committee recognises that many girls and women have HMB that can be treated with simple pharmacological agents, such as tranexamic acid, NSAIDs or combined hormonal contraceptives as the comment suggests. LNG-IUS is recommended as the first choice for women with no identified pathology, fibroids less than 3 cm in diameter or adenomyosis, however, another pharmacological treatment would be more appropriate for adolescent girls. This is reflected in the following

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					recommendation '1.5.3 If a woman with HMB declines an LNG-IUS or it is not suitable, consider the following pharmacological treatments: • non-hormonal: -tranexamic acid -NSAIDs (non-steroidal anti-inflammatory drugs) • hormonal: -combined hormonal contraception -cyclical oral progestogens.' Especially when dysmenorrhoea is a related symptom, NSAIDs might be the preferred option. We did not address adolescent girls as a separate group and the guideline considers and applies to all women with HMB regardless of age.
RCGP	Short	General	General	15% of ovarian cancers will have IMB and this is missed from the Ovarian cancer and HMB guidelines and there is an opportunity to address this in the guideline as it isn't anywhere.	Thank you for your comment. Ovarian cancer is not in the scope of this guideline. Your comment has been referred to the NICE surveillance review team.
RCGP	Short	General 1.2.1	General	GPs will not like intracavitary abnormality – which cavity is that? The uterus? The pelvis? The abdomen? It does not match clinical parlence. Take a history that covers intracavitary, histological or adenomyosis abnormality is largely meaningless in trying to be meaningful. Why not state "take a gynaecology,	Thank you for your comment. We have changed 'intracavitary abnormality' to 'uterine cavity abnormality' for clarity. We have also amended the recommendation to include a list of symptoms that might indicate abnormality causing HMB to make it clearer what should be considered when taking history.

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				sexual and obstetric history to exclude or suspect pathology". Please can this be looked at throughout.	
RCGP	Short	4 1.2.2	General	There may be objections if the woman feels she does not fall into normal discuss care options. If a woman is normal then she should not be medicalised. This needs rephrasing, please. That is, not everyone who insists they have a problem but in fact is healthy should be offered therapy/ care and this is implied on reading this sentence.	Thank you for your comment. The guideline defines HMB as 'excessive menstrual blood loss which interferes with a woman's physical, social, emotional and/or material quality of life'. As such, the definition relies on what the woman perceives as 'normal' or not, and not what the practitioner considers normal or not. The premise here is that it is ultimately determined by the woman herself, however, a discussion about the natural variability of menstrual cycle and possible care options is important to many women who might have concerns about whether their menstruation is 'normal' or 'heavy' and whether it warrants treatment. At the same time, discussing care options does not mean offering treatment.
RCGP	Short	4	10	Intracavity abnormality needs clarifying so that all users of this guidance can understand what this means as this is a change.	Thank you for your comment. We have changed 'intracavitary abnormality' to 'uterine cavity abnormality' for clarity and consistency with the terminology used in clinical practice. 'Uterine cavity abnormality' refers to submucosal fibroids and endometrial polyps. Persistent intermenstrual bleeding together with HMB are considered to be the main symptoms of uterine cavity abnormalities.

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RCGP	Short	4 5 7 Short 5 6 7	10 4 20, 21 12 12,13 3,4	We have concerns that the guideline will increase the number of women undergoing treatment for endometrial polyps and hyperplasia inappropriately resulting in psychological and physical distress to the women. The guideline is for the management and assessment of heavy menstrual bleeding but wanders into the areas of intermenstrual and irregular bleeding. It promotes hysteroscopy as a means of investigating these symptoms to detect intracavity pathology such as endometrial polyps and hyperplasia. There is no evidence that endometrial polyps or hyperplasia cause heavy menstrual bleeding or that the treatment of these relieves heavy menstrual bleeding. The recommendations state that these are causes of intracavity HMB but present no evidence of an association with HMB or efficacy of treatment on HMB. It is important that mistakes of the past (dilatation and curettage as a treatment for heavy menstrual bleeding) are not repeated. The increased use of hysteroscopy will be challenging to practice as a result of the increased resource (both human and monetary) that will be required. The clinical algorithm as formed by the recommendations requires that women with heavy menstrual bleeding and intermenstrual bleeding or obesity undergo hysteroscopy to detect polyps and hyperplasia. The reported prevalence of	Thank you for your comments. The committee did not agree that the guideline would increase the number of women undergoing treatment for endometrial polyps and hyperplasia inappropriately resulting in psychological and physical distress to those women. The identification of structural, focal or histological abnormalities enables targeted treatment, which should result in more effective management. It is true that polyps and hyperplasia may present with symptoms such as intermenstrual or irregular bleeding rather than HMB, but there is an overlap and women who experience heavy bleeding may present when additional symptoms such as irregularity occur. The evidence was compelling that hysteroscopy was the most accurate diagnostic test for uterine cavity pathology, and had supporting evidence of cost effectiveness relative to other diagnostic strategies. The scope of this partial update did not include updating the original guideline's analysis on the impact of HMB in which evidence relating to uterine pathology was reviewed, nor of history taking and examination in which the significance of persistent intermenstrual bleeding was defined. However the committee did update some of the recommendations based on more recent guidelines such as the RCOG management of endometrial

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				intermenstrual bleeding ranges from 2% (Wood 1977) to 18% (Shapley 2013) depending on populations studied. The prevalence of obesity is 27% of the English population (National Statistics 2017). The recommendation therefore requires a significant increase in the number of women to undergo hysteroscopy to detect or exclude pathology which has not been shown to cause heavy menstrual bleeding. The recommendations are at variance with other national guidelines. The proposed recommendations have removed the suggestion that women over the age of 45 undergo investigation for endometrial hyperplasia/cancer and replaced it with the recommendation concerning intermenstrual bleeding and a risk factor for hyperplasia and endometrial cancer (obesity). The incidence of hyperplasia and cancer increases with age and is rare under the age of 45 years and therefore removal of this cut off point will increase the number of women undergoing hysteroscopy. The NICE suspected cancer guidance (NG 12) uses a positive predictive value of symptoms from primary care for cancer of 3%. Premenopausal intermenstrual bleeding does not reach this threshold and therefore the heavy menstrual bleeding guidance is at variance with NG 12. It is also at variance with national guidance from the Faculty of Family Planning and Reproductive Healthcare concerning the management of	hyperplasia guideline in order to ensure that the NICE guidance reflected modern best practice. There is no evidence to define whether diagnosis and treatment of pathology or empirical pharmacological treatment would be the best first line option, and this is one of the research recommendations. Until such research is completed, it is unknown as to whether the identification and treatment of other pathologies would better treat HMB. The committee did agree that where underlying pathology was suspected that, in line with normal medical practice, it should be addressed. The committee noted that in their experience many women had unnecessary diagnostic tests (e.g. ultrasound and biopsy) which the evidence showed to be ineffective in identifying pathology and a source of delay in the woman starting effective treatment. More accurate tests should be better focused on those women most likely to benefit. As a result of stakeholder feedback, the recommendations have been restructured to ensure that hysteroscopy is used only where appropriate. If there is to be an increased use of hysteroscopy then the NHS would need to provide the resources, but the health economic model in both this guideline and the health technology assessment that was identified in the NICE update surveillance process

