

Stakeholder comments and responses on 1st consultation draft of HMB guideline

Organisation	Doc	Page no	Line no	Comments	Response
Action and Support Group for Medical Victims of Richard Neale				This organisation was approached but did not respond.	
Addenbrookes NHS Trust				This organisation was approached but did not respond.	
Airedale General Hospital - Acute Trust				This organisation was approached but did not respond.	
Anglesey Local Health Board				This organisation was approached but did not respond.	
Association for Continence Advice				This organisation was approached but did not respond.	
Association for Improvements in Maternity Services (AIMS)				This organisation was approached but did not respond.	
Association of British Health-Care Industries				This organisation was approached but did not respond.	
Association of the British Pharmaceuticals Industry,(ABPI)				This organisation was approached but did not respond.	
AstraZeneca UK Ltd				This organisation was approached but did not respond.	
Barnsley Primary Care Trust				This organisation was approached but did not respond.	
Barts and the London NHS Trust - London	HMB- full version	141	5	Saline infusion sonography has been recommended as the investigation of choice after initial triaging with ultrasound by the FDA in United States. There is an increasing body of evidence supporting the use of saline sonography after a positive ultrasound scan as opposed to diagnostic hysteroscopy. This is not reflected at all in the document. The conclusions from the group as far as Sonohysterography is concerned are both very vague and poorly referenced and do not give any clear guidance of the role saline hysterosonography should occupy.	Thank you for this comment. The GDG has debated SIS and has added further comment on the decision in the text of the main guideline document. However, the GDG still believe that ultrasound should be the initial imaging technique used.
Bedfordshire &				This organisation was approached but did not	

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Hertfordshire NHS Strategic Health Authority				respond.	
Biocompatibles UK Ltd				This organisation was approached but did not respond.	
Biosphere Medical Europe				This organisation was approached but did not respond.	
Boston Scientific Limited	NICE	General		Overall the guideline and its recommendations are strongly welcomed by Boston Scientific as they move treatment away from invasive surgery (hysterectomy) to less invasive treatments. Below are comments on specific points in the guideline that might need further clarification or changes.	Thank you
Boston Scientific Limited	NICE	General		For non-fibroid HMB, the guideline recommends second-generation techniques as the initial choice before first-generation and hysterectomy. However second-generation options are limited to TBEA and MEA whereas HydroTherm Ablation has been declared to be safe and effective for use in the NHS by IPAC and should be added to the list (see further comments in the following pages)	Thank you. These recommendations have been reworded, and all ablation methods are now mentioned.
Boston Scientific Limited	NICE	General		For fibroid-related HMB, UAE and myomectomy are preferred over hysterectomy. However the provision of UAE is not currently consistent across the country and the recommendation could have the perverse effect of shifting all non-hysterectomy treatment to myomectomy	Implementation of the guideline within the NHS is outside the scope of the guideline. However, NICE produce implementation advice for those having to implement the guideline within the NHS.
Boston Scientific Limited	NICE	General		To ease implementation of the guideline, a list of hospitals offering UAE should be added so that surgeons know where to refer patients	Thank you for this suggestion. This is mentioned in the full guideline.
Boston Scientific Limited	NICE	P17	1.5.1.3	According to expert opinion, HTA has the potential to be used on large, irregular uterine cavities with submucous fibroids. The particular feature of free circulating saline means that the surgeon can potentially treat a wider range of patients with the HTA compared to other second generation devices.	Thank for this information
Boston Scientific Limited	NICE	P.17	1.5.1.4 & 1.6.1.2	Wording slightly unclear as 1.6.1.2 could infer a preference to hysterectomy over UAE/myomectomy for patients with large fibroids or other (significant) symptoms, contrary to	The wording of 1.6.1.2 has been amended to avoid ambiguity. The wording was in no way meant to imply that

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				1.5.1.4.	hysterectomy was preferred.
Boston Scientific Limited	NICE	P.17	1.7.2.1	1) Safety: The need to undertake hysteroscopy pre-procedure underlines the potential safety issue with second-generation ablation techniques. The Cochrane review on endometrial ablation [ref 339, Full guideline] concludes that "...uterine perforation, which is the major complication of endometrial ablation, cannot be excluded without hysteroscopy". Among second-generation techniques, HTA is the only hysteroscopic technique allowing direct visualisation of the uterine cavity. Other devices are blind, which could be a concern as inappropriate placement has been related to uterine damage and perforation with trauma to adjacent organs. Compared to first-generation techniques, HTA maintains hysteroscopic guidance without increased risk of perforation by the resectoscope or roller-ball mechanisms.	Thank you. This information has been assessed and the recommendations changed accordingly. This includes the recommendation on correct visualisation prior to procedure.
Boston Scientific Limited	NICE	P.17	1.7.2.1	2) Cost and capacity implication: If the hysteroscopy is performed at a different time than the ablation, it will incur additional costs and capacity pressure. However as hysteroscopy is part of the HTA procedure, an initial exam will not be necessary thus avoiding the need for an extra (hysteroscopic) procedure.	Thank you for this information. This recommendation has been amended to make it clear that this should only be undertaken when dilation is part of the procedure.
Boston Scientific Limited	NICE	P.18	1.7.2.3	Second-generation endometrial ablation techniques are defined as MEA and TBEA in the guideline. This will undoubtedly limit the choice of patients. Alternative techniques such as HydroTherm Ablation (HTA) have been proven safe and effective and should be clearly mentioned in the guideline as well. The IP guidance published in April 2004 supports the use of HTA in the NHS [IPAC Guidance 51, Free fluid thermal endometrial ablation, April 2004]. 1) Equivalence with 1st generation: A Cochrane review compared the various ablation techniques against one another [ref 340, Full guideline]. The review concluded that women undergoing thermal ablation techniques ('2nd generation' techniques) had a similar reduction in bleeding and were as	The recommendation has been amendment to highlight that HTA is a treatment option for HMB.

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				<p>satisfied as women having hysteroscopic resection of the endometrium ('1st generation' techniques). HTA is included and 1 RCT comparing HTA to Rollerball Endometrial Ablation (REA) was identified. The RCT found no significant difference in: - treatment success (amenorrhea and hypomenorrhea), - need for further surgery - and most operative events. Patient satisfaction, a very important end point, was also equivalent between HTA and REA (83% vs 82%). Detailed analysis of efficacy: No significant difference in terms of success rate between REA and HTA: · At 12 months, success rates were 77% in the HTA group and 82% in REA group. The difference was not statistically significant. · After 2 years, success rates were equal to 92% in both groups. Success was measured by a simple questionnaire. At 3 years, success rates were 94% for HTA and 91% for REA. Amenorrhea Rate</p> <p>The review of the literature shows that the amenorrhea rate with HTA at 12 months varies between 33% to 56% and at 24 months between 31% and 47%. No significant difference was observed between HTA and REA. The HTA procedure produces similar results to REA: at 12 months, amenorrhea rates are 40% and 51% respectively (the difference is not significant). At 24 months, rates are 47% for HTA and 46 % for REA and at 36 months, 53% for HTA and 46% for REA. Quality of Life and Patient Satisfaction</p> <p>Overall, HTA improves quality of life and at least 80% of women are satisfied with HTA treatment. The RCT used a menorrhagia quality of life (QoL). Median QoL scores improved by 83% in the HTA group and 82% in the REA arm. Hysterectomy: Two women (1%) had a hysterectomy performed during 12-month follow-up after HTA. The 2 events were not procedure-related. 2) No difference between 2nd generation techniques: The systematic review did not come to any conclusions about the relative benefits and risks</p>	

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				of the different thermal endometrial destruction techniques. There is no comparative trial between HTA and alternatives such as MEA and TBEA. However, results from individual trials show (at least) equivalent success rates. 3) Safety aspects: The Cochrane review on endometrial ablation [ref 339, Full guideline] concluded that "...uterine perforation, which is the major complication of endometrial ablation, cannot be excluded without hysteroscopy". Except for HTA, other second generation techniques do not allow the use of hysteroscopic visualisation of the endometrium while the device is inserted and the procedure performed. The theoretical safety advantage of HTA should be noted. 4) Conclusion: Safety and efficacy of HTA has been proven and HTA should be added to the list of second-generation endometrial ablation techniques currently limited to MEA and TBEA. Amenorrhoea rate @ 12m Source MEA 36% - 40% FG, ref 339 TBEA 10% - 40% FG, ref 339 HTA 33% - 56% FG, ref 340	
Boston Scientific Limited	NICE	P.18	1.7.2.6	The Directions for Use for HTA state: The safety and efficacy has not been evaluated in patients: With a large uterine cavity (>10.5cm) ; With a small uterine cavity (Thank you for this information. In the guideline we refer the reader to the manufacturers' criteria for use of equipment.
Boston Scientific Limited	NCIE	P.18	1.7.2.4 & 1.7.2.5	Recommendations for HTA in the Directions for Use (DFU): The endometrium should be in a basal state prior to HTA. This can be accomplished by timing the menstrual cycle to the early proliferative phase or administering pre-treatment drugs	Thank you for this information. The GDG recommend for all ablation techniques that the healthcare professional refer to the manufacturers' own criteria for use, such as pre-treatment.
Boston Scientific Limited	NICE	P.18	1.7.2.8	A paper recently published on HTA confirmed that it is a procedure that can be safely performed in an outpatient setting and under local anesthesia. The study was conducted in an outpatient clinic and London and concludes that "These [HTA] features make it ideal for performing EA in an outpatient clinic. This initial study shows the feasibility and patient acceptability of this procedure under local anesthesia." Farrugia M., et	The GDG is aware of the data on location of ablation. However, recommendations on the location (primary or secondary care) of procedures are outside the scope of guideline, except in very specific circumstances where the interpretation of a recommendation is changed by location where it is undertaken.

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				al. Hysteroscopic endometrial ablation using the Hydro ThermAblator in an outpatient hysteroscopy clinic: Feasibility and acceptability. Journal of Minimally Invasive Gynecology (2006) 13, 178–182.	
Boston Scientific Limited	NICE	P 19	1.8	Boston Scientific strongly welcomes the Committee's recommendations to favour uterus-preserving treatments (UAE, myomectomy) over invasive surgical procedures such as hysterectomy for fibroid-related HMB. The choice of treatment is a decision that will be made by patients and their consultants according to patient preferences and conditions. However we would like to draw attention to the following as it might warrant a different level of recommendation for UAE.	Thank you. The GDG provide individual responses to the questions below.
Boston Scientific Limited	NICE			1) UAE provides better 'value for money' to the NHS As described in the Full guideline [p.230, L11-13, ref 417], UAE is less costly than surgery at 12 months and is a cost-effective therapy for the NHS. Moreover the hospital length of stay is significantly reduced after UAE compared to myomectomy: UAE Myomectomy p-value Length of stay 3.7 days 5.3 days < 0.001 Source: Mara M et al. Uterine fibroid embolization versus myomectomy in women wishing to preserve fertility: Preliminary results of a randomized controlled trial. Eur J Obstet Gynecol Reprod Biol. 2006 Jun 1;126(2):226-33. Reduction of length of stay will allow hospitals to treat more patients without additional investments, thus increasing efficiency. Moreover the increased activity will increase hospital revenue as hospitals receive payment according to activity (Payment by Results). The recovery time is also significantly reduced after UAE: UAE Myomectomy p-value Length of stay 13.6 days 30.0 days < 0.001 Source: Mara M et al. For patients, time to full recovery is an important aspect of any medical procedure and should be highlighted when options are presented. The impact on the national economy is also favourable as patients are able	Thank you for this data. Economic modelling of UAE was not undertaken for this guideline, and cannot be added at this stage. However, the guideline did include information from REST study that included economic evaluation of UAE.

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				to return to work more quickly.	
Boston Scientific Limited	NICE			2) A trend towards higher QoL following UAE: There is limited published comparative evidence between UAE and myomectomy. A paper published in August 2006 (therefore outside the research period for this guideline) found that median QOL questionnaire scores at 6 months were significantly higher in patients treated with UAE (p=0.041). The findings are indicative of a positive trend for UAE over myomectomy and should be included in any review of this guideline. [Siskin GP, et al. A Prospective Multicenter Comparative Study between Myomectomy and Uterine Artery Embolization with Polyvinyl Alcohol Microspheres: Long-term Clinical Outcomes in Patients with Symptomatic Uterine Fibroids. J Vasc Interv Radiol 2006; 17:1287–1295]]	<p>Thank you for this information. This paper has been considered and will be summarised in the guideline. However, it was not felt that any recommendation should be changed or made based on the paper.</p> <p>In addition, the GDG highlighted the different clinical circumstances in which the two treatments may be used.</p>
Boston Scientific Limited	NICE			3) Patient ownership: Even though UAE is strongly recommended, it is equally the case for myomectomy. Patients have the right to look for all possible treatment options and this guideline will help. But advice from a doctor is still the first source of information and should be neutral. Currently UAE is not consistently offered to patients who could benefit from it. As both treatments are equally supported, the current wording of the recommendation might have an (unwanted) detrimental effect on embolisation as it could shift all non-hysterectomy treatments to myomectomy. Surgeons should be encouraged to present advantages and disadvantages of both options to patients.	<p>Thank you. Implementation issues are outside the scope of the guideline. However, NICE do produce companion documentation on the implementation of guidelines.</p> <p>In addition, we make a recommendation that the patient version of this guideline is given to all women when they are referred for specialist treatment. This should give women access to the same list of treatment options as health professionals.</p> <p>The guideline recommends that UAE, myomectomy and hysterectomy are all explicitly discussed with a woman before a choice is made.</p> <p>It is felt that these recommendations should mean that women received a balanced picture of the available treatments.</p>
Boston Scientific Limited	NICE	P19	1.9.1.1	Alternatives to hysterectomy should be available to women, even if they have completed their families	We agree and the recommendation was not meant to imply anything different. We have amended the text to avoid any ambiguity.
Boston Scientific Limited	NICE	General	Treatme	It should be clarified for easier reading	Thank you for this suggestion. The algorithm is

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			nt Algorith m		being completely revised to improve the ease of use.
Boston Scientific Limited	Full guideline	P.53	L 7-12	Our organisation has not been invited to submit evidence but would have valued participating in the guidelines at an earlier stage	All stakeholder were invited (via e-mail) to submit evidence at the start of the guideline process.
Boston Scientific Limited				Attachments:	Thank you
British Association for Counselling and Psychotherapy (BACP)	Full	general		We are pleased to note that the guideline recognises the psychological impact of this condition and that the need for counselling and support is fully acknowledged.	Thank you.
British Association for Counselling and Psychotherapy (BACP)	Full	21	None provided	The guideline stresses the need for information, education and counselling. We would advocate the inclusion of a definition of counselling within the Glossary. For example, we would suggest: 'Counselling is one of the professional psychological therapies that provides individuals and families/carers with an opportunity to explore emotional, physical and psychological difficulties that they may be experiencing and to help them resolve specific problems, make informed decisions, develop coping strategies and improve relationships with others.'	Thank you for this information. We have incorporated this definition into the guideline glossary, and change the use of the term accordingly in the text.
British Association for Counselling and Psychotherapy (BACP)	Full	76	39061	Whilst we agree that counselling should include the elements mentioned, we suggest that the list should include the term 'psychological distress' as in our experience, a hysterectomy can often impact on a woman's sense of womanhood, regardless of age.	This term has been added to the list of glossary terms and is used as the basis for any recommendation on use of counselling in the guideline.
British Menopause Society				This organisation was approached but did not respond.	
British National Formulary (BNF)				This organisation was approached but did not respond.	
British Psychological Society, The				This organisation was approached but did not respond.	
British Society for Gynaecological Endoscopy	FULL	48	10	Should add hysteroscopic to laproscopic.	Thank you for this comment. We have made this amendment.
British Society for Gynaecological	FULL	49	17	Should include Nurse practitioners and GPwSI in Gynaecology.	Thank you for this comment. We have made this amendment.