				unscheduled bleeding in women using hormonal contraception. We would like to see a focus of the guideline onto heavy menstrual bleeding and a new guideline developed. A proposed solution is for the heavy menstrual bleeding guidance to just deal with heavy menstrual bleeding and for NICE to produce guidance on the controversial and difficult area of the management and treatment of irregular vaginal, intermenstrual and postcoital bleeding.	modelled that it was a cost effective diagnostic strategy. Thank you for the comments regarding intermenstrual bleeding and obesity. The recommendation on endometrial biopsy has been rephrased in order to ensure that it is only in the context of persistent intermenstrual bleeding and where obesity is associated with risk factors for hyperplasia that hysteroscopy would be recommended. Whilst hyperplasia may not cause HMB it may exist alongside it, and its detection is important given its premalignant potential. There is no citation in the comment as to which national guidelines this partial update is stated to be at variance with, but this update has used NICE methodology and is likely to be the most up-to-date evidence-based guidance. The previous guideline suggested an age cut off of 45 years for investigation of hyperplasia. This was not evidence based but a consensus based on expert opinion. For this partial update the committee was guided by more recent consensus from the RCOG Green-top Guideline on the management of endometrial hyperplasia, and agreed that focusing on high risk groups was a more logical approach than persisting with an arbitrary age cut-off. If an

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					age cut-off were to be used, younger women with a higher risk of pathology may be missed, and those with few risk factors but age over 45 years may be subjected to unnecessary investigation and delay of effective treatment. The NICE suspected cancer guideline outlines which groups should be referred under the suspected cancer fast- track pathways and is not intended to define whether any pre-malignant conditions may warrant investigation. The management of unscheduled bleeding in women using hormonal contraception is beyond the scope of this guideline. This guideline is focused on HMB but includes some guidance where women also have other symptoms such as persistent intermenstrual bleeding or pressure symptoms from fibroids, as these are common co-presentations. Isolated irregular and intermenstrual or postcoital bleeding are beyond the scope of this guideline but your comment has been referred to the NICE surveillance review team.
RCGP	Short	5	1.2.7	What is the rationale and cost effectiveness of detecting von Willebrand and what therapy is being suggested? Some Gps let women know they may have this and it does not need a test – it is a variant of normal, There is no specific medication for it and there are concerns about over diagnosis and cost to the NHS for no gain beyond explanation.	Thank you for your comment. The detection of von Willebrand disease is out of the scope of this guideline. Your comment has been referred to the NICE surveillance review team.

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RCGP	Short	5	4	Para 1.2.4 (and in several other places in the document). The guideline draws attention to aspects of the history that might point to intracavity abnormalities. The symptoms it mentions here are non-specific. It is unclear there sensitivity and specificity in accuracy to identify such abnormalities. It would help users to know: Are there other indicators?	Thank you for your comment. Persistent intermenstrual bleeding together with HMB are considered to be the main symptoms of uterine cavity abnormalities. We have amended the recommendations to say 'persistent intermenstrual bleeding' instead of 'intermenstrual bleeding'.
RCGP	Short	5	10	The concept of intracavity rather than structural anomaly will need careful explanation for the public and non-specialist Health Care Professionals.	Thank you for your comment. We have changed 'intracavitary abnormality' to 'uterine cavity abnormality' for clarity and to be consistent with language used in clinical practice. 'Uterine cavity abnormality' refers to abnormalities within the uterine cavity, namely submucosal fibroids and endometrial polyps. We have added the definition to the glossary in the Supplementary material document.
RCGP	Short	5	11	Why is adenomyosis in this guideline rather than endometriosis?	Thank you for your comment. Adenomyosis was excluded from the scope of the NICE Endometriosis guideline (NG73) and was consequently included in the scope of the NICE HMB guideline. The typical symptoms of adenomyosis include painful and heavy periods and therefore this falls under the scope of HMB.
RCGP	Short	6	1.3.11	Most young normal HMB patient do not all require an USS. This would be a lot of teens.	Thank you for your comment. The guideline committee agrees that most girls and young women with HMB will probably not need an ultrasound or other investigation. The guideline does not suggest that all women with HMB would require

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					investigations via imaging techniques such as an ultrasound scan. Recommendation 1.3.1 says: "Consider starting pharmacological treatment for HMB without investigating the cause if the woman's history and/or examination suggests a low risk of uterine cavity or histological abnormality or adenomyosis." The guideline committee believes that most young women with HMB would fall under this category.
RCGP	Short	6	1.3.12	Can you change MRIU to refer to secondary care? It is unclear about MRI indication and interpretation in primary care so there are concerns about wasted resources – if its needed will it actually prevent a referral.	Thank you for your comment. If an MRI investigation is considered for women with HMB with suspected adenomyosis, in practice this might necessitate a referral to secondary care, however, it is not usual in NICE recommendations to specify the care setting in which investigations should be undertaken as expertise and service configuration may vary and are subject to change over time.
RCGP	Short	6	1.3.3	Should there be risks of cervical shock and adult bradycardia mentioned in hysteroscopy (risks of 1 in 100) and ensuring departments have facilities to manage this.	Thank you for your comment. The guideline refers to an expanded document on the best practice in hysteroscopy, issued by the RCOG and that encompasses the exact risks associated with the procedures and how to manage them. It also covers the best practice setup for hysteroscopy clinics. We acknowledge the side effects of cervical dilation and manipulation. However, the information provided about adverse

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					events for any procedure or intervention mentioned in the guideline (including pharmaceutical agents) remains within the responsibility of the practitioner counselling the woman and gaining her consent for the proposed intervention. Hysteroscopy is no exception. Procedure specific consent forms and pharmaceutical information is beyond the scope of this guideline.
RCGP	Short	6	2	Taking a sexual history and considering STI/PID as a cause of HMB +/or IMB	Thank you for your comment. The committee considered that STIs are rarely the cause of HMB, however, the committee agrees that when taking history it is important to consider related symptoms and co-morbidities.
RCGP	Short	6	27	The move to hysteroscopy as initial investigation is prohibitively expensive and precludes good primary care management. Biopsy at the time of a mirena fit is satisfactory for someone with only moderately raise risk factors.	Thank you for your comment. The new guideline recommendations reflect our review of clinical and cost-effectiveness based on the best available evidence. Whilst current practice is varied, we do appreciate that some change to service organisation will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. The new guideline continues to recommend ultrasound as the initial investigation where the