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Endoscopy					
British Society for Gynaecological Endoscopy	FULL	50	17	Should read 4 gynaecologists.	Thank you for this comment. We have made this amendment.
British Society for Gynaecological Endoscopy	FULL	66	19	How can pelvic examination be excluded when your first line treatment is fitting an IUS.	Thank you. We have revised these recommendations accordingly. It is now explicitly stated that a physical examination is required prior to fitting an LNG-IUS
British Society for Gynaecological Endoscopy	FULL	72	5	Spelling – Ethamsylate.	According to BNF correct name is Etamsylate.
British Society for Gynaecological Endoscopy	FULL	124	17	Spelling – pallor.	This has been changed
British Society for Gynaecological Endoscopy	FULL	210	18	Risk of fluid absorption with REA is negligible – no veins are opened during the surgery so no fluid can enter the circulation.	Thank you for this information it has been incorporated.
British Society for Gynaecological Endoscopy	FULL	210	25	Add Novasure device – impedance controlled bipolar radiofrequency ablation.	Thank you for this comment. The GDG will look for a suitable way to mention this technique.
British Society for Gynaecological Endoscopy	FULL	210 onwards		Section 10.3 Endometrial ablation/resection. This section bases its evidence on three systematic reviews, two of which are Cochrane reviews and the other one a Health Technology Assessment review. The first Cochrane review compares endometrial destruction techniques with hysterectomy, the other two include studies comparing some or all destruction techniques. These latter studies (The last Cochrane review was published in 2005) conclude that there were very few significant differences in the main clinical outcomes (Garside et al 2004) or 'some differences were also found in amenorrhoea rates and satisfaction rates, but there did not appear to be a trend over time so these results may be due to chance (Lethaby et al 2005'. Despite this the draft NICE Guidelines suggest that 'second generation ablation techniques (MEA, TBEA) should be considered ahead of first generation techniques'. This recommendation was based on	<p>Thank you for this comment. The recommendation has been amended to state that HTA and bi-polar ablation techniques are treatment options for HMB.</p> <p>The GDG agree that the surgical skills associated with 1st generation techniques are important. Therefore, the recommendation on 1st and 2nd generation techniques has been split. The recommendation on 1st generation techniques specifies the circumstances under which it should be undertaken.</p>

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				the fact that the GDG felt results from a recent study (Cooper et al 2005) were important. This study gave a long term comparison of outcome of MEA and TCRE. Its main outcomes showed similar amenorrhoea and hypomenorrhoea rates and reduction in pain scores. Despite this hysterectomy rates were higher in the TCRE group and satisfaction rates were with MEA were higher. Hence it is difficult to justify recommending second generation techniques ahead of first generation techniques with the conclusion from one single study. It appears that TCRE and REA stood their ground well in systemic reviews which included as many as 19 studies, 12 of which were funded/partially funded by the manufacturers or had authors with conflict of interest. Hence the NICE guidelines should stick with the conclusions of systematic reviews until further systematic reviews which will include new data are published. with the future ATSM in hysteroscopic surgery (RCOG). Hysteroscopic resection is an essential skill which is necessary for the hysteroscopic management of submucosal fibroids, polyps and septa hence development and maintenance of this skill amongst gynaecologists is paramount. If NICE recommends second generation techniques as first line then it could potentially lead to the demise of hysteroscopic skills with the loop electrode which would have a major implication on skill based competencies. We need to ensure there are enough gynaecologists who could still perform such hysteroscopic surgery.	
British Society for Gynaecological Endoscopy	FULL	228	15	Myomectomy is not only performed hysteroscopically, and laparoscopically, but vaginally and by open surgery.	Evidence on all routes of myomectomy was reviewed (see 10.3) and is mentioned in the full version.
British Society for Gynaecological Endoscopy	FULL	249	6	The 3 subdivisions of the laparoscopic approach are correct. LAVH, LHa and TLH.	Thank you for this information.
British Society for Gynaecological Endoscopy	FULL	256	1	In comparing the laparoscopic approach to vaginal hysterectomy and abdominal hysterectomy, the three modes of the	Thank you for this information. The GDG considered these issues, but felt it to be inappropriate to include too much detail in the

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				laparoscopic approach are not considered separately. LAVH is closer to vaginal hysterectomy than TLH and therefore the three methods cannot be considered as the same in the conclusions. Indeed TLH can be considered as abdominal hysterectomy carried out through small holes with increased vision. Indeed in the oncology world, randomised studies comparing LAVH and TLH have been carried out and suggest different risks.	guideline.
British Society for Gynaecological Endoscopy	FULL	256	1	LAVH is merely vaginal hysterectomy with laparoscopic bilateral oophorectomy. Indeed in line 12 and subsequently it points out that complications from LAVH and vaginal hysterectomy are not different. If it is appropriate to do TAH when ovaries need to be removed then it follows that women admitted for laparoscopic removal of ovaries should also be encouraged to only have abdominal removal of ovaries. Also it would follow that the vaginal approach should be abandoned for hysterectomy in favour of the abdominal approach. This is again confirmed in the study reported on page 263.	Thank you. We have revised the recommendations to make it clear in what situations the laparoscopic route should be considered.
British Society for Gynaecological Endoscopy	FULL	256	1	Cost analysis study on page 266 demonstrates that LAVH is preferential to TAH when ovaries are to be removed. Thus with regards LAVH it would suggest that in fact if vaginal hysterectomy is to be recommended over TAH then the LAVH should also be recommended when the ovaries are to be removed. Of note there are no data presented on the complication rates of vaginal oophorectomy.	Thank you. We have revised the recommendations to make it clear in what situations the laparoscopic route should be considered.
British Society for Gynaecological Endoscopy	FULL	256	1	With regards to LHa the data again is conflicting but the argument is probably in favour of TAH over this approach from the data presented. However, there are no data presented assessing the longer term risks of wound hernia and it costs with the abdominal route. However, the assumption in the paper on cost analysis on this aspect does not adequately assess the theatre time costs. These will vary according to staff numbers in theatres, anaesthetic time, delay in	The GDG has reviewed this data, and although there are some limitations, recommendations must be made on the best available evidence. Staff numbers are taken into account in the calculation of theatre costs.

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				getting patients from the wards to theatre, coffee breaks etc. The effect not only on bed stay but on the number of beds that the hospital has, has not been fully assessed. Also with this method and others the data presented is largely six years old and there has been a vast increase in laparoscopic surgical expertise and this has not been allowed for. Throughout the review there has not been enough emphasis on surgical skills and the expertise variations and hence how this influences the choice in different centres.	
British Society for Gynaecological Endoscopy	FULL	256	1	With regards TLH there are no data presented and indeed there are series in the literature suggesting that in high risk women such as obesity then this approach is superior to TAH and indeed the inference with regards wound complication would suggest cost-effectiveness. Although only one reference is given there are several others revealed on a Medline search. Although the data relates to endometrial cancer, the act of removing the uterus is the same. It would seem inappropriate that just because a woman does not have cancer she is denied a TLH which has been shown in overweight women to be superior. Thus it would appear that in those cases where vaginal hysterectomy is not possible and the woman is overweight, TLH is the approach of choice. In other situations there are no data available in the literature (or at least not considered in the guidelines).	Thank you for this information. The nature of systematic reviews means that inclusion criteria have to be used. In the case of this guideline one of the main criteria was an HMB population. Therefore, studies assessing use of hysterectomy on women with cancer were not included. However, we have reviewed the recommendations on route of hysterectomy and amended them accordingly.
British Society for Gynaecological Endoscopy	FULL	260	12	In the comparison on subtotal and total hysterectomy the laparoscopic approach is not even commented on despite large series in literature.	Thank you for this comment. This section has now been amended.
British Society for Gynaecological Endoscopy	FULL	276	10	These conclusions are not valid. They should read that vaginal hysterectomy is the route of choice. Where the ovaries are to be removed then LAVH is the mode of choice. Where the patient is high risk and vaginal hysterectomy is not possible then TLH is possibly the route of choice. Data presented on LH suggests that the role is possibly inferior to TAH.	Thank you. The recommendations on route of hysterectomy have been revised to take greater account of criteria for use.

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British Society for Gynaecological Endoscopy	FULL	278	3	Consider specifying by name the types of hysterectomy to include the 3 subdivisions of laparoscopic hysterectomy.	The types of laparoscopic hysterectomy are outlined in the full guideline. (see 11.3)
British Society for Gynaecological Endoscopy	FULL	285	24	RCOG SSM in hysteroscopic surgery has guidance on training for endometrial ablation. The ATSM has further guidance including methods of assessing competence with OSATS, etc.	Thank you for this information. However, the guideline will not refer to specific training programmes, as it is not possible to list them all. Instead, the GDG have outlined a generic framework for training within which specific programmes can fit.
British Society for Gynaecological Endoscopy	FULL	290	21	SSMs are being converted into Advanced Training Skills Modules ATSMs and are awaiting ratification by PMETB.	Thank you for this information. However, the guideline will not refer to specific training programmes, as it is not possible to list them all.
British Society for Gynaecological Endoscopy	FULL	326		The paper used to assess likelihood of successful visualisation does not reflect current clinical practice/ experience. For hysteroscopy under GA unsuccessful visualisation occurs 1% of cases. For OP, hysteroscopy is unsuccessful between 2 to 4% of cases for women with HMB.	Thank you. The analysis used the best available source of data.
British Society for Gynaecological Endoscopy	FULL	327		Same paper – most women are investigated in a one stop setting so these costs are too high. Omit the cost of OP visit and recalculate.	The assumptions used in the model about where and when investigation took place were based on the clinical experience and advice of the GDG. The sensitivity analysis showed ultrasound to be cost effective even when the cost of providing hysteroscopy was less than half of the cost used in the base case (£210 base-case v £92 for hysteroscopy to generate the same cost per correct diagnosis.
British Society for Gynaecological Endoscopy	FULL	general		Further refs: Ghezzi F, Cromi A, Bergamini V, Uccella S, Beretta P, Franchi M, Bolis P. Laparoscopic-assisted vaginal hysterectomy versus total laparoscopic hysterectomy for the management of endometrial cancer: a randomized clinical trial. J Minim Invasive Gynecol. 2006 Mar-Apr;13(2):114-20. Bojahr B, Raatz D, Schonleber G, Abri C, Ohlinger R. Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique. J Minim Invasive Gynecol. 2006 May-Jun;13(3):183-9. Yu C KH, Cutner A, Mould T, Olaitan A. Total laparoscopic	Thank you for these references. They will be assessed for inclusion in the guideline. Any reference concerning conditions other than HMB cannot be included.

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				hysterectomy as a primary surgical treatment for endometrial cancer in morbidly obese women. BJOG. 2005;112:115-117.	
British Society for Gynaecological Endoscopy	FULL	general		Recent introduction of safer energy sources for intra-abdominal use eg harmonic scalpel and other instruments eg McCartney tube are likely to reduce the rate of vault haematoma and urinary tract injury respectively.	Thank for this information. This could be of interest when the guideline is up-dated.
British Society for Gynaecological Endoscopy	FULL	general		The guideline highlights the importance of individual patient assessment when deciding route of hysterectomy (page 276 line 14) and the need for well trained surgeons with sufficient throughput (Chapter 14, page 285). The BSGE commends drawing attention to these important but often neglected factors in surgical outcome. We are also grateful to NICE for highlighting the need for National Training programmes in laparoscopic surgery, which, we hope, the RCOG will carry forward in collaboration with the BSGE.	Thank you.
British Society for Gynaecological Endoscopy	FULL	general		EVALUATE showed which ever route was used for hysterectomy, patient outcome was good. Making surgeons operate in a way which they are not comfortable is going to mean a lot of retraining (80% of UK hysterectomies are still abdominal) or surgeons doing operations they are not trained for.	Thank you for this comment, we agree.
British Society for Gynaecological Endoscopy	NICE	5	5	Women seek help from not only their GP but also nurse practitioners and practice nurses. Etc. The guideline could acknowledge this by referring to primary health care professionals. The role of GPwSi in gynaecology could also be highlighted.	Thank you. The term healthcare professional has been added where it is appropriate.
British Society for Gynaecological Endoscopy	NICE		7.4.4	The suggestion that the Mirena IUS should be first line treatment by GPs does not fit with the experience members of the BSGE have of many GPs, few of whom fit the device. We would argue against the need for referral to secondary care only after the device has been fitted and found to fail as a form of treatment. For many patients the option of 'a coil' or any hormonal treatment is unacceptable.	The guideline states that all women should have access to recommended treatments but not where it should be fitted. In addition, the GDGs experience suggests that LNG-IUS can be fitted in general practice.
British Society for	NICE	9		Investigations for HMB. Can radiology services	Thank you. The GDG recognise that the

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Gynaecological Endoscopy				cope with the anticipated increased volume of referrals for scanning for HMB? These requests will be coming from primary care where the guideline anticipates quite rightly most of the medical management will occur. It could result in long waits for tests and delays in treatment for the women.	recommendations may impact on the numbers of ultrasounds carried out. This is an important issue for the implementation of this guideline.
British Society for Gynaecological Endoscopy	NICE	9		The guideline also assumes GPs will be able to undertake endometrial biopsies – this skill is not widespread in primary care. The comments of the RCGP will be pertinent around this point.	The guideline states that all women should have access to recommended treatments, although not all healthcare professionals can provide them they should be able to refer to someone who can.
British Society for Gynaecological Endoscopy	NICE	12		Physical examination should be further defined as examination of the abdomen, speculum examination and bimanual pelvic examination.	Thank you for this comment. We have made this amendment.
British Society for Gynaecological Endoscopy	NICE	13	1.2.4.2	The guideline only refers in passing to hysteroscopy and does not mention out-patient hysteroscopy at all. The GDG seem to have failed to take into account > 150 OP hysteroscopy clinics already in existence that provides excellent one stop services for women with menstrual problems. These clinics also increasingly offer treatment at the first visit ie inserting an IUS, removing polyps or treating fibroids and avoiding the women having to go onto a waiting list for surgery under GA.	Thank you, we accept this comment. However, service configuration is outside the scope of the guideline
British Society for Gynaecological Endoscopy	NICE	13	1.2.4.3	The guideline needs to mention women at high risk of endometrial pathology EG women with PCO, obese women, diabetic women and women with family history of endometrial cancer. A statement here would make sure that these women were not missed in primary care.	Thank you. The guideline highlights factors associated with HMB, and the link between pathology and HMB. The guideline includes a section that shows the likely risk of endometrial cancer in women with HMB is very low, and refers to the NICE guideline on suspected cancer where appropriate.
British Society for Gynaecological Endoscopy	NICE	17	1.7	There is no statement about the role of prior LSCS in the selection of 1st or 2nd generation ablation eg MEA is not recommended if LSCS scar thickness is < 10 mm.	Thank you. We stated in the recommendations that references to individual criteria of use should be made.
British Society for Gynaecological Endoscopy	NICE	17	1.7.2.1	Hysteroscopy should be undertaken when using a 2nd generation technique that requires dilatation prior to insertion of the device. TBEA does not	Thank you. This recommendation are been amended in response to this comment.

Organisation	Doc	Page no	Line no	Comments	Response
				usually require dilatation before treatment.	
British Society for Gynaecological Endoscopy	NICE	18	1.7.2.8	If the guideline is going to promote ablation under local anaesthetic then the DOH needs to be made aware of the perverse incentives that exist whereby a Trust would prefer to offer ablation under GA rather than LA as the payment will be higher. There is no incentive for a Trust to develop OP ablation as it will lose income.	Thank you for this comment. Anaesthetic and commissioning issues are outside the scope of this guideline.
British Society for Gynaecological Endoscopy	NICE	19	1.8.1.4	The public needed to be aware that there are subdivisions of Myomectomy with varying risks ie hysteroscopic, laparoscopic, vaginal and by laparotomy (open surgery).	Thank you for this comment. The sub-types of myomectomy are mentioned in the full guideline. However, it is impractical to mention all the types in recommendations.
British Society for Gynaecological Endoscopy	NICE	19	1.9.1.2	Consider specifying by name the types of hysterectomy to include the 3 subdivisions of laparoscopic hysterectomy.	Thank you, this will be considered.
British Society for Gynaecological Endoscopy	NICE	21	1.11.1.3	Complex procedures should include laparoscopic surgery and refer to the 2 ATSMs in laparoscopic surgery prepared by the RCOG/BSGE for PMETB.	Thank you. The list provided was not meant to be exhaustive, but we have added laparoscopic surgery to it. The guideline will not be able to refer to any specific training programmes.
British Society of Interventional Radiology	Full	229	14-22	On line 15-16 the RCT being discussed states there is less intra-procedure blood loss for UAE against hysterectomy. However lines 19-20 states that there was no significant difference between the two groups in terms of need for blood transfusion. Are these two statements compatible?	These results come from a systematic review that includes several RCTs. The difference in statements relates to the reporting of results from different RCTs.
British Society of Interventional Radiology	Full	229	14-24	There are 3 studies about to be published. The REST trial from Scotland is a RCT of UAE vs TAH. The EMMY trial from the Netherlands is also a RCT of UAE vs TAH. The HOPEFUL study (http://www.obs-gyn.ox.ac.uk/research/HOPEFUL) co-ordinated by Klim McPherson from Oxford compares TAH (459) to UAE (649) with at least 2 years follow up. The monograph of this study will be with the HTA by the end of September. The incidence of complications in all categories was less with UAE-severe 0.7% TAH vs 0.4% UAE, major 10.7% TAH vs 3.7% UAE, minor 14.8% TAH vs 13.7%	Thank you. This data has already been included in the guideline. The HOPEFUL study is still unpublished so could not be included in the guideline. However, the guideline mentions that it exists.

Organisation	Doc	Page no	Line no	Comments	Response
				UAE. HOPEFUL, REST and EMMY are in favour of UAE by about 1/3 in all categories except uterus preservation and pregnancy (where obviously UAE is preferable).	
British Society of Interventional Radiology	Full	230	39062	Further cost benefit analysis is available from the HOPEFUL document favouring UAE.	Thank you. The GDG is aware of this data. However, as it is not in the public domain at the time of final submission it cannot be included in the guideline.
British Society of Interventional Radiology	Full	231	38749	This sentence states there was no difference between UAE and TAH for need for blood transfusion (OR 0.21) hospital stay 1 week (OR0.11). Does this does make sense? Patients with UAE are usually in for an overnight stay although in unusual circumstances may stay for 2-3 nights. In my practice of over 250 patients I have never had a patient stay in for one week. If the odds ratio is 0.11 surely this is strongly in favour of UAE demonstrating there is a difference.	The statement is correct, as the confidence intervals for 1 week stay are (0.01 to 2.08). Therefore, even though an OR of 0.11 favours UAE, it is not statistically significant.
British Society of Interventional Radiology	Full	231	38904	The statement that the review concludes that "there is no evidence of benefit of UAE compared to surgery (TAH or myomectomy) for satisfaction". This sentence is misleading. What the review has demonstrated is equivalence of treatment for satisfaction of UAE vs TAH. As UAE is a less invasive procedure as demonstrated by all criteria and less costly then equivalence of satisfaction should be an argument in favour of performing UAE.	Thank you. This statement is a direct quote from a paper, so cannot be changed.
British Society of Interventional Radiology	Full	231	41548	This sentence refers to the limited ammount of DATA available. This should include the data which is about to be published of HOPEFUL, REST and EMMY.	Thank you. It is NICE policy that data available in the public domain can be included in a guideline, and this has been followed here. However, the REST and EMMY studies were included in the review, but the HOPEFUL study was still unpublished at final submission. However, the GDG were aware of the findings of this study.
British Society of Interventional Radiology	Full	235	13	This states there was no significant difference between AM and UAE for hospital stay one week yet the odds ratio is 0.11. As stated previously and stated on line 25 page 231 going onto the	The statement is correct, as the confidence intervals for 1 week stay are (0.01 to 2.08). Therefore, even though an OR of 0.11 favours UAE, it is not statistically significant.

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				following page there were significant differences in mean hospital stay between AM and UAE 2.9 vs 0 days ie in most instances UAE is at most an overnight stay.	
British Society of Interventional Radiology	Full	General		There is important data in the HOPEFUL monograph to be delivered to the HTA at the end of September and this data should be included in this draft for consultation.	Thank you. If this document is in the public domain prior to the submission of the guideline to NICE then it will be considered for inclusion.
British Society of Interventional Radiology	Full and Short	General		From a patient perspective it is important to know the relative risks of treatment, time to full recovery and return to work. This is important and should be emphasised. Are patients informed in a balanced and truthful way? Are patients informed about all the risks of TAH as they are of UAE?	Thank you for this comment. The guideline emphasises the importance of providing information to the patient.
British Society of Interventional Radiology	Full and Short	General		Recommendations around future research should focus on what we do not know ie fertility issues with subsequent pregnancy, patient selection (ie which patient group is ideally suited to UAE?) and technical issues such as choice of embolic agent and technique to increase success rates.	The GDG agree, and have already made a research recommendation to cover this issue.
Buckinghamshire Hospitals NHS Trust				This organisation was approached but did not respond.	
Campaign Against Hysterectomy (CAH)		General		The overall tenor of the report is good and thoroughgoing and I would not want to see it cut down at a committee stage. The whole body of recommendations should be retained unless amended by stakeholder comments. The following points outline what I feel to be omissions and deficiencies in the report:	Thank you.
Campaign Against Hysterectomy (CAH)		Page 63 line 4		No mention of ovaries, although there is a fuller report with specifications, there is not enough emphasis	Both the full and NICE versions of the guideline contain a specific section / chapter on ovaries.
Campaign Against Hysterectomy (CAH)				on preserving healthy ovaries, rather only looking for reasons to remove them - that is justifying surgical removing absolutely healthy organs. Statistics show that ovarian cancer is one of the smallest of all cancers and yet thousands of women have prophylactic oophorectomies every year. This cannot be justified. It should not	The GDG believe they have covered this issue in the recommendations on oophorectomy.

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				happen.	
Campaign Against Hysterectomy (CAH)		Page 63 line 17		Clinicians remit to "balancing risks"? This is why a guideline in being prepared, as their assessment of risk is far greater than the risk actually is, and this is why far too many hysterectomies are being done. Very difficult now to find unbiased assessment of risks. xxx has announced recently that 6000 too many hysterectomies are being performed on women over the age of 45 - out of the remit of this guideline I know, but this should show NICE the drift of thinking about hysterectomy. Where is the "balance" going to come from when exactly the same clinicians will doing the assessments? Surely this implies a complete re-training of all gynaecologists?	Thank you for this comment.
Campaign Against Hysterectomy (CAH)		Page 64 line 6		Norethisterone associated with legal action in USA. NSAID's and tranexamic acid reported to me more often than not as being ineffective	Thank you for this information.
Campaign Against Hysterectomy (CAH)		Page 65 line 1		Do not agree, other methods for dealing with large fibroids other than hysterectomy e.g. myolysis and myomectomy	This recommendation was meant to highlight the criteria where hysterectomy should be considered, not a treatment list for fibroids. The guideline outlines in detail the treatments (UAE, Myomectomy and hysterectomy) that can be used to treat HMB in the presence of fibroids. The recommendation has been reviewed and revised.
Campaign Against Hysterectomy (CAH)		Page 65 line 4		No mention of preserving fertility. Fertility should be preserved at all costs. There is too much attention on surgery and not enough attention on the individual patient. Clinicians should always be aware of ..what if? What if a woman lost her children in a disaster ? she should always be able to keep the option to have more children, even if she says that she has completed her family. Life is never certain.To lose your children and also the possibility of having more children is a terrible thing.	We make recommendations and comments about fertility throughout the guideline.
Campaign Against Hysterectomy (CAH)		Page 65 line 7		No mention of MRI assisted laser myomectomy	Thank you for this comment. This is currently being evaluated by NICE in a separate document, but is considered not to be in routine use within the NHS.
Campaign Against		Page 66		HMB occurs naturally in pre-menopausal women	This is what we have tried to capture in this

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Hysterectomy (CAH)		line 1		for a short to medium period, but rarely lasting for longer than 2 years. Why hysterectomise when what is happening is NORMAL. There is very poor understanding of what is normal amongst gynaecologists. They don't look for normal only focusing on the merest hint of abnormal for the purpose of doing surgery.	statement.
Campaign Against Hysterectomy (CAH)		Page 66 line 8		Proper diagnosis involves measurement of blood loss. Blood loss is highly subjective and no one knows how to measure it accurately. Surely attention to finding a scientific method of measuring HMB would benefit every one. A study carried out in 1998 showed that more than 50% of women diagnosed with HMB did not have it.	The GDG agree, and have made a research recommendation to this effect. However, the GDG have defined HMB on the impact that it has on the women rather than arbitrary measures.
Campaign Against Hysterectomy (CAH)		Page 67 line 15		Wrong. Acute hypothyroid women already diagnosed will be having thyroxine so there WILL BE NONE OF THE SYMPTOMS of hypothyroidism - that includes HMB. It is sub-acute women you have to worry about, because due to medical bigotry they will never be treated. If you do not fall on to the acute side of an arbitrary line then your hmb is nothing to do with hypothyroidism. 5-10% of the women who come to me for advice are sub acute hypothyroids. I pass them on to expert help groups and they get appropriate treatment and hmb recedes. Medics - GP's and Gynaecologists generally - do not recognise that sub acute hypothyroidism is a condition, as the hypothetical line prevents these women being treated. Medicine has gone into reverse doctors 40 years ago recognised sub acute level hypothyroidism but they do not now.	Thank you for this comment.
Campaign Against Hysterectomy (CAH)		General		This poses the question are human beings machines or highly complex organisms with not two absolutely alike barring multiple birth siblings. So why one size fits all?	Thank you for this comment.
Campaign Against Hysterectomy (CAH)		Page 68 line 17		Why 12 cm ? Is this just another arbitrary measurement. Treat the patient as a complete entity, stop looking only at symptoms!	Thank you for this comment. The GDG reviewed the recommendation.
Campaign Against Hysterectomy (CAH)		Page 68 line 24/5		What will this contain? Unless it contains information on all alternatives including the option	The GDG have outlined detailed implementation advice on the information pack (chapter 4)

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				for no treatment it will be no good	In addition, the recommendation has been changed to explicitly state that the patient version should be used as a source of information.
Campaign Against Hysterectomy (CAH)		Page 69 line 2		The first question should be "Is this necessary?"	Thank you for this comment.
Campaign Against Hysterectomy (CAH)		Page 69 line 13		Bravo	
Campaign Against Hysterectomy (CAH)		Page 69 line 16		Bravo	
Campaign Against Hysterectomy (CAH)		Page 69 line 20		Bravo	
Campaign Against Hysterectomy (CAH)		Page 77 line 7		Unless diseased. ovaries should NEVER BE REMOVED . Prophylactic removal should be outlawed. Ovarian cancer is one of the smallest cancers there is. Effective Healthcare in Medicine 1999 - Women's Pelvic Cancers - said that ovarian cancer "was so rare" that the average GP would only see one case every FIVE YEARS. Why do this? It is castration and cruel.	Thank you. We have added a recommendation to make this clear.
Campaign Against Hysterectomy (CAH)		Page 78 line1-7		RCOG specify only experience of hysterectomy for progress to consultant level. How can the body of gynaecologists trained in this way convert to a new regime? They are the same people. Without a big stick at their backs they will carry on doing the same thing. Some are so bigoted that even re-training will not alter their belief in this surgery.	Thank you.
Campaign Against Hysterectomy (CAH)		Page 79 line 6-9		This does not happen now. How are you going to enforce it?	The GDG have no power to outline enforcement of the guideline. However, audit standards based on the guideline are outlined by CASPE.
Campaign Against Hysterectomy (CAH)				Comments proforma completed, but lost in email transfer.	
Central Liverpool PCT				This organisation was approached but did not respond.	
Change People				This organisation was approached but did not respond.	
Chartered Society of Physiotherapy				This organisation was approached but did not respond.	

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CIS'ters				This organisation was approached but did not respond.	
City Hospitals Sunderland NHS Trust				This organisation was approached but did not respond.	
Commission for Social Care Inspection				This organisation was approached but did not respond.	
Connecting for Health				This organisation was approached but did not respond.	
Conwy & Denbighshire NHS Trust				This organisation was approached but did not respond.	
County Durham and Darlington Acute Hospital Trust				This organisation was approached but did not respond.	
Cytac UK Limited				This organisation was approached but did not respond.	
Denbighshire Local Health Board				This organisation was approached but did not respond.	
Department of Health	Full	General		The Department of Health's opinion is that the full guideline could be very useful in providing clear and concise standards for the care of women with heavy menstrual bleeding.	Thank you.
Department of Health	Full	General		The Department of Health considers that further clarity is needed as to how much of the care could or should be carried out in Primary Care or the community.	Thank you for this comment. We would like to highlight that service configuration is outside the scope of NICE guidelines.
Department of Health	Full	General		We think that the development of the guideline should take into consideration the Department of Health's white paper on "care closer to Home".	Thank you for this comment. We would like to highlight that service configuration is outside the scope of NICE guidelines.
Department of Health	Full	General		The Department of Health considers the Algorithm on page 82 to be very complicated and we would welcome it if this could be made clearer, akin to the algorithms provided by xxx at the implementation meeting. These could be adapted to show how local protocols could define the appropriate place of care.	Thank you. We have revised the algorithm to improve the clarity. However, issues relating to location of services are outside the scope of NICE guidelines (except in special circumstances where the meaning of a recommendation is fundamentally linked to location).
Department of Health	Full	63	10	The Department of Health would welcome the addition of the following lines to this section as we feel that the current wording implies that a woman should only have Endometrial biopsy if she " is	Thank you. We have amended the text accordingly.

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				aged 45 years and over and has declined or failed medical treatment". Would you please consider making this clearer by adding "...has persistent intermenstrual bleeding or is aged 45 years..etc"	
Department of Health	Full		14	The Department of Health feels that this statement could be clearer and include a definition of when, in the pathway of care, the woman is going to be referred to secondary care. Most of the evidence presented (pages 143-153, 5.3.1 and 5.3.2) relates to information prior to hysterectomy. We would be grateful for clarification as to whether the text should say that all women with menorrhagia should be given an information pack after conservative treatment has failed, or perhaps prior to surgical intervention.	<p>The GDG have reassessed the recommendations in order to improve the referral criteria throughout the guideline. This has included specifying specific criteria for use of treatments and investigations.</p> <p>In relation to the information pack, the woman should receive this when first referred to a specialist.</p>
Department of Health	Full		14	The information on (pages 157-160, 5.4.5) aims to be holistic for all women with heavy menstrual bleeding and implies (as would seem to be appropriate) that women should have information on presenting with the problem. Provision of written information is currently very variable and often relates to a specific procedure after the decision has been made eg Mirena leaflet, total abdominal hysterectomy or vaginal hysterectomy.	<p>Thank you. The guideline provides a section on implementation advice for information and education.</p> <p>The guideline makes no recommendation on information for all women as no evidence was found to support this, whereas evidence was found for provision of information at time of referral to a specialist. However, The GDG have highlighted the Understanding NICE Guidance that is on the NICE website. We trust this will be a useful resource for the service.</p>
Department of Health	Full		14	Providing a leaflet with the minimum data set mentioned on page 159 would have significant cost implications and it would need to be clear who was responsible – Primary care or secondary care.	Thank you. The recommendation was based on RCT evidence on effectiveness and cost-effectiveness. The guideline now recommends that the patient version of the guideline be used for this purpose.
Department of Health	Full		14	If a leaflet is to be given when the woman presents then of necessity, the leaflet would need to be provided in Primary care but with full discussions between primary and secondary care so as to accurately represent the options available locally.	Thank you.
Department of Health	Full	64	4	The Department of Health considers the evidence relating to the health economics of medical treatment of menorrhagia to be (page 165) in	Thank you. It is outside the remit of NICE guidelines to specify where an intervention should be undertaken.