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					uterus is palpable abdominally and where a history or examination suggests a pelvic mass
RCGP	Short	7	9	The list of risk factors needs extending to include women with diabetes, hypertensive women, those with a family history of ovarian and endometrial cancer, taking oestrogen only HRT etc. Making sure that primary care clinicians understand who is at higher risk of developing endometrial pathology will ensure that the correct women are referred for hysteroscopy and not for US scan with consideration of 'blind' biopsy but it will allow the majority of women to be managed closer to home with less invasive intervention and ensure that the financial costs are managed and commissioned services can manage the demands within the financial and clinical resources available.	Thank you for your comment. The list of risk factors provided is not an exhaustive list of all the risk factors for endometrial pathology but an example of the most important factors to consider in women with HMB. In addition, women using hormone replacement therapy would not be in the scope of this guideline since they would not be premenopausal women with HMB. In general, the risk of endometrial cancer is very low in premenopausal women with HMB (Pennant et al., 2017). However, there are some factors that warrant further investigations via endometrial biopsy. Persistent intermenstrual or irregular bleeding, and infrequent bleeding in women who have polycystic ovary syndrome or are obese were considered the 'red flags' for endometrial pathology in women with HMB. In addition, women taking tamoxifen and women with failed treatment for HMB were considered at higher risk for endometrial pathology warranting an investigation via biopsy. Pennant ME, Mehta R, Moody P, Hackett G, Prentice A, Sharp SJ, Lakshman R. Premenopausal abnormal uterine bleeding and risk of endometrial

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					cancer. BJOG. 2017 Feb;124 (3):404-411. doi: 10.1111/1471-0528.14385. Epub 2016 Oct 20.
RCGP	Short	7	12	Pelvic Ultrasound scanning should be clarified as transvaginal scanning if acceptable as this provides a clearer vision of the endometrium to assess for pathology, especially in obese women.	Thank you for your comment. The guideline committee did not want to specify the mode of pelvic ultrasound scan because transvaginal and transabdominal ultrasound scans are not mutually exclusive and in some cases both can be used to complement each other. In practice, clinicians will likely offer transvaginal ultrasound scan for obese women for clearer vision, as suggested.
RCGP	Short	9	1.4.3	Here the guideline runs from IS to embolization but it should have 1.53 first with medical models of care like short term NSAI and tranexamic acid.	Thank you for your comment. The recommendations in this section were not part of the 2017 partial update and were incorporated from the 2007 guideline to be under one heading. We accept the point that information about other pharmacological treatments would also be helpful, however, evidence for this was not reviewed during the 2017 partial update but will be flagged to the surveillance review team
RCGP	Short	10	29	No detailed recommendation has been made about the use of combined contraception as either flexible extended cycling or E2Val/DNG – both of which would be good primary care options – CHC are just dismissed	Thank you for your comment. The committee has systematically examined the evidence for available hormonal therapeutic agents in the context of HMB. However, we did not compare the effectiveness of different combined hormonal contraceptives, therefore, we are not able

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					to recommend specific combined hormonal contraceptives.
RCGP	Short	10 11 12	29 1 17 18	Hormonal treatments can be used on a continuous basis – continuous CHC and continuous progestogens – rather than cyclical as written	Thank you for your comment. In our evidence review and analysis, we found evidence that cyclical oral progestogen can be effective in treating HMB. However, we did not find any evidence on the effectiveness of continuous progestogens and have therefore included a research recommendation on the effectiveness of the progestogen-only pill, injectable progestogens, and progestogen implants in alleviating HMB. The guideline committee is, however, aware that in clinical practice continuous progestogen is used to treat HMB and is aware that in its licensed use as a contraceptive it may suppress menstruation and therefore could benefit a woman with HMB. We have added a recommendation about this.
RCGP	Short	11 15 21 22	22 10 13 20 3	Use wording ‘specialist care’ or ‘any qualified provider’ as this care might be provided by primary care service, or private provider but does not need to be traditional secondary care	Thank you for your comment. We have replaced 'secondary care’ with 'specialist care' as suggested.
RCGP	Short	18	22	‘Blind’ endometrial biopsy is tolerated in the majority of women and when used with transvaginal US scanning is acceptable, and cost effective for the majority of women who do not have history or clinical findings suggestive of intrauterine or histological concerns – need listing as discussed previously	Thank you for your comment. The guideline committee thinks that currently many women undergo painful endometrial biopsies unnecessarily. We recommend that endometrial biopsies should only be taken when there is an increased risk of endometrial pathology or there is

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					visual proof of potential abnormality. The new guidance recommends that endometrial biopsy should be taken only in the context of diagnostic hysteroscopy to maximise the effectiveness of biopsies in detecting endometrial pathology. Diagnostic hysteroscopy should be offered to women who have symptoms to suggest a uterine cavity abnormality, such as persistent intermenstrual bleeding alongside HMB, as it is a more accurate investigation for these abnormalities compared to an ultrasound scan. Endometrial biopsy in the context of diagnostic hysteroscopy should be considered for women who have a high risk of endometrial pathology. The guideline committee wants to emphasise that when performed according to current best practice guidelines, including appropriate information provision for the woman, advising the woman to take analgesia beforehand, and using miniature hysteroscopes, outpatient diagnostic hysteroscopy should be well tolerated and accepted by majority of women. Hysteroscopy also allows for a one-stop 'see-and-treat' service which can reduce the number of visits and speed the treatment for HMB.
RCGP	Short	20	3 - 5	There are Primary care clinicians performing diagnostic and treatment hysteroscopy procedures but there are significant costs to training and limited training places. With increasing work in primary care this expectation that primary care clinicians are available to be trained is a	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned.

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				concern. Outlay for equipment costs is high requiring significant investment as well as ongoing sterilisation and maintenance costs.	Whilst current practice is varied, we do appreciate that some change to service organisation and staff training will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. However, NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made.
Royal College of Nursing	Short	General	General	As a non-specialist nurse endometrial ablation – 'avoid pregnancy or use contraception" - for what time frame? Or is this indefinitely?	Thank you for your comment. Yes, pregnancy should be avoided or contraceptives used indefinitely. In general, a woman should not consider endometrial ablation if there is any chance she would like to become pregnant in the future. There is an increased risk of pregnancy complications, including miscarriage, after endometrial ablation. The ablation itself is not a contraceptive method and the woman will need to continue using contraception afterwards. The advice is usually to continue using contraception indefinitely, encouraging the woman to seek a permanent contraceptive method (for example, sterilisation or vasectomy in a male partner). It should be noted that an intrauterine contraceptive device is not suitable after endometrial ablation.