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				<p>favour of LNG-IUS but is not clear as to the threshold at which any intervention would be recommended. We think that a clearer definition of what happens in primary and secondary care would help rectify this. Currently as the text stands, the Department feels that the recommendation could be interpreted to say that any woman presenting to her GP complaining of heavy periods should be offered LNG-IUS as “first-line treatment”. We feel that is likely to have significant implications for training and service provision in primary care and consider that as first line treatment, on initial presentation, the far less invasive offer of tranexamic acid or NSAIDS would more acceptable to the woman.</p>	<p>“Thank you.</p> <p>The LNG-IUS recommendation was based on the available evidence on effectiveness and cost-effectiveness (based on primary care costs), and this clearly showed that LNG-IUS should be used as first-line treatment, if long-term used is expected.</p> <p>The GDG has revised the recommendation to highlight that the need for long-term use “a) Levonorgestrel-releasing intrauterine system (LNG-IUS) provided long-term (5 years) use is anticipated”</p> <p>The GDG have also added a recommendation stating that NSAIDs or TX acid can be used while waiting for definitive treatment, such as LNG-IUS</p> <p>With regards to where this would be undertaken. The economic model was based on fitting taking place in primary care, and the GDG felt that suitable expertise was available within primary care to undertake fitting of LNG-IUS or could easily be put in place.”</p>
Department of Health	Full	64	4	<p>It is not clear to us that the evidence or economic review has taken into account the increased cost of requiring increased provision of LNG-IUS in primary care. We would welcome further clarification on this point and whether it is intended that LNG-IUS be used as a first line for longterm treatment or intervention</p>	<p>Thank you. The recommendation was made on the basis of long-term use (5 years). Economic analysis (based on primary care costs) has shown that over this time-scale LNG-IUS is the most cost-effective option. Furthermore, the analysis showed that at all time periods up to 5 years LNG-IUS was the most cost-effective treatment. (The 5 year limit is based on the licenced length of use.)</p> <p>The GDG is also aware of a number of successful GP services for fitting of LNG-IUS for HMB.</p>

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Department of Health	Full	64	4	The Department of Health would welcome a clearer algorithm than the one found at page 82.	Thank you. The GDG have amended the algorithm to improve the clarity.
Department of Health	Full	66	17	The Department of Health feels that this statement could be confusing. If first line treatment was Tranexamic acid or NSAIDs then it is logical not to examine in the absence of history suggesting pathology, but to initiate insertion of LNG-IUS without examination (GPP) does not seem logical. We would be grateful for clarification.	Thank you. The GDG agree that this statement is illogical, and it has been amended accordingly.
Department of Health	Full	68	17	Having recommended that physical examination is not necessary, then these problems would not be detected	We recommend that physical examination should not be undertaken in women in whom fibroids are not suspected.
Department of Health	Full		24	See comments above (page 63, line 14)	Thank you.
Department of Health	Full	71	Whole page	The order of statements on this page is logical but not given the statement previously that LNG-IUS should be first line treatment.	Thank you for this comment.
Department of Health	Full	73	7	The Department of Health considers that this statement emphasises the problem of trying to be concise. We do not feel that this stands alone as a recommendation without knowing what "other symptoms" are referred to. We think it would be helpful if detail on the symptoms was available either at this point or at least a reference to their location in the guidance explicitly noted.	Thank you. The recommendation has been amended. The GDG has tried to define other symptoms, where possible.
Department of Health	Full	73 and 74	19 & 9	The Department of Health would consider it helpful to change the order and put "women must be counselled on the need to use effective contraception..." (from page 74) immediately after "Endometrial ablation should not be undertaken on women wishing to become pregnant..." We think this is a more logical order and also safer from the standpoint of risk management.	Thank you. We have combined the recommendations into one.
Department of Health	Full	77	13	The Department feels that the numbering and references to the text are not always helpful. For example: Chapter 13.6 appears to be just a repeat of the statements. Would you therefore consider amending this to just refer to "Chapter 13"?	This is a requirement of NICE formatting.
Department of Health	Full		19	The referral for genetic counselling should take	Thank you. We have added this to the end of the

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				place prior to making a decision about treatment.	recommendation.
Department of Health	Full	78	38872	The Department of Health would welcome clarification that there is the infrastructure and the tools to enable it. We would also welcome clarification from the GDG that there is an existing “accredited training programme...” for each “established procedure”? Also who will assess and what measures will be used to assess “acquisition of competence”? Clinicians is a broad generic term. To avoid confusion, is there any reason why “Gynaecologists” should not replace the word Clinician?	The area of education and training is under constant review. Therefore, the GDG felt they should no be too specific in regards to courses available. Instead, the GDG refers the healthcare professional to the relevant professional body.
Department of Health	Full		9	As above ?gynaecologist instead of clinician.	Thank you for this comment. We now specify, where appropriate, whether who should undertake a procedure
Department of Health	Full		14	As above – gynaecologist. Also page 79, 1 and 6.	Thank you for this comment
Department of Health	Full	90	23	Is this correct in view of subsequent evidence eg page 97 line 14?. There are several studies where endometrial polyps are found in cases of HMB. Also page 103 line 22.	There is no evidence linking polyps with HMB i.e. prevalence of polyps is the same in HMB and non-HMB populations.
Department of Health	Full	103	15	The Department would find it helpful if the wording of the second sentence, what “other symptoms of vaginal bleeding” could be clarified. We feel that if the sentence was more precise it may reduce referrals to secondary care.	Thank you. The GDG has amended the text to outline 'other symptoms'
Department of Health	Full	242	15	We feel that this statement could be seen as condoning double standards. If MRI is preferable then the guideline should not allow for second best.	Thank you. The GDG has examined this point, and have changed the recommendation to specify that MRI should only be undertaken where further information is required.
Department of Health	Full	288-293	general	Would you consider making allowances for trainees to operate as the guidance does not always makes it clear.	Thank you. The GDG has assumed that those in training will be under supervision of someone who is competent to perform a procedure.
Department of Health	Full	289	3	In this section you state that any operator must have “completed an accredited training programme...before undertaking any procedure”. As the statement stands it could preclude any trainee from operating. This could be resolved by mentioning the need for direct supervision by fully trained and competent trainer.	Thank you. This change has been made in the text and to the relevant recommendation.
Department of Health	Full	290	all	The Department feels that this page is implies	Thank you. NICE guidelines do not address

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				that clinical networks in gynaecology should be developed and we think it would probably be useful for commissioning purposes if the guideline used that term.	service organisation issues.
Department of Health	Full	302	6	The Department of Health believes that there would be significant knock on effects to suggesting that not all consultants would need to be trained in hysterectomy eg cover for the obstetric unit if hysterectomy required for massive haemorrhage. The Departments feels that suitable expertise must be available and that this expertise could be within a clinical network.	Thank you for this comment. This relates to a discussion point made by the GDG and is not a recommendation. The GDG feel that this question at least needs to be raised.
Department of Health	Full		23	The Department thinks that it would be more helpful if the guidance to referred to the gynaecologist having the appropriate advanced skills rather than the place. Currently there is no definition of a "specialist centre" and instead the quality of care depends more on the individual than the place.	Thank you. The GDG that location should not be mentioned in any of the recommendations, as this is outside the remit of NICE guidelines.
Department of Health	Full	291	42522	We would consider it helpful if this section mentioned of gynaecologists in training. Could Line 10 be amended to read "...accredited training being completed prior to a procedure being undertaken without supervision".	Thank you. The GDG agree that it is important to mention the appropriate professional, where possible. However, these recommendations potentially covering gynaecologists, radiologists, GPs and nurses, so they generic term is used.
Department of Health	Full		12	The Department of Health would consider it beneficial to the guidance if further consideration was given to the suggestion of "specialist centres" and "accreditation by a central body". Our understanding is that there is no formal system for accreditation of service standards in gynaecology and no tools to undertake accreditation. Also where surgery is concerned it is the surgeon primarily, not the place. There are implications for the choice agenda in suggesting restricting practice to "specialist centres" and no evidence to show improvement in outcome as long as the surgeon is competent.	The GDG has tried to reflect the need for accreditation to be carried out by those best placed to do so. However, we are unable to be more specific due the fluid nature of education and training.
Department of Health	Full	292	15	The Department would find it helpful if evidence on decision making (as well as other factors mentioned) was included in the development of a clinical governance framework.	Thank you. This change has been made.

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Dudley Group of Hospitals NHS Trust				This organisation was approached but did not respond.	
ECLIPSE Trial Management Group	FULL	163	11-	<p>The systematic review used to describe the clinical effectiveness of LNG-IUS compared with pharmaceutical treatments identified 4 randomised controlled trials. Irvine 1998 LNG-IUS vs norethisterone, n=44, 3 month follow-up. Cameron 1987 Progestasert vs mefenamic acid vs danazol vs norethisterone, n=30, for 2 cycles, groups not comparable at baseline Reid 2004 LNG-IUS vs mefenamic acid, n=51, 6 month follow-up, company sponsored. Lahteenmaki 1998 LNG-IUS vs continuing existing medical therapy for women on waiting list for hysterectomy, n=56, 6 month follow-up. This collection of small trials represents the sum of evidence for LNG-IUS over other medical therapies. There is no advantage of norethisterone over tranexamic acid or mefenamic acid (Lethaby 2006) and it has only a level 3 recommendation in the Royal College of Obstetrics and Gynaecology evidence based guidelines. The study of Irvine compares LNG-IUS against a less favourable comparator (norethisterone), yet the odds ratio for amenorrhoea (significant) and satisfaction of treatment (non-significant) are based on this small 3 –month follow-up trial. Progestasert is not available in the UK. Quality of life is not discussed in the draft guidelines for any of the four trials identified in the review. The trial by Lahteenmaki did report QOL, measured using visual analogue scales. The design selects women awaiting a hysterectomy and offers them the option of randomisation between continuing their existing treatment and LNG-IUS. The lack of blinding and choice of treatment is likely to have influenced the women's attitude to treatment, therefore is inherently biased for QOL against existing therapy. The most relevant trial is that of Reid, yet this only compared LNG-IUS against one medical therapy in a small group of women. There was a</p>	Thank you for this comment. The GDG agree that the available evidence is incomplete. However, the evidence does highlight the effectiveness of LNG-IUS is at least comparable with other pharmaceutical methods. This data in conjunction with the health economic results was the basis of the recommendations on pharmaceutical treatment.

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				significant difference in the reduction of objective menstrual blood loss (MBL) from baseline between the two groups, favouring LNG-IUS, but the data was too skewed to be combined in meta-analysis. The author was also in receipt of funding from the manufacturer of LNG-IUS.	
ECLIPSE Trial Management Group	FULL	166	10-	We ask why the GDG does not place higher emphasis on patient reported outcome measures, such as health related quality of life or symptom specific rating scales. Whilst objective, measurement of MBL is not correlated with women's perception of the severity of their menorrhagia. Also, considering the value placed on adverse events, the draft guidelines do not cite any side effects for LNG-IUS compared with medical therapies. The study of Reid is the only one to report side effects in any detail: no significant differences were seen for nausea, diarrhoea, ovarian cysts, respiratory infections and mood swings but significant differences in favour of oral medication for breast tenderness, irregular periods or intermenstrual bleeding and pelvic pain.	Thank you. The GDG outline quality of life (page 62) as one of the primary outcome measures. Where data on quality of life was available it was reported. We also cross refer to the LARC guideline, where these issues are considered in detail.
ECLIPSE Trial Management Group	FULL	167	13-	In the reviews of combined oral contraceptives (Iyer 2000, Coulter 1995), no randomised trials of LNG-IUS against COCs were identified.	Thank you. The GDG is aware of this.
ECLIPSE Trial Management Group	FULL	187	5-	In the reviews of tranexamic acid (Coulter 1995, Lethaby 2004, Wellington 2003), no randomised trials of LNG-IUS against tranexamic acid were identified. The GDG concluded tranexamic acid causes a clinically significant reduction in MBL.	The GDG is aware of studies comparing TX acid with other medical treatments. These studies showed a significant decrease in MBL with TX acid, and this was the basis for the recommendation made.
ECLIPSE Trial Management Group	FULL	General		In summary, there is only one direct comparison of LNG-IUS against the pharmaceuticals recommended as second line treatments, in a small trial (n=51) of LNG-IUS against mefenamic acid with short term follow-up (6 months) (Reid 2004). Any other conclusions about the relative effectiveness of these classes of therapies must therefore be based on unrandomised or indirect comparison, which are subject to systematic biases. We dispute the GDG's interpretation of the	Thank you. The GDG has considered this issue in detail. Whilst they agree that the current ECLIPSE study will provide useful direct comparisons of the treatment options, the GDG would highlight that RCT data is available on the effectiveness of the individual treatments. The GDG feels this information, alongside the health economics model, means the recommendation made is justified.

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				<p>data that brings them to the recommendation of LNG-IUS as the first line treatment when pharmaceutical treatment is felt to be necessary and hormonal treatment is acceptable. We contend that there is insufficient clinical and cost-effectiveness data to reach this conclusion. We are disappointed that the draft guidelines did not acknowledge the existence of the ECLIPSE Trial. This is a multicentre pragmatic randomised trial assessing the clinical and cost-effectiveness of LNG-IUS against medical therapy, according to the RCOG algorithm, in a primary care population. The trial intends to recruit 1200 women with subjective menorrhagia from centres in the West and East Midlands. The primary outcome measure is the Shaw Questionnaire, a symptom specific patient reported quality of life instrument. Secondary outcomes measures including SF-36 and EuroQol EQ-5D, subsequent procedures and discontinuation rates, dysmenorrhea, patient satisfaction and resource usage. Women will be followed up for up to 10 years. This trial will provide the most reliable and robust evidence of the comparative advantages and disadvantages of LNG-IUS compared with other medical treatments (tranexamic acid, mefenamic acid and oral contraceptive pill), in the most appropriate setting and will address cost-effectiveness from a UK perspective. Furthermore, it is funded by the Department of Health's Health Technology Assessment (HTA) Programme, which identified the question as one important to the NHS and women and, as yet, lacking clear evidence. It is therefore pre-emptive that NICE should anticipate the results of ECLIPSE and recommend LNG-IUS as the first line treatment. The impact of this recommendation on the ECLIPSE trial is likely to be devastating to recruitment. Patient preference plays a clear role in the management of menorrhagia and a young, informed population is likely to be aware of NICE and its guidance. Any attempt by investigators to</p>	

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				recruit to ECLIPSE seemingly in the face of authoritative guidance is likely to be difficult and the trial would probably be forced to close. If this were to happen, this unique opportunity to establish the evidence for a clear patient care pathway would be lost. We would therefore like the NICE GDG to reconsider their recommendation regarding LNG-IUS as first line treatment. It would be more consistent with the data to recommend the algorithm provided by the RCOG guidelines and participation in the ECLIPSE trial in areas where the trial is recruiting.	
ECLIPSE Trial Management Group	FULL	HEALTH ECONOMICS		<p>The health economics sections of the report give an overview of a Markov model-based cost-effectiveness analysis of alternative approaches to treating HMB compared to a no treatment option. The use of a model based analysis is to be supported as there is clearly much uncertainty relating to the costs and benefits of treatments for HMB and a modelling framework is ideally suited to demonstrate, and explore the importance of, the inherent uncertainty. The researchers have developed a straightforward model, in consultation with clinical colleagues, and have populated the model with data (predominantly from the study by Hurskainen et al, 2001), assumptions and opinions. The results suggest a considerable cost increase and a considerable benefit (in terms of QALYs gained) through the routine first line use of LNG-IUS. The base case result is £840 per QALY gained. The uncertainty in this result is, however, not explored at all and so the result could be highly misleading. It is clear from the presented analysis that the uncertainties inherent in these clinical and policy questions are considerable. It is, therefore, surprising that the analysis has explored uncertainty in a rudimentary and opaque fashion. The sensitivity analysis in this work is crucial. We are told in the text of Appendix A that there is some robustness of the results to variation in the model inputs. However, the detail is not provided</p>	<p>It is agreed that the introduction of more sophisticated methods of exploring uncertainty would not overcome the perceived limitations of the parameter inputs of the model. However, the model draws on the best evidence available as directed and agreed by the guideline development group.</p> <p>A series of one-way sensitivity analyses shows that variations in key inputs in the model have little impact on the relative outcomes. Further details of the sensitivity analysis that was undertaken have been included in the guideline at Appendix A.</p> <p>Further research on comparisons of medical and surgical treatments for HMB should be undertaken if it can be demonstrated that the uncertainty associated with the results of the model developed for this guideline can be reduced and that the additional cost of reducing the uncertainty is warranted.</p>

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				<p>and so we are left without confidence that the authors' interpretations are appropriate. The analysis uses only point estimates for model inputs and so an important and missing element from this model-based analysis is a probabilistic sensitivity analysis (PSA), sampling from distributions placed around the main inputs. This would begin to demonstrate more fully the uncertainties in the model results which are currently hidden. The use of PSA does not by itself, however, overcome the central weakness of the effectiveness evidence feeding the model and such analytic extensions should not be viewed as a substitute for high quality randomised controlled trial-based data. The analysis relating to LNG-IUS draws very heavily on the Hurskainen trial. This was a relatively small trial (n=236 women in total) which directly compared LNG-IUS and hysterectomy. Thus, the trial only includes women who were willing to be randomised between LNG-IUS and hysterectomy, and so it seems reasonable to raise concerns in relation to the appropriateness of using data from that trial in the context of first line treatments for HMB. This would be less problematic if data were also being drawn from more relevant trial sources or if the uncertainties inherent in using these data had been fully explored in the model-based analyses. On the former, there is clearly a paucity of appropriate data on which to draw currently and so the authors rely solely on this one small trial. This highlights the central importance of the ECLIPSE study in providing clinically relevant and robust data for the UK setting. Indirectly this guideline work reveals the need to support the continuation ECLIPSE in order that decision making in this clinical area can be founded on a stronger and more reliable effectiveness and cost-effectiveness evidence base.</p>	
ECLIPSE Trial Management Group	FULL	References		Some of the trials cited are in fact different publications from the same trial eg Istre 2001 (ref 268) and Raumaro 2004 (270) are the same trial.	The GDG is aware that many of the papers referenced are from the same trial, and took this into account when making conclusions. The