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Royal College of Nursing	Short	6	18 - 20	Many hospitals will be offering a diagnostic service only and will be constrained by the procurement of instruments and working with what is available. "See-and-treat" has its pros and cons – 'patient consent' is a process and not just one conversation about a treatment. Women need time to consider a permanent treatment option. However, the service needs to redesign itself if "see-and-treat" is integral to its HMB service in that, treatment information should be offered pre-appointment with time allocated during pre-appointment to discuss potential treatment and its implications to ensure that assimilation of information has occurred to gain meaningful and legal consent.	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made. Whilst current practice is varied, we do appreciate that some changes to service will be required to ensure that hysteroscopy services are organised according to best practice (including a service organisation that enables 'see and treat' in a single setting where feasible). We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term, which is why the recommendation acknowledges that a service organisation that enables 'see and treat' in a single setting may not always be feasible.
Royal College of Nursing	Short	6	1.3.3	Agree that hysteroscopy has increased specificity /sensitivity, however as per earlier comment, it is uncertain how this may impact on primary care and overall costs. Redesign of services – GPs could employ nurse specialists into GP practices to reduce referral costs. Perhaps consider	Thank you for your comment. The considerations about how services could be redesigned in order to facilitate the implementation of this guideline are interesting and will be

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				offering hysteroscopy in-house – include newer scopes which are disposable and single use.	considered by NICE where relevant support activity is being planned.
Royal College of Nursing	Short	6	10	We would welcome the change to hysteroscopy for the investigation as a first line treatment but in reality this is going to be both ultrasound and hysteroscopy.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. Whilst current practice is varied, we do appreciate that some change to service will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. However, NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made.
Royal College of Nursing	Short	6	15	Should this link to the Royal College of Obstetrics and Gynaecology (RCOG) best practice guidelines?	Thank you for your comment. It is not normal practice to link to guidelines from other bodies than NICE in the recommendations. However, we refer to the RCOG Green-top Guideline on Best Practice in Outpatient Hysteroscopy in the 'Committee's discussion of the evidence' section in the Diagnosis evidence report.

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Royal College of Nursing	Short	10 1.5.21	12	If "see-and-treat" is a viable option for a service provider then having the space, equipment and expertise in an outpatient clinic to offer a scope, endometrial ablation and a scan at the same time may be very challenging for many services.	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made. Whilst current practice is varied, we do appreciate that some changes to service will be required to ensure that hysteroscopy services are organised according to best practice (including a service organisation that enables 'see and treat' in a single setting where feasible). We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term, which is why the recommendation acknowledges that a service organisation that enables 'see and treat' in a single setting may not always be feasible.
Royal College of Nursing	Short	10	17	In some populations who have multiple fibroids over 3cm but a normal cavity an IUS can be indicated, this suggests it should not be offered.	Thank you for your comment. The section titled 'Treatment for women with fibroids of 3 cm or more in diameter' from recommendation 1.5.7 onwards covers the treatment options for this group of women. As is suggested, LNG-IUS is one of the treatment options for fibroids 3 cm or more, bearing

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					in mind the considerations for the size, location and number of fibroids.
Royal College of Nursing	Short	12	23	In many areas ulipristal is only given after a specialist review and cannot have a first prescription by a GP, this will restrict the availability of this.	Thank you for your comment. NICE guideline recommendations are based on the best available evidence of cost and clinical effectiveness. Whilst recognising that implementation of NICE guidelines may sometimes be difficult, NICE guidelines should drive service provision rather than the other way round. The committee would hope that this guideline would make it easier for a first ulipristal prescription to be given by the GP where appropriate. Your comments will be considered by NICE where relevant support activity is being planned.
Royal College of Nursing	Short	13	1	Consider adding 'do not use progestogen only contraception at the same time' to this sentence.	Thank you for your comment. Contraindications for different treatments are part of the general considerations when deciding on a treatment and are therefore not mentioned or listed here for any treatment option.
Royal College of Nursing	Short	18	4	Some healthcare professionals may not understand when to and when not to examine, this needs to be more explicit in the guidelines.	Thank you for your comment. We have made minor amendments to recommendations 1.2.4 and 1.2.5 which outline when to offer a physical examination (see below). Hopefully this will make it clearer to health professionals when to examine.

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					1.2.4 If the woman has a history of HMB with other related symptoms (see recommendation 1.2.1) offer a physical examination. [2007, amended 2017] 1.2.5 Carry out a physical examination before all investigations or LNG-IUS fittings. [2007, amended 2017] Also see recommendation 1.2.1: 1.2.1 Take a history from the woman that covers: • the nature of the bleeding • related symptoms, such as persistent intermenstrual bleeding, pelvic pain and/or pressure symptoms, that might suggest uterine cavity abnormality, histological abnormality, adenomyosis or fibroids • impact on her quality of life • other factors that may affect treatment options (such as comorbidities or previous treatment for HMB). [2007, amended 2017]
Royal College of Nursing	Short	19	23	A good opportunity for more nurses to train in hysteroscopy, as the nurse hysteroscopist has already proven to be cost effective.	Thank you for your comment in support of the guideline recommendations.
Royal College of Nursing	General	General	General	The Royal College of Nursing welcomes the update of these guidelines. The RCN invited members who care for women's health and sexual health to review the document on its behalf.	Thank you for your comment in support of the guideline.

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				The comments below reflect the views of our members.	
Royal College of Nursing	General	General	General	It should be recognised that Integrated Sexual Health Services are often not commissioned to insert IUS for heavy menstrual bleeding, unlike under the old CASH Service. So if GPs cannot fit an IUS then they would need to refer patients to specialist services other than sexual health (local contractual arrangements dependent). This change needs to be recognised in these guidelines.	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. It is not within the remit of a NICE clinical guideline to address how clinical services should be commissioned.
Royal College of Nursing	General	General	General	Overall we welcome the additions and the changes made in the guidelines. We consider that the biggest impact is the recommendation of hysteroscopy over scanning for some women and this is likely to have training implications. Although it is suggested this can take place in primary care some areas of the country have GPs who do not even undertake vaginal examinations or fitting of IUS so this would be a be task. We welcome the chance that this would give to training more nurse hysterscopists.	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. Whilst current practice is varied, we appreciate that some change to service and staff training will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We agree that this is likely to provide opportunities to train more nurse hysteroscopists.
Royal College of Obstetrics and Gynaecology	Short	General	General	I feel there is a lack of clarity over advice to primary care providers and those in secondary care. Whilst there is acknowledgement that hysteroscopy is recommended as a first-line investigation, this would require changes to services. As the guidance stands, I can see a massive increase in secondary care referrals prior to any management being started within primary care.	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. The guideline is for use in both primary care as well as secondary care. Primary care will be the first

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					setting in which women with HMB will present. Most GPs / community gynaecologists can prescribe pharmacological treatments and fit LNG-IUS devices. Thus recommendations 1.5.2 and 1.5.3 are separated from 1.5.5 which refers to secondary care interventions. However, the guideline recommendations do not preclude secondary care from considering treatment alternatives that could also be provided in primary care. The committee believes that management will usually commence in primary care and that the new guideline recommendations will not substantially alter current practice with regard to secondary care referral. Whilst current practice is varied, we do appreciate that some change to service will be required as a result of the recommendation to offer hysteroscopy for women with suspected polyps, submucosal fibroids or endometrial pathology. We recognise that in the context of current resource/capacity constraints that this may be challenging to implement, particularly in the short term. However, NICE recommendations are intended to reflect the best available evidence on clinical and cost-effectiveness, and the committee believed that the evidence reviewed justified the recommendations made.
Royal College of	Short	General	General	A very well written and thought guideline that includes important changes and updates. Overall, I am in agreement	Thank you for your comment in support of the guideline.