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				The authors should have grouped them in the same way as the Cochrane authors do eg Marjoribanks 2006 (340) to avoid misrepresenting the quantity of evidence.	reason they are included is that different information (outcomes and follow-ups) are reported in each paper.
ECLIPSE Trial Management Group		Refs		Irvine GA, Campbell-Brown MB, Lumsden MA et al. Randomised comparative trial of the levonorgestrel intrauterine system and norethisterone for treatment of idiopathic menorrhagia. British Journal of Obstetrics and Gynaecology 1998; 105:(6)592-8. Cameron IT, Leask R, Kelly RW et al. The effects of danazol, mefenamic acid, norethisterone and a progesterone-impregnated coil on endometrial prostaglandin concentrations in women with menorrhagia. Prostaglandins 1987; 34:(1)99-110. Reid PC and Virtanen-Kari S. Randomised comparative trial of the levonorgestrel intrauterine system and mefenamic acid for the treatment of idiopathic menorrhagia: a multiple analysis using total menstrual fluid loss, menstrual blood loss and pictorial blood loss assessment charts. BJOG: an International Journal of Obstetrics and Gynaecology 2005; 112:(8)1121-5. Lahteenmaki P, Haukkamaa M, Puolakka J et al. Open randomized study of use of levonorgestrel releasing intrauterine system as alternative to hysterectomy. British Medical Journal 1998; 316:(7138)1122-6. Lethaby AE, Cooke I, and Rees M. Progesterone/progestogen releasing intrauterine systems for heavy menstrual bleeding. (Cochrane Review). In: Cochrane Database of Systematic Reviews, Issue 4, 2005. Oxford: Update Software. Iyer V, Farquhar C, and Jepson R. Oral contraceptive pills for heavy menstrual bleeding. (Cochrane Review). In: Cochrane Database of Systematic Reviews, Issue 2, 2000. Oxford: Update Software. Coulter A, Kelland J, Peto V et al. Treating menorrhagia in primary care: An overview of drug trials and a survey of prescribing practice. International Journal of Technology Assessment in Health Care 1995; 11:(3)456-71. Lethaby A, Farquhar C,	Thank you for these references. These have been reviewed.

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				and Cooke I. Antifibrinolytics for heavy menstrual bleeding. (Cochrane Review). In: Cochrane Database of Systematic Reviews, Issue 4, 2004. Oxford: Update Software. Wellington K and Wagstaff AJ. Tranexamic acid: a review of its use in the management of menorrhagia. Drugs 2003; 63:(13)1417-33.	
ECLIPSE Trial Management Group (2)		general		How can NICE make a general recommendation that the Mirena coil should be first line medical treatment when there have been no comparative trial of Mirena v medical treatment? This recommendation is particularly odd when the NHS HTA programme is funding an RCT, the ECLIPSE trial comparing the two therapies in primary care. I would strongly request that this recommendation be altered to one saying there is no clear evidence one way or the other. If this is not done I would anticipate that the ECLIPSE trial will experience impossible recruitment problems and the question will never be answered.	Thank you. The GDG has revised the recommendation on pharmaceutical treatments to sound less prescriptive. The GDG also now mention the ECLIPSE trial in the guideline.
Endometriosis SHE Trust (UK)				This organisation was approached but did not respond.	
Faculty of Family Planning and Reproductive Health Care				This organisation was approached but did not respond.	
FEmISA	NICE version	General		The NICE version does not reflect the decisions made in the full version. The NICE version appears to present the status quo – i.e. hysterectomy first line treatment, whereas the Full version recommends drugs and then for larger fibroids surgery or UAE	Thank you. We have revised the NICE version to better reflect the content of the full version.
FEmISA	General	Diagnostic Protocols		The diagnostic protocols recommended do not comply with the Government guidelines for the '18 week patient journey' and 3-week diagnostic journey which are Government targets for 2008. If a patient has fibroids and wants UAE she will have to have both ultrasound and MRI scan within 3 weeks, which might be difficult. An algorithm needs to be developed to ensure women are not excluded from UAE because of these	Government policy issues, such as targets, are outside the scope of the guideline. The guideline is based on best available evidence. This will be passed to the Implementation team at NICE for their consideration when drafting the tools.

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				Government targets.	
FEmISA	Full version	General page 56		There is more weight given to systematic reviews and meta-analyses than randomised controlled trials. RTCs and case series, particularly with newer procedures such as UAE give more detailed and useful information and should be regarded as a superior level of evidence to systematic reviews	Thank you. The methodology used in NICE guidelines is that where an existing well-conducted systematic review of RCTs has been undertaken then this data will be used. However, this does not exclude the GDG looking at the individual RCTs that were included in this systematic review (and in many cases this is what happened). In addition, RCTs that are not included in an existing systematic review are also examined.
FEmISA	Full version	General		It would appear that no evidence has been considered on the morbidity and mortality associated with each treatment. This is a very grave oversight. It is very important from the patient's perspective that the risks of each treatment are known and weighed up. Only the hospital readmission rates seem to have been considered. Please see FEmISA comparison chart attached	Thank you. All the studies reviewed were examined for information on morbidity and mortality.
FEmISA	Full version	General		It is important that the length of recovery time and how long it takes for the patient to get back to work and back to normal life are considered.	Thank you. Both these variables were considered in the reviews.
FEmISA	Full version	P301		Age has an effect on side effects e.g. hysterectomy in mid 40's is very likely to bring on early menopause	Thank you. Evidence on the effect of age was considered by the GDG in relation to all treatments.
FEmISA	Full version	P309		The economic analysis does not include the costs to patients in both terms of morbidity and mortality, days off work [particularly for the self-employed] and economic and social costs i.e. extra help to look after children/elderly parents while women patients recover from treatment	Thank you. The economic analysis was undertaken according to the NICE technical manual which states that the analysis should be undertaken from the perspective of the health care provider/system.
FEmISA	Full version	P314 and 315		The costs used for ultrasound and surgery do not appear to be the official NHS procedure costs. Why not?	Thank you. The model used detailed costing as this was more likely to reflect the true cost to the provider than tariffs.
FEmISA	Full version	P314 and 315		There is also no economic comparison for UAE in this section, although costs are quoted elsewhere.	The data on UAE was judged to be insufficient to include in the model at the time of development
FEmISA	Full version	P324		Why haven't the costs of MRI been included in the economic analysis? The model also doesn't seem to include 're-dos' where the modality	MRI was not considered to be an appropriate first-line investigation for the exclusion of structural abnormalities of the uterus and was therefore not

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				chosen hasn't successfully diagnosed the condition.	considered as part of this model; as indicated in the guideline MRI may be part management for HMB where fibroids are present.
FEmISA	Full version	P63		Patients should be fully informed of all possible treatments and all the risks and side effects [morbidity, mortality, time to return to work, time to being completely well]	We agree with this statement and have tried to capture this in the recommendations
FEmISA	Full version	P65		Large fibroids should not be treated by hysterectomy as a first line – there should be a choice of hysterectomy, UAE and myomectomy	Thank you. This recommendation was meant to highlight the circumstances under which hysterectomy can be considered, and does not exclude other treatment options. The GDG have reworded the recommendations to highlight all the available treatments.
FEmISA	Full version	P77	1.3	Removal of ovaries – This recommendation is completely unacceptable – ovaries that are not diseased should not be removed, unless the patient specifically requests this. No evidence seems to have been presented on why removal of healthy ovaries should even be considered, nor the adverse effects on long term health of doing this. Missing paper Removing organs "just in case"--is prophylactic removal of the ovaries a good thing? J Epidemiol Community Health. 2006 Mar;60(3):186-7. Clarke A, Chang YM, McPherson K	Thank you. The GDG agree with this statement, and made the recommendations to reflect this. The wording of the recommendation has been changed to be more explicit on this point. A second recommendation will be added stating that consent should be obtained before ovaries are removed.
FEmISA	General	Diagnostic protocols		Question – Do the suggested protocols ensure that endometrial cancer is ruled out at an early stage or is it possible for a woman to be treated with drug therapy for many years when in fact she has endometrial cancer warranting very early treatment.	This issue was discussed and a recommendation on endometrial biopsy made. The wording of this has been amended to make it explicit this is for excluding endometrial cancer. In addition, NICE have already produced guidance on referral for suspected cancer.
FEmISA	Full version	P106		Impact of treatments on life – this is very important and has not been given full enough consideration	Thank you for this comment. The GDG used impact on quality of life as one of the primary outcome measures (page 62).
FEmISA	Full version	P229	UAE	Systematic Review – this Cochrane review only looks at follow up after UAE and hysterectomy for up to 6 months after the procedure. C.f. quality of life Ref 425 – Fibroid registry study showed an good improvement on the quality of life after 12 months with UAE	Thank you for this comment. All this data was taken into account when making recommendations.

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FEmISA	Full version	P229	UAE	Pain & return to work are not mentioned but are very important to patients Ref 419 shows that pain is less with UAE. Return to work UAE 28.1 days versus 63.4 days for hysterectomy. In fact this figure for UAE is much higher than other studies for UAE	Thank you. Both these variables were explicitly considered by the GDG. This information is contained in the evidence tables
FEmISA	Full version	P229	UAE	An important paper on long term follow up for patients undergoing UAE is missing – Walker WJ, Barton-Smith P BJOG 2006 apr; 113(4):464-8 postal questionnaire from 172 patients 5-7 years post UAE – important findings premature menopause in only 1 of 172 patients – compare this with hysterectomy	This paper is included in the review (ref 604)
FEmISA	Full version	Hysterec tomy General		The considerable morbidity and mortality associated with hysterectomy does not seems to have been considered and many important papers on this are missing – Maresh MJA et al - The VALUE national hysterectomy study: description of the patients and their surgery - British J Obstet & Gynae March 2002 Vol. 109 302-312. J Obstet Gynaecol. 2005 Jul;25(5):469-75. Self-reported bladder function five years post-hysterectomy. McPherson K, Herbert A, Judge A, Clarke A, Bridgman S, Maresh M, Overton C. Health Expect. 2005 Sep;8(3):234-43. Psychosexual health 5 years after hysterectomy: population-based comparison with endometrial ablation for dysfunctional uterine bleeding. McPherson K, Herbert A, Judge A, Clarke A, Bridgman S, Maresh M, Overton C. Qual Saf Health Care. 2005 Feb;14(1):41-7. Readmission to hospital 5 years after hysterectomy or endometrial resection in a national cohort study. Clarke A, Judge A, Herbert A, McPherson K, Bridgman S, Maresh M, Overton C, Altman D.	All these studies were assess and are included in the review (refs 369, 385, 386).
FEmISA	General			It is very important that women have a choice in their treatment and FEmISA fully endorses the findings on this.	Thank you for this comment
FEmISA	General			It is very important that full details of the treatments their benefits and risks, including short and long term morbidity and mortality are told	The GDG agree that information provision to women is central, and that is why it has such a prominent position in the guideline.

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				objectively to patients. FEMISA and the Fibroid Network have been conducting a study on what women have been told about the different treatments for fibroids and these have been grossly distorted in favour of hysterectomy. Extract from interim findings attached separately.	
Fibroid Network Charity				This organisation was approached but did not respond.	
Gloucestershire Hospitals NHS Trust	DRAFT	6	Line 1	Fibroids are very uncommon in girls/women age 10-30 including those suffering HMB. This document is appropriate to women over 30 but does not really address HMB in the younger age group.	The GDG agrees that fibroids are uncommon in women under 30, even those with HMB. However, the guideline covers both fibroid induced and non-fibroid HMB. This has included an assessment of vWD, which is seen as a leading cause of HMB in young women.
Gloucestershire Hospitals NHS Trust	DRAFT	21	1.10.1.2	There is no good evidence that hysterectomy with conservation of ovaries increases the risk of premature ovarian failure. This is a theory lacking substantiation.	This recommendation was based on the clinical experience of the GDG.
Gloucestershire Hospitals NHS Trust	DRAFT	21	1.10.1.5	It would be totally impractical to refer every woman with a family history of ovarian cancer for genetic counselling. A family history should be taken and those with two first degree relatives of ovarian or ovary/breast cancer should have consideration of such referral.	Thank you. The GDG have reworded this recommendation in light of this comment to highlight the groups in which such counselling should be undertaken.
Good Hope Hospitals NHS Trust				This organisation was approached but did not respond.	
Gorlin Syndrome Group				This organisation was approached but did not respond.	
Greater Peterborough Primary Care Partnership-North PCT				This organisation was approached but did not respond.	
Guerbet Laboratories Ltd				This organisation was approached but did not respond.	
Haemophilia Society, The	NICE	13	1.2.3.5	Could the term coagulation disorder be followed by 'e.g. von Willebrand's disease', recent research has suggested that many health care professionals confuse a bleeding disorder with conditions such as thrombosis and an example may help to allay this confusion.	Thank you. This change has been made.
Haemophilia Society, The	NICE			Considering that between 5 – 24% of women	Thank you for this information. The GDG do not

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				presenting with menorrhagia have von Willebrand's disease can this be stated more strongly, perhaps; 'Testing for coagulation disorders such as von Willebrand's disease should be routinely undertaken on women with heavy menstrual bleeding since menarche where no other pelvic abnormalities can be found.' Or 'Details of all previous bleeding episodes including PPH, nose bleeds, easy bruising and prolonged bleeding from small cuts and scratches and after surgery should be noted to determine if investigations into a bleeding disorder such as von Willebrand's disease are necessary'.	feel that the wording of the recommendation should be changed. The issues with the evidence are that some is based on secondary care groups, and some are based on women with vWD who report menorrhagia.
Haemophilia Society, The	Full version	130	38998	Could this be stated more strongly as previous point above.	Thank you. The GDG has reworded this recommendation for clarity
Haemophilia Society, The	Full version	276	5	Could we add in that investigations for other causes of HMB such as a bleeding disorder have been investigated.	Thank you. The GDG feel that their previous recommendation on bleeding disorders should be sufficient.
Haemophilia Society, The	General	General		Could there be reference to the new UK Haemophilia Centre Doctor's Organisation guidelines on the obstetric and gynaecological management of women with inherited bleeding disorders, which contains details on the tests and treatments for von Willebrand's disease and other inherited bleeding disorders.	Thank you. Unfortunately, the guideline can only refer to other NICE guidance.
Healthcare Commission				This organisation was approached but did not respond.	
Heart of England NHS Foundation Trust	FULL	63	4	First line should still be tranexamic acid or COCs.	Thank you. The GDG has considered all the available evidence and made a different conclusion. However, the GDG has added a new recommendation stating that NSAIDs and TX acid can be used while waiting for first-line treatments.
Heart of England NHS Foundation Trust	FULL	63	11	Age 40 and over (refer to table 2.1 page 101).	Thank you. The "age 45 and over" is not a limit, but an example of indication. If a woman has other symptoms and is aged less than 45 then a biopsy can be undertaken. However, it was after 45 years that the GDG felt that it should be routine when a woman presents with HMB.