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Obstetrics and Gynaecology				with the content of the guideline and the arguments for the changes made by the authors, as outlined in the 'Recommendations that have been deleted or changed' section.	
Royal College of Obstetrics and Gynaecology	Short	General	General	I disagree that replacing the term "structural abnormality" with "intracavitary abnormality" makes it more precise. Since there aren't many "intracavitary abnormalities" (perhaps polyps, submucosal fibroids and septum) it may be best to just list them?	Thank you for your comment. We have amended the wording to uterine cavity abnormality for clarity and consistency with terminology used in clinical practice. We have also added the definition of the term to the glossary in the Supplementary material document.
Royal College of Obstetrics and Gynaecology	Short	**4** **1.2.3**	**General**	Given that 1.2.7 suggests those with large fibroids should be offered referral to secondary care, is offering a VE not unreasonable at the outset?	Thank you for your comment. We have amended the recommendations to clarify that if the woman's history suggests fibroids, a physical examination should be offered. A physical examination should also be carried out before all investigations or LNG-IUS fittings.
Royal College of Obstetrics and Gynaecology	Short	**5** **1.2.4**	**6**	"offer" a physical examination. Then in 1.2.5 line 10 – "carry out a physical examination before all". I don't think there is enough emphasis on the importance of examination when an abnormality is suspected.	Thank you for your comment. The guideline recommends that when history suggests an abnormality or when an investigation is warranted, physical examination should be offered and carried out. We have amended the wording of the recommendations on physical examination slightly which hopefully makes this clear.
Royal College of Obstetrics and Gynaecology	Short	6 1.3.4	**General**	Pain and hysteroscopy – there are a number of patient lobbying groups in favour of stronger analgesia than suggested.	Thank you for your comment. The guideline committee is aware of concerns over analgesia for hysteroscopy. According to a survey conducted among British Society for Gynaecological Endoscopy (BSGE) members, outpatient hysteroscopy is, in current practice, unfortunately

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					not always performed according to best practice guidelines and instead might use outdated techniques (for example larger scopes, non-vaginoscopic technique and unnecessary endometrial biopsies) and many women endure pain unnecessarily. The RCOG Green-top Guideline on Best Practice in Outpatient Hysteroscopy outline processes and procedures that aim to minimise discomfort and pain for the woman. We have emphasised this in the new recommendations. In addition, if the woman declines outpatient hysteroscopy, an option of hysteroscopy under general or regional anaesthesia should be offered.
Royal College of Obstetrics and Gynaecology	Short	6 1.3.2	**8**	How are submucous fibroids "suspected" particularly if no physical examination has been undertaken?	Thank you for your comment. Submucosal fibroids could be suspected on the basis of history and examination. For example, if history shows persistent intermenstrual bleeding together with HMB this might indicate submucosal fibroids. The guideline recommends offering a physical examination if history suggests any abnormality, including submucosal fibroid.
Royal College of Obstetrics and Gynaecology	Short	7 1.3.11	**General**	I note the emphasis on adenomyosis. I am not familiar with the evidence behind this, but are we sufficiently confident in the sensitivity of the symptoms to screen for adenomyosis, and for those involved in USS or MRI scanning outwith publishing research groups to reliably identify adenomyosis as compared to subsequent histology? If this pathway isn't clear, might there be	Thank you for your comment. Adenomyosis is a common condition and there is a growing body of evidence related to its significance in the context of HMB, and the expertise for identifying adenomyosis and the evidence base for treating it is ever expanding. Identifying

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				evidence that symptoms correlate with treatment outcomes well enough to miss out these scanning options (particularly the expense of MRI)?	adenomyosis can be beneficial to an individual woman because adenomyosis might not respond favourably to pharmacological treatments (or endometrial ablation) and therefore treatment pathways might be different, however, the evidence base for this is still limited. At the same time the group of women with suspected adenomyosis who would undergo MRI instead of transvaginal or transabdominal ultrasound is expected to be a small subset and therefore the cost would not be significant.
Royal College of Obstetrics and Gynaecology	Short	**9** **1.4.4**	**10-11**	"opportunities for discussion" – is this not part of a routine consultation? Or are you suggesting this should be done separately?	Thank you for your comment. This part of the guideline has not been updated and this recommendation is not intended to say when and how this discussion should take place.
Royal College of Obstetrics and Gynaecology	Short	**11** **1.5.4**		Is it worth defining second generation? (I note is was deleted from the previous guideline)	Thank you for your comment. Second-generation endometrial ablation is defined in the glossary of the guideline as 'A surgical treatment for heavy menstrual bleeding that involves destruction of the lining of the womb without using continuous direct visualisation of the endometrium with a hysteroscope.'. The glossary can be found in the Supplementary material document.
Royal College of Obstetrics and	Short	**11** **1.5.8**	**25**	In addition to TXA and/or NSAIDs, other pharmacological treatments could also be considered (e.g. Ulipristal acetate), while more definite treatments (e,g, surgical) are being organised.	Thank you for your comment. The guideline committee agrees that ulipristal acetate can be used effectively as an interim treatment for HMB to improve symptoms while more definitive treatments

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Gynaecology					are being organised. To reflect this, we have amended the recommendation on pretreatment before surgery to say: 'Pretreatment with gonadotrophin-releasing hormone analogue or ulipristal acetate before hysterectomy and myomectomy should be considered if uterine fibroids are causing an enlarged or distorted uterus.'
Royal College of Obstetrics and Gynaecology	Short	12 1.5.13	**26**	Why is 102g/L used as the haemoglobin cut-off level? Is this arbitrary?	Thank you for your comment. The haemoglobin level cut-off of 102g/litre comes from the evidence that the recommendation is based on. The evidence was among women who had fibroid-related anaemia defined as haemoglobin level of 102g/litre or lower without macrocytosis. The NICE Clinical Guidelines Update Team reviewed the evidence and developed the recommendation in 2016, i.e. it was not part of the 2017 partial guideline update.
Royal College of Obstetrics and Gynaecology	Short	14 1.5.21	**General**	I don't see how inserting a hysteroscope keeps this as a 'non-hysteroscopic ablation'	Thank you for your comment. The guideline makes a clear distinction between first-generation endometrial ablation techniques (that are hysteroscopic guided and delivered through the hysterscope, hence labelled hysteroscopic), and second-generation endometrial ablation techniques that are performed without relying on hysteroscopes and without delivering the ablation technique through a hysteroscope (hence the term non-hysteroscopic). This does not preclude the use of hysteroscopy in specific circumstances as an adjunct to the technique. In this instance, the

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					recommendation clearly describes one such situation where cervical dilatation is needed and deemed difficult or where there is a suspicion of cervical perforation or the structural condition of the uterine cavity needs ascertaining.
Royal College of Obstetrics and Gynaecology	Short	14 1.5.21	**General**	Is it necessary to use all three – i.e. if a hysteroscopy has been normal, is it still necessary to use ultrasound?	Thank you for your comment. We have amended the recommendation to say 'ultrasound may be used' to be consistent with the guidance from the Medicines and Healthcare products Regulatory Agency.
Royal College of Obstetrics and Gynaecology	Short	**14** **1.5.21**	**12**	"Use ultrasound" - should this be "consider the use of" – this recommendation would require either the presence of a trained sonographer at the procedure or additional training given to the operator. Resource and manpower implications.	Thank you for your comment. We have amended the recommendation to say 'ultrasound may be used' to be consistent with the guidance from the Medicines and Healthcare products Regulatory Agency.
Royal College of Obstetrics and Gynaecology	Short	15	12 - 13	"concomitant treatment of submucous fibroids" – this is suggested in the context of OP hysteroscopy in community settings. Surely a secondary care management?	Thank you for your comment. The guideline committee is aware that currently outpatient hysteroscopy and especially 'see-and-treat' service for submucosal fibroids or endometrial polyps rarely take place in community settings. However, increasing access and availability of such one-stop services could result in avoiding delays in effective treatment as well as cost savings, providing that safety of the service is assured.

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Royal College of Obstetrics and Gynaecology	Short	**15**	**13**	Change levonorgesterol-releasing to levonogestrel-releasing	Thank you for your comment. This error has been corrected.
Royal College of Obstetrics and Gynaecology	Short	**21**	25 - 26	"No evidence found about hysteroscopic removal of fibroids but committee agreed it is an effective treatment". Surely this is anecdotal if there is no evidence and efficacy cannot be assured.	Thank you for your comment. While no clinical evidence from randomised controlled trials was found, hysteroscopic removal of submucosal fibroids is commonly used in clinical practice and observational evidence has shown it to be effective and safe. The guideline recommends to 'consider' (rather than 'offer') it for treatment of submucosal fibroids and at the same a research recommendation was made to study the effectiveness of hysteroscopic removal of submucosal fibroids compared to other uterine-sparing treatment for women with HMB.
TERUMO	Short	General	General	We would like to report our significant concern about the recommendations from the HMB Guideline update. We do not have the capacity to critique, deconstruct or approve the complex research and evidence review (ER2) presented by the Guideline Committee to support these recommendations. However we would like to point out the significant regression that the updated guideline would create for patient access to minimally-invasive, uterus-preserving treatments. Clinicians in charge of patients with HMB in secondary care are consultant gynaecologists who may naturally favour and advise treatments they are in	Thank you for your comment. UAE and myomectomy are recommended first-line treatment options for women with fibroids 3 cm or more in diameter, alongside pharmacological treatments and hysterectomy (1.5.10) because they were found to be effective in the treatment of HMB. Second-generation endometrial ablation is also recommended as a first-line treatment for women with HMB with no identifiable pathology, or

				charge of – as opposed to treatments where a referral to an Interventional Radiologist is needed. We are concerned that the changes in the guidelines – and especially the more positive recommendation towards hysterectomy in the patient pathway – will reduce the choice available to patients with HMB needing a non-drug intervention. The table below has taken extracts from the 2007 Clinical Guideline (CG44) and compared with the update currently up for consultation, to illustrate and highlight our two main areas of concern: 1) UAE, myomectomy and endometrial ablation are far from appearing as first-line treatment options (as they did in 2007) 2) More worryingly, it looks like hysterectomy is now back as part of the options to consider for HMB – whereas it was clearly the opposite in 2007 We are concerned by these changes and would be grateful to understand – in simpler terms that in ER2 – what has motivated and justified those changes and if original recommendations from 2007 on hysterectomy could be reinstated.	fibroids smaller than 3 cm in diameter and with severe symptoms if the woman declines pharmacological treatments (1.5.5). Our network meta-analysis and other published good quality systematic quantitative reviews did not demonstrate any clear superiority of endometrial ablation over LNG-IUS, other pharmacological treatments or hysterectomy in this population. The guideline committee carefully reviewed the evidence for the most effective treatment for HMB. The evidence reviewed did not show a clear hierarchy of the different treatment options and hysterectomy was one of the treatments that showed good outcomes in both the short and long term. In order to facilitate a woman's choice, the committee felt it was important to offer a range of treatment options to women, including hysterectomy. In our network meta-analysis, second-generation endometrial ablation or pharmacological treatments were not superior to hysterectomy. The committee does not anticipate that hysterectomy will be provided as a first-line treatment other than in exceptional circumstances, where this reflects the woman's choice, she has severe symptoms and does not wish to preserve her uterus/fertility for example. The guideline is clear that women's preferences are important when

					2007 HMB Clinical Guideline	**2017 (updated CG for consultation)**	agreeing treatment (see recommendation: "When agreeing the treatment options for HMB with the woman, take into account the woman's preferences") and therefore the committee did not want to make a recommendation that did not allow hysterectomy as a first-line treatment in any circumstances.
					For women with large fibroids and HMB **HMB in women with fibroids of 3 cm or more in diameter:**	*[1.7 pg 13-14]* For women with large fibroids and HMB, and other significant symptoms such as dysmenorrhoea or pressure symptoms, referral for consideration of surgery or uterine artery embolisation (UAE) as <u>first-line treatment</u> can be recommended[10]. [2007] 1.7.2 UAE, myomectomy or hysterectomy should be	*[1.5.12 pg 12]* Consider a choice of the following treatments for HMB in women with fibroids of 3 cm or more in diameter: • pharmacological: 10 • non-hormonal: 11 • tranexamic acid 12 • NSAIDs 13 • hormonal: 14	

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					considered in cases of HMB where large fibroids (greater than 3 cm in diameter) are present and bleeding is having a severe impact on a woman's quality of life. [2007] 1.7.3 When surgery for fibroid-related HMB is felt necessary then UAE, myomectomy [2007] must all be considered, discussed and documented. [2007] 1.7.4 Women should be informed that	• ulipristal acetate (see recommendation 1.5.13) • LNG-IUS 16 • cyclical oral progestogens 17 • combined hormonal contraception 18 • uterine artery embolisation 19 • surgical: 20	

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					UAE or myomectomy may potentially allow them to retain their fertility. [2007] 1.7.5 Myomectomy is recommended for women with HMB associated with uterine fibroids and who want to retain their uterus. [2007] 1.7.6 UAE is recommended for women with HMB associated with uterine fibroids and who want to retain their uterus and/or avoid surgery. [2007]	• myomectomy 21 • hysterectomy. [2017]	

					1.7.7 Prior to scheduling of UAE or myomectomy, the uterus and fibroid(s) should be assessed by ultrasound. If further information about fibroid position, size, number and vascularity is required, MRI should be considered. [2007]		
				Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or	*1.6 pg 12-13]* *1.6 Non-hysterectomy surgery for HMB* 1.6.4 Endometrial	*[… 1.5.4 pg 11]* 1.5.4 If treatment is unsuccessful, the woman declines pharmacological treatment, or	