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					The epidemiological data shows that the incidence of cancer doubles every five years between the age of 20 and 60. The GDG it was the step after 45 that the risk became significant. In fact, the analysis showed that the likelihood of a woman with HMB having endometrial cancer before 45 were less than 1 in 10000
Heart of England NHS Foundation Trust	FULL	63	14	Not a workable option, we suggest a referral proforma from primary to secondary care. Can supply suitable proforma if requested.	Thank you for this comment.
Heart of England NHS Foundation Trust	FULL	64	4	Uterine size up to 14 weeks can be ablated depending on pt choice.	Thank you for this information. The GDG recommend that established safety limited for each technique is followed.
Heart of England NHS Foundation Trust	FULL	68	6	Age 40 and over.	Thank you. The GDG feel that 45 years is the most appropriate age. This is based on the epidemiological data that shows a rapid increase in cancer occurs around this age.
Heart of England NHS Foundation Trust		70	5	Again first line should not be LNG-IUS.	Thank you. Based on the assessment of the evidence (effectiveness and cost-effectiveness), the GDG feel that LNG-IUS should be the first pharmaceutical treatment to be considered.
Heart of England NHS Foundation Trust	FULL	70	6	Tranexamic acid/NSAIDs can be used in combination as they have a synergistic action when used together.	Thank you. As no evidence was available on the use of these in combination the GDG felt it could not make a recommendation on this.
Heart of England NHS Foundation Trust	FULL	71	2	Check if therapeutic dose offered and compliance attained for at least 3 cycles (not months).	Thank you. This change has been made.
Heart of England NHS Foundation Trust	FULL	71	8	They can also be used effectively in combination.	Thank you. Due to the lack of evidence on this area it was decided not to make a recommendation.
Heart of England NHS Foundation Trust	FULL	73	5	Ethamsylate (spelling).	According to BNF correct spelling is Etamsylate
Heart of England NHS Foundation Trust	FULL	73	16	MEA can be used in larger uteri.	Thank you for this. The guideline refers the reader to the limits specified by the manufacturer.
Heart of England NHS Foundation Trust	FULL	73	14	Outpatient hysteroscopy before planned ablation is acceptable as cavity assessment is unlikely to change.	Thank you for this comment. The GDG has debated this issue, and made what it feels is the appropriate recommendation about the need for hysteroscopy prior to ablation.
Heart of England NHS Foundation Trust	FULL	74	4	Again 10 weeks size negotiable up to 14 weeks with MEA personal data (SI).	Thank you for this comment. The GDG highlight that the clinician should refer to the specific

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					manufacturers' own criteria for use of any ablation technique. The GDG recognise that this may vary, but 10 weeks was chosen as a safe limit.
Heart of England NHS Foundation Trust	FULL	75	1	GnRh-a contraindicated in potential cases of UAE.	Thank you for this comment. The GDG has made a recommendation highlighting that use of GnRHa should be stopped if UAE is scheduled.
Heart of England NHS Foundation Trust	FULL	75	4	UAE should be first line (non surgical) not myomectomy.	Thank you. Based on the available evidence, the GDG did not feel that it could make a distinction between myomectomy and UAE. In addition, the GDG feel that they have made clear recommendations on both these interventions.
Heart of England NHS Foundation Trust	FULL	77	13	Poorly worded risk should relate to retaining ovaries.	This recommendation has been reworded for clarity.
Heart of England NHS Foundation Trust	FULL	77	23	What is meant by 'ovarian dysfunction' in this context.	This refers to problems such as pre-menstrual syndrome, and this has now been stated in the recommendation.
Hexham General Hospital				This organisation was approached but did not respond.	
Hospital Infection Society				Thank you for inviting HIS to comment on the guidelines. However, the Society has not comment to make at this time. Introduction to our comments We are providing feedback on the following sections of the draft guidance: Non Hysterectomy Surgery for HMB – NICE; Hysterectomy - NICE	Thank you
Johnson & Johnson Medical & Ethicon	NICE	18	1.7.2.3	Although we consider the guidance to be a positive step we believe this statement inappropriately infers that all Thermal Balloon Endometrial Ablation (TBEA) techniques offer equivalent efficacy and cost effectiveness. TBEA procedures vary greatly in technique, operative time and technology and therefore evidence relating to one procedure cannot be deemed as transferable. We would like to draw your attention to the previous Guidance relating to Endometrial Ablation techniques, NICE Guidance 76, where it was recognised that evidence is not transferable from one TBEA technique to another. It concluded	Thank you for this comment. The GDG will consider this information. However, NICE guidelines usually only specify generic methods rather than specific manufacturers.

Organisation	Doc	Page no	Line no	Comments	Response
				only the THERMACHOICE TBEA and Caverterm TBEA procedures had appropriate levels of clinical evidence supporting them. We believe this still to be the case as all data referenced within the supporting evidence table specifically quotes the THERMACHOICE or Caverterm procedures as the technique assessed. The class effect cannot be applied across technologies and techniques. On this basis we would suggest 1.7.2.3 takes the form of: "Second generation ablation procedures (microwave ablation [MEA] and thermal balloon ablation [TBEA]) should be considered ahead of first generation techniques. The selection of an appropriate MEA or TBEA technique should consider where RCT data is available to show efficacy and cost effectiveness rates with long term follow up"	
Johnson & Johnson Medical & Ethicon	NICE	18	1.7.2.8	We consider this to be a positive statement, however we would like to draw your attention to the following peer reviewed publications, which support the use of TBEA not only with Local Anaesthetic but also in an outpatient environment. This evidence concludes that patient outcomes and cost effectiveness are equivalent to those achieved in a in-patient environment and as such we suggest 1.7.2.8 takes the form of: "Ablative techniques should be undertaken under local anaesthetic, in an out-patient environment where appropriate". • Thermachoice endometrial ablation in the outpatient setting, without local anaesthetic or intravenous sedation. (Duffy, Marsh et al 2006) Fertil Steril 2005; 83:715-20. • Randomised Controlled Trial Comparing Thermachoice III Endometrial Balloon Ablation In The Outpatient Versus Daycase Setting. (Duffy, Marsh et al 2006) NB. Submitted and accepted to "Fertility & Sterility" for publication in November edition.	Thank you. Specifying the location of procedures is outside the remit of this guideline (except in special circumstances where the meaning of a recommendation can be misinterpreted if location is not specified).
Johnson & Johnson Medical & Ethicon	NICE	17	1.6.1.2	We concur with this assessment.	
Johnson & Johnson Medical & Ethicon	NICE	18	1.7.2.4	We concur with this assessment.	

Organisation	Doc	Page no	Line no	Comments	Response
Johnson & Johnson Medical & Ethicon	NICE	19	1.9.1.2	We would like to bring to your attention a selection of peer reviewed clinical publications which we believe support the use of Laparoscopic Hysterectomy. Where clinical skill sets allow, we believe that this evidence supports the use of a Laparoscopic approach as an effective technique. We believe the evidence being submitted suggests that efficacy rates of a laparoscopic approach show equivalence to that of the abdominal approach and that the socio economic benefits justify support as a first line treatment option. We would suggest that 1.9.1.2 therefore takes the form of: "The route of Hysterectomy should be considered in the following order, first vaginal and second abdominal. The choice between open or laparoscopic hysterectomy should be taken following consultation between the patient and physician" Laparoscopic Supercervical Hysterectomy for the large uterus. (Lyons et al – 2004) J Am Assoc, Gynecol Laparosc 2004 – 11(2):170-174. A comparison of Laparoscopic Supercervical Hysterectomy and Total Abdominal Hysterectomy Outcomes. (Sarmini et al – 2005) Journal of Minimally Invasive Gyne, 12, 121-124	Thank you. We will consider the submitted evidence. If it meets inclusion criteria then it will be summarised within the guideline.
L'Arche UK				This organisation was approached but did not respond.	
Leeds Teaching Hospitals NHS Trust				This organisation was approached but did not respond.	
Liverpool Women's Hospital NHS Trust				This organisation was approached but did not respond.	
Luton and Dunstable Hospital NHS Trust	NICE	8, 14	18, 1.3.1.1	Patients should be given an 'information pack' – no evidence or resource suggested. Referrals are also not always clear (Warner et al).	Thank you for this comment. This recommendation was based on RCT evidence, which is presented in the full version. The evidence behind recommendations is not presented in the NICE version. In addition, economic modelling is undertaken to establish the cost-effectiveness of a recommendation. However, generic resource issues in the NHS are not.

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Luton and Dunstable Hospital NHS Trust	NICE	10	5	First line Mirena – suggesting this should be used in all age groups; not appropriate in young women i.e. 17-23 yrs where COC more appropriate.	Thank you. No mention is made of age in this recommendation, and all the recommendations should be applied using clinical judgement.
Luton and Dunstable Hospital NHS Trust	NICE	12	1.2.3.2	In DUB Hb is normal but ferritin low. Seems illogical to check for a normal value.	This recommendation was based on the clinical experience of the GDG, and included considerable debate about the costs and benefits of using the test.
Luton and Dunstable Hospital NHS Trust	NICE	18	1.7.2.8	May be undertaken – not, should be undertaken.	Thank you. This recommendation has been removed.
Luton and Dunstable Hospital NHS Trust	NICE	24	4.2	PBAC is of no value, why persist in talking about it. Reid PC, Coker A, Coltart R. Assessment of menorrhagia using a pictorial chart: a validation study. BJOG 2000107:320-322.	Thank you for comment. The need for objective measurement of MBL is commonly asked about by patients and health professionals. The evidence suggests uncertainty about the value of objectively measuring MBL, and the recommendation has reflected this.
Luton and Dunstable Hospital NHS Trust	NICE/full	General		Does the guidance have to be full of three letter acronyms? Would suggest that this makes it hard for the non-specialist to follow.	Thank you for this comment. Acronyms are fully defined in the NICE and full guideline.
Luton and Dunstable Hospital NHS Trust	FULL	165		Cost data comparing different treatment appears flawed. Most GP practices now have practice nurses trained in family planning, if not all COC consultations. GPs receive a fee for IUS insertion via a National Enhanced Service scheme. It hasn't been added to the cost of the GPs time in the table. The practice nurse has only been allocated 10 mins to assist with IUS fitting, when it takes much longer to undertake.	Thank you for this comment. The time estimates were as suggested by GDG based on their clinical experience.
Maidstone and Tunbridge Wells NHS Trust				This organisation was approached but did not respond.	
Maternity Health Links				This organisation was approached but did not respond.	
Medicines and Healthcare Products Regulatory Agency (MHRA)				This organisation was approached but did not respond.	
Mental Health Foundation				This organisation was approached but did not respond.	
Microsulis Medical Limited	Full Version	212	16	MEA has updated superior figures than that currently quoted in this document - 5 – 7 year clinical data which supports 65% amenorrhea rate	Thank you. The figures in the guideline are based on those studies that met the inclusion criteria.

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				– Most recent publication supporting this evidence is BJOG April 2005 Volume 112 pg 470-475.	
Microsulis Medical Limited	Full Version	215	38991	There is an additional study, JAAGL, August 2004 in which MEA clearly shows stronger results than TCRE.	Thank you. This evidence will be assessed.
Microsulis Medical Limited	Full Version	215	8	Is vomiting not a characteristic of General Anaesthetic rather than ablation treatment?	Thank you.
Microsulis Medical Limited	Full Version	217	19	Please clarify “TBEA dominates all other ablation techniques”.	The word 'dominates' is a term used when an intervention is less costly but is equal or more effective than the alternative to which it is being compared.
Microsulis Medical Limited	Full Version	218	22	Please clarify costing from the Garside study - Currently list price for both MEA and TBEA are comparable. As MEA also involves shorter theatre time Microsulis would have expected lower or equal treatment costing for MEA.	The source of costs for the second generation ablation methods included submissions from the device manufacturers as well as estimates of the required procedure time by the investigators
Microsulis Medical Limited	Full Version	222	38966	MEA has significantly higher satisfaction and amenorrhea figures quoted in many clinical studies than TBEA. Most recent publication supporting this evidence: BJOG April 2005 Volume 112 pg 470-475.	Thank you for this information. This study was included in the review and data on satisfaction is included in the evidence tables.
Microsulis Medical Limited	Full Version	222	15	Microsulis Medical Instructions for Use state that MEA can treat cavities with large fibroids providing access can be gained in to the cavity. This is what currently differentiates MEA to other products on the market.	Thank you for this information. The guideline refers the reader to individual manufacturers' criteria for safe use.
Microsulis Medical Limited	Full Version	222	18	Please clarify costing from the Garside study - Currently list price for both MEA and TBEA are comparable. As MEA also involves shorter theatre time Microsulis would have expected lower or equal treatment costing for MEA.	Please refer to the Health Technology Appraisal report where this information is outlined in detail.
Microsulis Medical Limited	Full Version	222	18 - 24	Please footnote references – is this Garside again?	Thank you. Evidence statements are summaries of the review and are not referenced. The evidence included in this statement is outlined in the previous section.
Microsulis Medical Limited	Full Version	223	43435	Thank you recognising this important study. As MEA has been highlighted should MEA not be recommend above other ablation devices?	Thank you. Based on assessment of all available evidence, the GDG did not feel they could make a recommending differentiating between different types of ablation.

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Microsulis Medical Limited	Full Version	224	7	MEA does not require pre thinning along with other TBEA's. Microsulis recommends pre thinning but it is not mandatory - all clinical data has been carried out using pre treatment however there are currently many sites in the UK choosing not to use pre treatment who are achieving excellent results.	Thank you. This GDG will consider this information.
Microsulis Medical Limited	Full Version	224	10	MEA device has been developed to treat cavities up to 14cm. Microsulis instructions for use state this. This is what differentiates MEA and other techniques currently on the market to allow larger patient audience. JAAGL publication supports this statement Aug 2004 Vol 11.3 pg. 395.	Thank you for this information. Readers of the guideline are referred to manufacturers' own instructions on use of their equipment.
Microsulis Medical Limited	General Comment			Microsulis is continuously educating the surgeon and users of the MEA system on our technology and ablation device. What are NICE currently recommending to companies on education of the primary health care sector and most importantly the patient?	The recommendations made in NICE guidelines are for health professionals within the NHS. The recommendations on patient education are that they receive a patient-specific version of this guidance. The recommendations on competencies were made to ensure that a recognised standard was obtained by anyone wishing to undertake a procedure. There is no requirement in any of these recommendations for a commercial company to be involved.
Microsulis Medical Limited	General Comment			NICE states that in the first instance whenever possible ablation should be carried out under local anaesthetic. Microsulis would welcome guidelines from NICE as to the clinical pathway for local v general anaesthetic.	Thank you. This recommendation has been removed as it was outside the remit of the guideline.
Microsulis Medical Limited	General Comment			It is hard to distinguish between different studies due to order of reporting. Is it possible to make all the studies have the same order in terms of reporting data, i.e. outcome, time, anaesthesia etc. This will make the studies more comparable.	Thank you. Structured information is shown in the evidence tables. This was contained within a separate document.
Mid Staffordshire General Hospitals NHS Trust				This organisation was approached but did not respond.	
National Council for Disabled People, Black, Minority and Ethnic Community (Equalities)				This organisation was approached but did not respond.	
National Endometriosis				This organisation was approached but did not	

Organisation	Doc	Page no	Line no	Comments	Response
Society				respond.	
National Osteoporosis Society	NICE Version	21	5 (Section 1.10.1.3)	The National Osteoporosis Society urges the Guideline Development Group to add osteoporosis to the list of long term risks of bilateral oophorectomy. It is important that the fracture risk of these women, particularly those who are under 45 years of age, is assessed and that treatment is provided if necessary.	Thank you. This term has not been added as the GDG felt it was impractical to provide a full list of risks associated with oophorectomy, though the GDG do recognise that osteoporosis is one of them.
National Osteoporosis Society	Full Version	51	20	The Technology Appraisal on primary prevention of osteoporosis in post-menopausal women is still under development – the expected publication date is TBC and not September 2005.	Thank you. This has now been amended
National Osteoporosis Society	Full Version	51	22	The Technology Appraisal on secondary prevention of osteoporotic fractures in postmenopausal women was issued in January 2005 (TA87), but is currently being reviewed	Thank you. This has now been amended
National Osteoporosis Society	Full Version	51	24	The Technology Appraisal on strontium ranelate for the prevention of osteoporotic fractures in post-menopausal women with osteoporosis has now been combined with the review of TA87 and will not be developed separately	Thank you. This has now been amended
National Osteoporosis Society	Full Version	285	6	The National Osteoporosis Society urges the Guideline Development Group to add osteoporosis to the list of long term risks of bilateral oophorectomy. It is important that the fracture risk of these women, particularly those who are under 45 years of age, is assessed and that treatment is provided if necessary.	The GDG has decided to remove this list from the guideline. A number of comments have highlighted various risks of oophorectomy, and the GDG feel there are too many to list all of them.
National Patient Safety Agency				This organisation was approached but did not respond.	
National Public Health Service - Wales				This organisation was approached but did not respond.	
Newcastle PCT				This organisation was approached but did not respond.	
NHS Direct				This organisation was approached but did not respond.	
NHS Health and Social Care Information Centre				This organisation was approached but did not respond.	
NHS Quality				This organisation was approached but did not	

Organisation	Doc	Page no	Line no	Comments	Response
Improvement Scotland				respond.	
North Tees and Hartlepool NHS Trust				This organisation was approached but did not respond.	
Northwest London Hospitals NHS Trust				This organisation was approached but did not respond.	
Nuffield Dept of Obstetrics and Gynaecology				This organisation was approached but did not respond.	
Pelvic Pain Support Network	NICE	21	1.11.2.2	This should be monitored and enforced.	Thank you for this comment. This should be an auditable standard, and audit standards based on the recommendation sare outlined by CASPE
Pelvic Pain Support Network	NICE	22	1.11.3.1	This should be monitored by feedback from patients.	Thank you for this comment.
Pelvic Pain Support Network	FULL	11	3	Add name of stakeholder- Pelvic Pain Support Network.	Thank you. The stakeholder list has been up-dated
Pelvic Pain Support Network	FULL	106	6,7,8	This is a general problem in gynecology particularly where chronic pelvic is also a factor.	Thank you for this comment
Pelvic Pain Support Network	FULL	125	3,4	From a clinical point of view examination during a period helps to detect some abnormalities that would require further investigation, eg rectovaginal nodular disease.	Thank you for this comment.
Pelvic Pain Support Network	FULL	159	41699	All health professionals should be made aware of this and practice should be monitored externally.	Thank you. We agree and hope that this will be widely distributed.
Pelvic Pain Support Network	FULL	271-274		There is no mention of nerve damage/increase in severe chronic pain in these tables. This is known to be a serious complication and should be reported as such. It has a more major effect on the QOL of patients than many of the complications listed in these tables. eg. Pfannenstiel incision and ilio-inguinal nerve damage. Pudendal nerve damage etc .	Thank you. These tables are based on the best available evidence, but unfortunately cannot cover all studies or adverse events.
Pelvic Pain Support Network	FULL	292	25-26	This should be discussed openly with the patient. Information about competence should be offered by the clinician and patients should be encouraged to ask about clinician competence.	Thank you. This was discussed by the GDG and is stated in the full guideline. However, it was not felt necessary to make a recommendation on this issue.
Pelvic Pain Support Network	FULL	291	12	These clinicians SHOULD be within specialist centres.	Thank you. We are revising these recommendations as it has been highlighted that specifying location of treatment is outside the scope of NICE guidelines.

Organisation	Doc	Page no	Line no	Comments	Response
Pelvic Pain Support Network	FULL	343	5	delete "probably".	Thank you. We will consider this revision.
Pelvic Pain Support Network	FULL	343	44136	Monitoring should be undertaken by external rather than internal assessors.	
Pelvic Pain Support Network	NICE	6&7		Details of the surgical practice of individual gynecologists should be in the public domain.	Thank you. The GDG have discussed the issue of making figures publicly available, and this is stated in the full version. However, it was not felt that a recommendation on this was needed, given that a number of robust recommendations on competency have been made.
Pelvic Pain Support Network	NICE	7		Decisions are made for patients on the grounds of what is available in the area where the patient lives –this is frequently down to availability of resources and expertise and NOT what is in the best interest of the patient. second opinions are rarely offered or suggested to patients.	Thank you for this comment. The guideline will be launched with implementation support from NICE. This should hopefully improve the speed with which recommendations are adopted.
PERIGON (formerly The NHS Modernisation Agency)				This organisation was approached but did not respond.	
Pfizer Limited				Thank you for the opportunity to comment on these guidelines. We have no substantial remarks to contribute on this occasion.	
Princess Alexandra Hospital NHS Trust				This organisation was approached but did not respond.	
Queen Mary's Hospital NHS Trust (Sidcup)				This organisation was approached but did not respond.	
Regional Public Health Group - London				This organisation was approached but did not respond.	
Rotherham Primary Care Trust				This organisation was approached but did not respond.	
Royal College of General Practitioners	Algorithm	1		Algorithm is generally clear and helpful but the fact that arrows are only included at the distal end of lines causes some confusion, especially around the physical examination section at top of page 1.	Thank you. Based on a number of comments, the algorithm is being completely reviewed. The aim will be to provide a simplified version which is more accessible for the user.
Royal College of General Practitioners	NICE version	general		This is a helpful summary. However, much of the information is repeated several times – to make it more used friendly it would be helpful to reduce the length by reducing duplication.	Thank you. The GDG and editors will remove duplication from the recommendations.

Organisation	Doc	Page no	Line no	Comments	Response
Royal College of General Practitioners	NICE version	general		Definition of HMB does not mention whether regular or not. Management of irregular menstrual bleeding indicating an ovulation different from regular HMB. This needs to be defined better.	The reason that regular is not mentioned is that after assessing the epidemiological evidence the GDG felt that the natural variability in menstruation makes it difficult to include this term.
Royal College of General Practitioners	NICE version	general		Concern of GPs often over likelihood of underlying cancer. This is discussed at length in long document but not mentioned in short. Would be helpful to indicate the unlikelihood of underlying endometrial cancer if bleeding regular to reduce unnecessary investigations. No mention of lifestyle causes e.g. smoking and particularly being overweight.	Thank you. The recommendation on endometrial biopsy has been amended to make it explicit that this is for endometrial cancer.
Royal College of General Practitioners	NICE version	general		Regarding epidemiology of HMB in community xxx wrote an article for Women's Health Medicine Journal June 2005 Called Menorrhagia; Who and When to Refer. In this she used 2 epidemiology articles published in the RCGP journal around 2004. NICE might wish to have copies of these. Please Contact RCGP if you need her to forward on references.	These articles were authored by a member of the GDG and were included in the review.
Royal College of General Practitioners	NICE version	general		Regarding the Algorithms - these are too muddled and not either patient or GP friendly. The Algorithm produced by the RCOG on menorrhagia much better.	Thank you. Based on a number of comments, the algorithm is being completely reviewed. The aim will be to provide a simplified version which is more accessible for the user.
Royal College of General Practitioners	Full version	44	4	The object to the statement ' it is thought by some doctors to be unimportant; firstly is it evidence based, second if not it's a subjective personally held belief which devalues a guideline document.	Thank you. This statement was meant to highlight the current situation in order to highlight the need for a guideline. However, the statement has been removed.
Royal College of General Practitioners	Full version	47	6	Is resolution meant, or would improvement or some other word be more appropriate.	Thank you. As the primary outcome measure is quality of life the term resolution seemed most appropriate.
Royal College of General Practitioners	Full version	77	22	Having rather than have???	Thank you. This has been amended.
Royal College of General Practitioners	Full version	96	4,5,6	The statement 'studies on women....' Is unhelpful as it is; Are the GDG trying to say that symptoms of serious pathology are similar in nature and incidence to that of the normal population?	Thank you. The text has been revised to improve the clarity of the statement.
Royal College of General Practitioners	Full version	97	Lines 1-9	This study looks at AUB not HMB; the GDG has already made a statement that there is no link between polyps and HMB, does this contradict	The term AUB is used in much of the research literature on investigations as it is not assumed that a woman has HMB or pathology until after an

Organisation	Doc	Page no	Line no	Comments	Response
				that?	investigation. For accuracy, the review reports the patient population as defined in the research studies.
Royal College of General Practitioners	Full version	97	42675	See above.	Thank you.
Royal College of General Practitioners	Full version	97	18-23	This study is of referrals for hysteroscopy, not prevalence rates or causes for HMB.	Thank you. This section of the guideline summaries the evidence on prevalence of pathology in women with HMB, not prevalence rates or causes. Much of this comes from diagnostic studies, as well as epidemiology studies. This specific study examined women referred for hysteroscopy for investigation of menorrhagia, and reported the pathology found in this group.
Royal College of General Practitioners	Full version	98	21-25	Same argument as above.	Thank you. This section of the guideline summaries the evidence on prevalence of pathology in women with HMB, not prevalence rates or causes. Much of this comes from diagnostic studies, as well as epidemiology studies.
Royal College of General Practitioners	Full version	124	17-18	Do the GDG mean pallor?	Thank you. This has been amended.
Royal College of General Practitioners	Full version	124	17-18	A personal thought of xxx is that; bedside assessment has a poor correlation with HB level, but could not quote evidence for this; perhaps a better sentence might run 'general examination, including assessment for pallor, may be helpful', or some such.	Thank you for this comment. This change has been made.
Royal College of General Practitioners	Full version	126	42705	Is there not a difference in the 2 groups in that more irregular bleeding in the hypothyroid group; no mention of HMB but the statement says no link between thyroid disorders and menstrual disturbance; does this need qualifying in terms of significance?	Thank you for this comment. This was the information provided in the research paper.
Royal College of General Practitioners	Full version	129	13-15	...but as ferritin is part of the assessment of anaemia which is prevalent in the HMB group.	The GDG has debated in-depth the issue of whether to measure ferritin or not. The group concluded this test would add little to management of HMB.

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Royal College of General Practitioners	Full version	162	42614	This contradicts the statement made earlier (page 126, line12-16).	Thank you. We have revised this statement.
Royal College of General Practitioners	Full version	182, 183, 184	General	There are several studies comparing add back, but these ,apart from the one study (page 183, lines 14-22) are looking at uterine fibroids; they also talk of symptomatic fibroids but this is not qualified; is symptomatic meaning hmd or pressure or what; this needs qualifying. The studies seem to be looking at modifying the side effects of GnRH-a and there seem a lot of them that measure? Non helpful things; does it matter if a fibroid has shrunk; what does that mean for the patient?	GnRH-a is included as it is a treatment for uterine fibroids, a main symptom of which is HMB. Where possible menstrual blood loss outcomes are reported, but in many studies this is bundled in global outcomes for all fibroid related symptoms (pressure, etc.)
Royal College of General Practitioners	Full version	185	14-17	Only one study (page 183, lines 14-22) allow anything to be said about HMB; lots said about fibroids though; is this a relevant POEM?	Thank you. It was not clear to the GDG was POEM related to.
Royal College of General Practitioners	Full version	187	13-15	So, are the studies in women with IUD; is that relevant for HMB? In those without what were the results or is that what is in the guideline?	This is relevant to HMB. As IUD induced HMB is easily treated by the removal of the IUD. This is mentioned as it is a potential bias in the conclusion of this systematic review reported.
Royal College of General Practitioners	Full version	191	7	IUD or IUS???	Thank you. The terms IUD and LNG-IUS relate to different interventions. We will clarify this in the text.
Royal College of General Practitioners	Full version	191	39022	Am I correct in my reading of this paragraph; that as the ci for nsaid v IUD (or is that IUS) and nsaid v. oc stretch pos to neg. then they may be equally effective.	Yes, you are correct in your reading of the figures. However, the CIs also show high uncertainty.
Royal College of General Practitioners	Full version	201	6	The study (found?) that.....	Thank you. The text has been amended.
Royal College of General Practitioners	Full version	208	41518	As the 2006 review said surgery was good, up to 5 yrs, is that hysterectomy or endometrial ablation; also why should it not be used in the face of that evidence; the GDG holds great value on a preserved uterus; what evidence for this faced with the satisfaction and lack of long term problems following hysterectomy which the group later present for hysterectomy; the argument seems contradictory as it stands.	Thank you. 1) The 2006 review included any study comparing a surgical option against a pharmaceutical option. In reality (see 9.1) this was usually LNG-IUS versus ablation in populations who were referred for surgery. 2) the guideline does not say that hysterectomy should not be used, only that it should not be used as a first-line treatment, unless in special circumstances.
Royal College of General Practitioners	Full version	211, 212, 213	general	Lots on all the different ablation techniques; seems they are all the same and yet on p 218	Thank you. As was stated in the health economics section, the model was sensitive to

Organisation	Doc	Page no	Line no	Comments	Response
				hysterectomy more cost effective	change based on a woman's utilities.
Royal College of General Practitioners	Full version	218	15-19	Very little made of the studies to look at the improved view for the surgeon which seems to have been a prime reason for the intervention; ok no difference in outcome satisfaction but what about operating time and complications (p220 says no major adverse effects; what is major?).	Thank you for this comment. This was not examined as a specific question. However, several surgeons were on the GDG and their clinical knowledge and experience is included in the recommendations.
Royal College of General Practitioners	Full version	224	general	If mentioning counselling then should it not also include that medical and ablation therapies carry high rates of further surgical intervention needed as shown by the studies.	Thank you. The term counselling has been changed to discussion. However, the GDG felt that likelihood of further treatment should be discussed with women. This is made clear in the 'implementation advice' section of the education chapter.
Royal College of General Practitioners	Full version	246	39057	Why were these women having an IUS if it were not for menorrhagia (assuming not contraception); I'm confused.	This relates to a specific study rather than any recommendation in the guideline. Women were entered into the study on the basis of having subjective HMB. The study then undertook a sub-group analysis comparing those with or without objective menorrhagia (>80ml).
Royal College of General Practitioners	Full version	246	14-16	Ah; a preference study; avoid hysterectomy, but conflicts with p 247 lines 4-7 with good patient satisfaction post hysterectomy.	Thank you. These are the results of two separate studies that the guideline is reporting.
Royal College of General Practitioners Wales				This organisation was approached but did not respond.	
Royal College of Nursing	Nice version	13	1.2.4.3	Hysteroscopy is of more diagnostic value and less painful for the patients if intermenstrual bleeding, treatment failure and before other treatments. Endometrial biopsy does not have the sensitivity to pick up on endometrial polyps	Thank you for this comment. The GDG have reworded these recommendations to clarify why they are being used. The term biopsy has been removed from the hysteroscopy recommendation. A separate recommendation on biopsy has been added, with indications for use. In addition, a note has been added referring people the NICE guideline on referral for suspected cancer.
Royal College of Nursing	Nice version	15	1.4.1.1	It would make more practical sense for women who visit a GP to be given the second line treatment while waiting for an IUS if required as there may be some delay with fitting.	Thank you. The recommendation has been added.
Royal College of Nursing	Nice version	15	1.4.1.2	There is no mention of using the 2 medications together- tranexamic and NSAID	Thank you. Due to a lack of evidence on this area it was decided not to make a recommendation.
Royal College of Nursing	Nice version	17	1.7.2.1	Why is this suggested? Some of the treatments are less effective if the cavity has had saline	Thank you. This recommendation has been revised to clarify the situations when it should be

Organisation	Doc	Page no	Line no	Comments	Response
				introduced.	undertaken. The statement was based on manufacturer criteria for use and procedures used in research studies.
Royal College of Nursing	Nice version	18	1.7.2.8	There needs to be an appropriate catch up with the HRG tariffs in order for this to happen.	Thank you for this comment. It has been highlighted elsewhere that this issue is outside the scope of guideline so the recommendation has to be removed.
Royal College of Nursing	Nice version	13	1.2.4.1	This assumes that there is access to scans and that the sonographers are trained and able to give an accurate assessment of the endometrium.	Thank you. This is correct. The guideline was developed to provide a summary of best practice assuming availability of investigations and treatments.
Royal College of Obstetricians & Gynaecologists	Both	General		Very useful document – most welcome.	Thank you
Royal College of Obstetricians & Gynaecologists	NICE	5	18	“Will be able to trust” implies distrust which, though it may be the case for some, sets the wrong tone for this document.	The introduction in the NICE version has been substantially rewritten to make it more concise. The wording suggesting here will be considered in this rewrite
Royal College of Obstetricians & Gynaecologists	NICE	9	23	Add “ and what clinical facilities are available locally” or if this doesn’t matter (because if the clinician suggests a mode of treatment his/her Trust does not have as an option) needs to say the clinician then has to refer on to a centre where that treatment option is available, but the patient shouldn’t have to start from scratch i.e. go through the whole referral/ outpatient thing again i.e. need a seamless care pathway for delivery of all treatment options.	The introduction in the NICE version has been substantially rewritten to make it more concise. The wording suggesting here will be considered in this rewrite.
Royal College of Obstetricians & Gynaecologists	NICE	10	10	Cyclical norethisterone appropriate for irregular cycles not HMB.	Thank you. Based on the evidence reviewed, the GDG felt that it could also be used in HMB.
Royal College of Obstetricians & Gynaecologists	NICE	10	21	Please give examples of ‘other symptoms’ or refer to elsewhere in this document if done elsewhere to avoid repetition.	Thank you. The term fibroids and other symptoms have been removed from the recommendation as it was felt that it was not possible to list all of them.
Royal College of Obstetricians & Gynaecologists	NICE	10	31	Need to qualify when there are to be exceptions to this order e.g. certain previous intra-abdominal surgery.	Thank you. A new recommendation has been added to highlight the circumstances under which laparoscopic surgery would be used.
Royal College of Obstetricians & Gynaecologists	NICE	12	4	It would be helpful to have something here about the impact of the symptoms on the woman’s life.	Thank you. In the full version of the guideline we provide in-depth information on the impact of