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				diagnosed adenomyosis	ablation should be considered in women with HMB who have a normal uterus and also those with small uterine fibroids (less than 3 cm in diameter). [2007] 1.6.5 In women with HMB alone, with a uterus no bigger than a 10-week pregnancy, endometrial ablation should be considered preferable to hysterectomy. [2007]	symptoms are severe, consider referral to secondary care for: • investigations to diagnose the cause of HMB (see section 1.3), if needed, taking into account any investigations the woman has already had **and** • alternative treatmen	

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						t choices, including: • pharmacological options not already tried (see recommendation 1.5.2 and 1.5.3) • surgical options: • second-generation endometrial ablation	

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						• **hysterectomy. [2017]**	
				General (across different types of HMB and fibroid size)	*[1.8 pg 14-15]* **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**		

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					• 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]	
				We would like to quote the introduction of the recent Women's Health All Party Parliamentary Group report on *Informed Choice? Giving women control of their*		

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				healthcare to support our previous comments about the critical need for unbiased information. *Introduction* *The All-Party Parliamentary Group on Women's Health has found that across the country women are not being treated appropriately when it comes to their physical, mental and gynaecological health. The group surveyed over 2,600 women and sent an FOI to hospital Trusts and found unacceptable treatment for women with fibroids and endometriosis. The group found that women are not getting the right diagnosis and information about treatments making it extremely difficult for them to decide the best care for themselves. If women cannot even get the right diagnosis and information about treatments, how can they possible decide what is the best care for themselves? Women deserve every opportunity to take control of their own healthcare and this group is striving to empower women so they have this potential.*	
TERUMO	Short	11 1.5.4	2 - 13	It is clear when comparing 2007 guidelines to the current update for consultation that hysterectomy is proposed to be a treatment option on equal footing to other treatment options. The consideration which was given to alternatives to hysterectomy such as endometrial ablation has disappeared. The very clear recommendation that hysterectomy should not be used as a first-line treatment solely for HMB has disappeared. Could NICE and the Guideline Development Group describe the rationale for this significant change?	Thank you for your comment. The committee carefully reviewed the evidence for the most effective and safe treatment for HMB. The evidence did not show a clear hierarchy of the different treatment options and hysterectomy was one of the treatments that showed good outcomes in both the short and long term. Second-generation endometrial ablation was also found to be an effective treatment for HMB with fibroids smaller than 3 cm in diameter or no identified pathology. The guideline includes both of these as treatment options. The

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					committee felt it was important to offer a range of treatment options to the woman. The committee agreed that it is important to allow the choice of hysterectomy when it is considered clinically appropriate. For some women hysterectomy might be the most appropriate and desirable treatment option. Currently, some women might have to go through attempts of different unsuccessful treatments prolonging suffering before being offered the option of hysterectomy. The committee wants to avoid this in future, offering women a wider choice of options. The committee does not anticipate that hysterectomy will be provided as a first-line treatment other than in exceptional circumstances where this reflects the woman's choice where, for example, she has severe symptoms and does not wish to preserve her uterus/fertility.
TERUMO	Short	12 1.5.12	8 - 22	It is clear when comparing 2007 guidelines to the current update for consultation that hysterectomy is proposed to be a treatment option on equal footing to other treatment options. The consideration which was given to alternatives to hysterectomy such as UAE and myomectomy in 2007, in particular because they can allow patients to retain their uterus, has disappeared. The very clear recommendation that hysterectomy should not be used as a first-line treatment solely for HMB has disappeared.	Thank you for your comment. The committee carefully reviewed the evidence for the most effective and safe treatment for HMB. The evidence did not show a clear hierarchy of the different treatment options and hysterectomy was one the treatments that showed good outcomes in both short and long term. The committee agreed that it was important that myomectomy and UAE should be offered as alternatives to hysterectomy and the rationale for the recommendation is discussed in

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				Could NICE and the Guideline Development Group describe the rationale for this significant change? ,	detail in the committee's discussion of the interpretation of the evidence (see https://www.nice.org.uk/guidance/gid-ng10012/documents/evidence-review-2, page 105). The committee felt it was important to offer a range of treatment options to the woman but also felt that it is important to allow the choice of hysterectomy when it is considered appropriate. For some women hysterectomy might be the most appropriate and desirable treatment option. Currently, some women might have to go through multiple attempts of different unsuccessful treatments prolonging suffering before being offered the option of hysterectomy. The committee does not anticipate that hysterectomy will be provided as a first-line treatment other than in exceptional circumstances where this reflects the woman's choice where, for example, she has severe symptoms and does not wish to preserve her uterus/fertility.
The Gynaecology Group	Short	5	26	"Do not carry out thyroid testing for women……" Perhaps this could be misunderstood so might be more accurate written as "thyroid hormone testing…"	Thank you for your comment. We have changed the wording as suggested.

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The Gynaecology Group	Short	6	24	"consider hysteroscopy under anaesthesia" This is a little ambiguous as the assumption would be this doesn't include local anaesthesia, perhaps "hysteroscopy under general or regional anaesthesia" would be more precise Despite running an outpatient hysteroscopy clinic I feel, as do many patients, that they are often not offered hysteroscopy under general anaesthesia and can feel coerced into having a procedure with no/local anaesthesia. If the patients are to make an informed decision re their ongoing investigation they must be informed that having the procedure under a general is an option, albeit not what we would tend to recommend. "If a woman declines outpatient hysteroscopy, consider hysteroscopy under anaesthesia". This suggests that if a woman declines an outpatient hysteroscopy "we" as clinicians may not suggest having the same procedure under a GA. If the patient warrants an outpatient procedure but declines it in an outpatient setting then almost inevitably she warrants it under a GA . I would therefore suggest "If a woman declines outpatient hysteroscopy then hysteroscopy under general or regional anaesthesia should be offered"	Thank you for your comment. As suggested, the guideline committee has amended the recommendation to say 'If a woman declines outpatient hysteroscopy, offer hysteroscopy under general or regional anaesthesia.
The Gynaecology Group	Short	9	3	Would it be prudent to add in here additional side-effects of the LNG-IUS , which are often not mentioned to	Thank you for your comment. The section about information for women about HMB was outside the

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				patients progestogenic side-effects of mastalgia, bloating and mood changes	scope of the 2017 partial update and therefore was not amended.
The Gynaecology Group	Short	9	23	Suggest "bladder/bowel function". Many patients aren't made aware of the potential for long-term alteration in bowel function post-hysterectomy	Thank you for your comment. The section about information for women about HMB was outside the scope of the 2017 partial update and therefore was not amended.
The Gynaecology Group	Short	9	24	"need for further treatment" - I'm not quite sure what is meant by this as this is a guideline on HMB and this section is discussing hysterectomy	Thank you for your comment. The 'need for further treatment' refers to, for example, the possible need for hormone replacement therapy after hysterectomy if the ovaries were to be removed. The section about information for women about HMB was outside the scope of the 2017 partial update and therefore was not amended.
The Gynaecology Group	Short	13	18	"When discussing the route of hysterectomy (laparoscopy, laparotomy or vaginal) with the woman, carry out an individual assessment and take her preferences into account" This is a good opportunity to ensure patients are having a full and complete discussion regarding hysterectomy and we should be especially minimising patients having a laparotomy for a normal size uterus without concurrent pathology. To promote a complete discussion with patients and ensure they are making an informed decision perhaps this could read; "When discussing with the woman the route of hysterectomy (laparoscopy, laparotomy and vaginal), carry out an individual assessment taking her preferences	Thank you for your comment. The guideline committee acknowledges that laparoscopic hysterectomy is the standard route for hysterectomy in most clinical settings. The route of hysterectomy was not within the scope of the review as no new evidence had been identified in the surveillance review, therefore, it was not prioritised in the scope of this partial update to review the different routes of hysterectomy. We agree that an individual assessment and discussion with the woman should be undertaken. Your comment has been referred to the NICE surveillance review team.

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				into account and referring her onwards to a suitable clinician if required"	
The Haemophilia Society	Short	5	19 - 20	Many women have no family history of a bleeding disorder, so only referring women with a family history , could exclude those with a spontaneous mutation, who are undiagnosed. It would be sensible to also include women who have unexplained bruising and bleeding such as nosebleed, gum bleeds and heavy bleeding after childbirth and surgery. All common, but frequently missed symptoms of a bleeding disorder. Heavy menstrual bleeding is often the most obvious symptom, so can lead to a diagnosis where other symptoms have been ignored.	Thank you for your comment. The guideline committee acknowledges the issue, however, this section was not in the scope of the 2017 partial update and has not been amended.
The Haemophilia Society	Short	5	17	We are pleased to see that you included checking for a coagulation disorder, however these are complex conditions and many medical practitioners, including haematologists have no knowledge of these conditions, the tests are exceptionally sensitive and usually need to be carried out in a hospital that has expertise in this area This would usually be a haemophilia comprehensive care centre. It would be positive if this could be included in the guidance.	Thank you for your comment. Laboratory tests for HMB were outside the scope of this partial update but we have referred your comment to the NICE surveillance team.
The Society and College of Radiographers	Short	7	General	***Women with possible larger fibroids 11*** 1.3.9 Offer 2-dimensional pelvic ultrasound for women with HMB if any of the following apply: □ their uterus is palpable abdominally □ history or examination suggests a pelvic mass □ examination is inconclusive or difficult, for example in women who are obese. **[2017]**	Thank you for your comment. The guideline committee agrees that for obese women ultrasound scan may be difficult or inconclusive and we have added discussion about this to the Diagnosis evidence report.

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				The Society and College of Radiographers feels there should be an acknowledgement that in the obese patient, the pelvic ultrasound may be difficult or inconclusive due to poor scan resolution.	
The Society and College of Radiographers	Short	7	1.3.9 1.3.10	Refer to transabdominal and transvaginal ultrasound examinations. The two techniques are complementary and not mutually exclusive. An examination that commences as a transabdominal scan may need to proceed to transvaginal (provided informed consent is given). A transabdominal scan will often also give further information and a useful additional overview of pelvic structures if the examination initially commenced as a transvaginal scan.	Thank you for your comment. The guideline committee agrees that abdominal and transvaginal ultrasound scans are not mutually exclusive and are often used in conjunction to complement each other. However, we use the term pelvic ultrasound to encompass both techniques and leave it to the woman and clinician to decide which technique, or both, should be used.
The Society and College of Radiographers	Short	19	General	**Ultrasound for women with possible larger fibroids** Hysteroscopy is not able to detect abnormalities outside the uterine cavity, such as subserous or intramural fibroids, or adenomyosis. When an examination suggests a large, or several fibroids, pelvic ultrasound (transvaginal or transabdominal) is recommended instead of hysteroscopy and is likely to be particularly cost-effective. in this context. When abdominal or vaginal examination is difficult to perform or inconclusive	Thank you for your comment. While an ultrasound scan (both abdominal and vaginal) can be difficult to perform in obese women, the guideline committee still considers ultrasound scan to be better than physical examination in detecting abnormalities such as larger fibroids.

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				(for example, because the woman is obese) pelvic ultrasound should be offered to identify any abnormalities that might have otherwise been suggested by examination. The Society and College of Radiographers feels this section implies that transabdominal and transvaginal ultrasound can resolve a difficult digital examination. If it was difficult to perform a digital examination, then it is likely that a transvaginal scan will also be difficult to perform.	
The Society and College of Radiographers	General	General	General	The Society and College of Radiographers would like to see reference to the fact that all who conduct ultrasound examinations must be suitably trained and assessed as competent to do so, they are operator dependent.	Thank you for your comment. The committee agrees that the quality and accuracy of ultrasound examination depend on the competence of the examiner and in practice not all GPs and gynaecologists are adequately trained to perform and interpret a pelvic ultrasound scan adequately. We have added discussion about this to the Diagnosis evidence report.
UK Clinical Pharmacy Association	Short	12	5, 6, 7	We are concerned that this paragraph doesn't clarify which treatments would not be beneficial. Could the committee extrapolate on this? Consider rewording this to (for example): "for fibroids greater than 3cm, pharmacological treatment should be considered but practitioners should be aware that for fibroids that are substantially larger than 3cm, benefit of pharmacological treatment may be limited."	Thank you for your comment. This recommendation was included to ensure that the size of the fibroids is taken into account whilst discussing treatment. The committee considered that frequently used pharmacological treatments such as tranexamic acid, NSAIDs, combined hormonal contraceptives and progestogen are unlikely to be effective for large fibroids. We have amended the recommendation to say 'effectiveness of

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					pharmacological treatments (excluding ulipristal acetate) may be limited in women with fibroids that are substantially greater than 3 cm in diameter'.

Document processed	Organisation name – Stakeholder or respondent	Disclosure on tobacco funding / links	Number of comments extracted	Comments
Short and App C	Bayer plc	Current Situation 1. • Bayer does not have direct or indirect links with, or funding from, manufacturers, distributors or sellers of smoking products but Bayer provides pesticides for crops, which would therefore include tobacco crops. 2. • Bayer is a member of the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) (http://www.coresta.org/) within the scope of recommendations of pesticides used for protection of tobacco plants. 3. • It is also a member of country and EU business federations such as the Confederation of British Industry (CBI) and 'Business Europe', which include tobacco companies. 4. Past Situation • In 2006, Bayer and its subsidiary Icon Genetics piloted a new process for producing biotech drugs in tobacco plants. Icon Genetics was acquired by Nomad Bioscience GmbH from Bayer in 2012.	3	

Registered stakeholders