Organisation	Doc	Page no	Line no	Comments	Response
Gynaecologists				What there is does not address this.	HMB on women and have made several recommendations relating to this (section 1.1).
Royal College of Obstetricians & Gynaecologists	NICE	12	8	Unable to know there is no pathology on the basis of history alone. That flies in the face of all basic medical care .History alone cannot be sufficient. Risk of opening clinician to clinical negligence. Must always go with examination, investigation: maybe initiate management while waiting results.	Thank you. The GDG have discussed this point. The conclusion of the discussion was that oral pharmaceuticals (NSAIDs, TXA and COC) did not require an examination or investigation prior to use. Other treatments, such LNG-IUS, GnRH-a or any surgery, would require further examination and investigation in order for safe and appropriate use to be undertaken.
Royal College of Obstetricians & Gynaecologists	NICE	12	25	Last line should read 'symptoms or signs'.	Thank you. This has been amended
Royal College of Obstetricians & Gynaecologists	NICE	13	7	What time of cycle is ideal for TV USS?	Thank you. This was not considered by the GDG.
Royal College of Obstetricians & Gynaecologists	NICE	13	10	Is there an ET for which biopsy is recommended? – see RCOG Guideline No 5 1999: Presumably a TV USS.	Unfortunately, we are not clear what the acronym ET relates to.
Royal College of Obstetricians & Gynaecologists	NICE	14	7	Who should provide the information?	NICE guidelines, where possible, try not to specify who should provide a treatment.
Royal College of Obstetricians & Gynaecologists	NICE			1.3.1.2 is the same as 1.3.1.7.	Thank you. This amendment has been made.
Royal College of Obstetricians & Gynaecologists	NICE	14	8	The LNG-IUS is the most effective intervention but this statement may put the GPs off initiating simple, effective therapies such as COCP or tranexamic acid. Not many GPs are happy to insert the IUS & this may increase hospital referral. Some women benefit from a short duration of treatment and the IUS is only cost effective if used for a long time. There are good arguments in favour of both COCP and tranexamic acid being regarded as first line.	The GDG is aware of several successful training programmes for GPs wanting to learn to fit LNG-IUS, and there is no evidence that GPs would refer all women to secondary care for fitting. In addition, the GDG have added a recommendation that simple oral treatment can be used while waiting for more definitive interventions
Royal College of Obstetricians & Gynaecologists	NICE	17	5	UAE should be clearly stated as a treatment only for fibroids (see IPGO 94 Guidance).	Thank you. The recommendations throughout the guideline have been examined to ensure that the criteria for use are clear.
Royal College of Obstetricians & Gynaecologists	NICE	17	14	Specify hysterectomy in consideration for surgery.	Thank you. This amendment has been made.

Organisation	Doc	Page no	Line no	Comments	Response
Gynaecologists					
Royal College of Obstetricians & Gynaecologists	NICE	17-18	General	Should the guideline include a statement on other 2nd generation ablative methods currently available? Presumably evidence will be published fairly soon.	Thank you. This recommendation has been change to cover all routinely used types of ablation.
Royal College of Obstetricians & Gynaecologists	NICE	18	13	Some units do not carry out endometrial thinning at all prior to MEA. No good evidence that it is needed. Study quoted in full version is rather limited.	Thank you. The guideline makes no recommendation that endometrial thinning is require, only the scheduling can be used as an alternative where it is used.
Royal College of Obstetricians & Gynaecologists	NICE	18	23	Change to 'Ablative techniques may be undertaken with local analgesia where appropriate'.	It has been highlighted elsewhere that this subject is outside the remit of the guideline so has had to be removed.
Royal College of Obstetricians & Gynaecologists	NICE	19	6	Reference needed as all we are aware of to guide this recommendation is personal audit. IPGO 94 Guidance suggests more evidence is needed.	Thank you for this comment. No specific review was undertaken on pregnancy after any treatment. The recommendation is based the GDGs knowledge of the literature and experience.
Royal College of Obstetricians & Gynaecologists	NICE	18	23	Including patient choice.	Thank you. The recommendation has been reworded to improve clarity.
Royal College of Obstetricians & Gynaecologists	NICE	19	15	There is the potential of risking retention fertility as well.	Thank you for this comment. The GDG will consider it when amending the recommendations.
Royal College of Obstetricians & Gynaecologists	NICE	19	28	Evidence favouring vaginal hysterectomy is not all that strong (see full guideline). We feel the argument may be based on health economics. A large number of hysterectomies are done for abnormalities such as fibroids, and vaginal hysterectomy in such cases may not be appropriate in the hands of most ordinary gynaecologists. Agree strongly with 1.9.1.3 & would propose that this statement comes first. If it must be included, the next statement could then read "taking these factors into consideration, the route of hysterectomy".	Thank you. The guideline contains a series of recommendations relating to hysterectomy. These make it clear that individual assessment is essential to deciding the route of hysterectomy. We have reordered and reworded the recommendations to improve clarity.
Royal College of Obstetricians & Gynaecologists	NICE	20	7	Risks need to be spelt out as immediate and long term: there are Scottish figures showing straightforward hysterectomies but significant re-admission rate over the next 10 years due to symptoms of adhesions. Also, not sure of data on residual/ resultant pain as in dyspareunia. And	The majority of this data is contained within the evidence tables.

Organisation	Doc	Page no	Line no	Comments	Response
				whether don't believe in effect/ no effect on orgasm/ sexual dysfunction/ "post hysterectomy syndrome" needs to go in anyway.and address subtotal hysterectomies (maybe comes later in text).	
Royal College of Obstetricians & Gynaecologists	NICE	21	1	There is good evidence that ovarian function is not affected by hysterectomy: Simpson et al, 2005, Climacteric, 8, 300-3; Metcalf et al 1992, J Endocrinol, 135, 597-602	This evidence has been considered, but the GDG do not feel the recommendation should be changed.
Royal College of Obstetricians & Gynaecologists	NICE	21	11	Correct to 'women found to have a family history of ovarian or breast cancer'...	Thank you. This text has been amended
Royal College of Obstetricians & Gynaecologists	NICE	21	13	Only 3 months is surprising: down regulation/ add back has to kick in and then need to await resolution of 'placebo' effect. 3 months is too short for any Rx if want to exclude placebo effect once treatment fully effective.	This recommendation has been amended and reference to 3 months removed.
Royal College of Obstetricians & Gynaecologists	NICE	21	15	Statement could be clarified by stipulating what is meant by ovarian dysfunction ie pelvic pain or premenstrual syndrome.	This change has been made.
Royal College of Obstetricians & Gynaecologists	NICE	21	28	Clinicians can be appointed to posts who can do the initial investigation/ management and pass on by care pathway if not competent for surgical management. You should not need to be a surgeon to see these women. See RCOG documents on Future Role of Consultant.	Thank you. The recommendations on competency are meant for those wishing to be undertake procedures. They do not restrict others from referring woman to these individuals.
Royal College of Obstetricians & Gynaecologists	NICE	24	12	Correct treatment to treated.	Thank you. 'Treatment' is correct.
Royal College of Obstetricians & Gynaecologists	NICE	24	22	Explain PBAC.	Thank you. This acronym has been expanded.
Royal College of Obstetricians & Gynaecologists	NICE	24	25	Correct simply to simple.	This correction has been made.
Royal College of Obstetricians & Gynaecologists	NICE	25	38841	Correct affect to effect. Surely this is not an area for new research.	This amendment has been made.
Royal College of Obstetricians &	NICE	30		No algorithm.	Algorithm is produced as a separate document and was available on the NICE website.

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Gynaecologists					
Royal College of Obstetricians & Gynaecologists	FULL	63	39061	This paragraph is not clear and whether any of these circumstances (persistent intermenstrual bleeding, is aged 45 years and over and has declined or failed adequate medical treatment) or the combination necessitate taking an endometrial biopsy.	Thank you. This recommendation has been amended to improve the clarity.
Royal College of Obstetricians & Gynaecologists	FULL	64	38899	The evidence level for effectiveness of these treatments is given but it is not clear if this evidence applies to the order in which these interventions should be considered. Could the GDG please explain the basis on which they have ordered these treatments given that LNG-IUS is an invasive intervention compared with oral medication.	Thank you for this comment. The order of treatment was based on effectiveness and cost-effectiveness data. The GDG has added a statement to the full version outlining this decision process behind this. In addition, the recommendation wording has been amended to highlight the need for healthcare professionals consideration of the most suitable treatment option.
Royal College of Obstetricians & Gynaecologists	FULL	65	38749	Hysterectomy should not be the first line of therapy even if there are large fibroids or other symptoms.	The recommendation was not meant to imply that hysterectomy should be a first-line treatment. The recommendation outlines the criteria where hysterectomy can be considered. The wording has been changed to avoid this interpretation.
Royal College of Obstetricians & Gynaecologists	FULL	65	38841	Assessment of uterine size by comparison with gestation duration is very inaccurate, subjective, dependant on patient's body mass index and with the increasing separation between obstetrics and gynaecology it would not be long before a gynaecologist would not know how big is a 10 week-size uterus. A more measurable parameter is the uterine cavity depth as assessed by ultrasound or hysteroscopy and most techniques accept a cavity of 10-12 cm deep as the upper limit for ablation.	The GDG agree that gestational age is an inaccurate measure, but it is the measure used in many research studies and this is what has to be reported in the review.
Royal College of Obstetricians & Gynaecologists	FULL	68	38903	This paragraph is not clear and whether any of these circumstances (persistent intermenstrual bleeding, is aged 45 years and over and has declined or failed adequate medical treatment) or the combination necessitate taking an endometrial biopsy.	Thank you. The recommendation has been amended to improve the clarity.
Royal College of Obstetricians &	FULL	72	16-17	This is imprecise statement. It is the uterine cavity that should be normal/regular and the fibroid is	Thank you. The GDG that more specific criteria should be followed before undertaken ablation

Organisation	Doc	Page no	Line no	Comments	Response
Gynaecologists				intramural or grade 2 with minimal distortion to the cavity to qualify for endometrial ablation.	and that why the recommendations specify that the manufacturers own criteria should be followed. This recommendation is meant to specify the general conditions for considering endometrial ablation.
Royal College of Obstetricians & Gynaecologists	FULL	73	13-15	This is a very controversial statement. Different techniques have different requirements and one can not generalise that "hysteroscopy should be undertaken post-dilatation, pre-procedure". Not all techniques require dilatation and many are undertaken under sedation or local anaesthetic in the outpatient/office environment. Such requirement would prolong operating time, increase cost with no added benefit to the patient. Furthermore, and more critically, this recommendation is not consistent with previous NICE guidance publications in relation to ablation treatments.	Thank you. This recommendation has been revised to reflect the fact that not all ablative techniques require dilation.
Royal College of Obstetricians & Gynaecologists	FULL	74	38872	Assessment of uterine size by comparison with gestation duration is very inaccurate, subjective, dependant on patient's body mass index and with the increasing separation between obstetrics and gynaecology it would not be long before a gynaecologist would not know how big is a 10 week-size uterus. A more measurable parameter is the uterine cavity depth as assessed by ultrasound or hysteroscopy and most techniques accept a cavity of 10-12 cm deep as the upper limit for ablation.	The GDG agree that gestational age is an inaccurate measure, but it is the measure used in many research studies so the one that has to be reported in the reviews.
Royal College of Obstetricians & Gynaecologists	FULL	77	19-21	There are clear referral criteria for women with family history not only of ovarian cancer, but also breast /ovarian cancer families.	Thank you for this comment. The recommendation has been amended accordingly.
Royal College of Obstetricians & Gynaecologists	FULL	77	22-25	In clinical practice, a 3 month period of ovarian suppression is often followed by another 3 months of suppression plus hormone replacement therapy to ensure that the woman is tolerant of HRT and no recurrence of symptoms.	Thank you for this information. The GDG will consider it when revising the recommendations.
Royal College of Obstetricians & Gynaecologists	FULL	78	21-25	The word "imaging" is more appropriate than "radiological" as ultrasound is not radiology.	The term radiology is used as UAE is included in the guideline, however, the term imaging does need to be added to differentiate ultrasound.
Royal College of	FULL	96-104	General	Section on prevalence of uterine pathology in	The section took data on prevalence from the

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Obstetricians & Gynaecologists				HMB is heavily biased to hysteroscopic/endometrial biopsy studies whereas in the past 5-10 years a large number of studies examined the use of ultrasound in the investigation of HMB.	sources that were available. In many case this was from diagnostic studies rather than epidemiological studies. The diagnostic studies included both hysteroscopic and ultrasound examinations.
Royal College of Obstetricians & Gynaecologists	FULL	200	20-25	The GDG comment on prognostic study and factors that affect outcome. However, dysmenorrhoea has been identified in a long term follow-up study after TBEA as a factor leading to hysterectomy. The 6 year follow up period in the study also highlighted the probability of avoiding hysterectomy according to uterine position (Amso et al, Uterine endometrial thermal balloon therapy for the treatment of menorrhagia: long-term multicentre follow-up study. Human Reproduction Vol.18, No.5 pp. 1082-1087, 2003). The GDG place emphasis on hysterectomy avoidance when discussing LNG-IUS but reference to that not found when discussing ablation treatments.285	In the section of surgery as a first line treatment the GDG highlight that avoiding hysterectomy was of high value. This influenced the recommendations on ablation and hysterectomy. However, this statement will also be added to the ablation section.
Royal College of Obstetricians & Gynaecologists	FULL	285	18-19	No national data on the training in gynaecological ultrasound have been available previously. During 2002 and early 2003, a national survey was undertaken, based on the RCOG consultant and specialist database for the UK and ROI. Among the questioned asked were whether they undertook transvaginal scanning, and whether the individual has undergone a structured training programme. The findings were presented in a number of specialty meeting but such survey is not normally published in journals but feeds into the debate on the need for structured training and indeed was used to justify the rationale for establishing an accredited diploma course at Cardiff university in obstetric and gynaecological ultrasound. There are also a number of university based accredited programmes for ultrasound education mainly for sonographers and are accredited by CASE (Consortium of Associations for Sonography Education), however, the Cardiff University course is mainly aimed at obstetricians and gynaecologists. Additionally, the RCOG special skills modules in obstetric and	Thank you for this very interesting information. The GDG has tried to keep recommendations on training and competencies as generic as possible in order to avoid future changes in name of training programmes.

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				gynaecological ultrasound are structured schemes but only the obstetric module is assessed formally. The main relevant results of the survey are summarised below: Region Questionnaires sent Respondents (%) Undertake TVS (%) Trained (%) Scotland 129 62 (48% 37 (60%) 12 (33% England 1124 461 (41%) 228 (50% 86 (38% Wales 66 37(56%) 16 (43%) 11 (69%) Northern Ireland 46 30 (65%) 28 (93%) 3 (11%) UK & ROI 1439 609 (42%) 321 (53%) 114 (36%)	
Royal College of Obstetricians & Gynaecologists	FULL	290	17-19	It is not clear what the GDG meant by “felt that where possible, ultrasound should be undertaken in a dedicated gynaecological ultrasound unit”? If they mean in an integrated gynaecology outpatient setting with the philosophy of a “one-stop” clinic where history, examination and investigation are undertaken in one setting to facilitate patient care then they should be made explicit. The statement is too vague and such a unit does not exist.	The GDG feel that the statement is accurate. The GDG think that ultrasound for gynaecological problems should be undertaken in a unit dedicated to doing this.
Royal College of Pathologists				This organisation was approached but did not respond.	
Royal College of Physicians of London				This organisation was approached but did not respond.	
Royal College of Psychiatrists				This organisation was approached but did not respond.	
Royal Shrewsbury Hospital NHS Trust				This organisation was approached but did not respond.	
Royal Surrey County Hospital				This organisation was approached but did not respond.	
Schering Health Care Ltd	Full version	165	1	The guideline states that ‘No UK based comparisons of LNG-IUS with any other medical or surgical treatment strategies were identified as part of the review.’ Further to our previous communication via the submission of evidence proforma, we have had our manuscript accepted for publication in Current Medical Research and Opinion, subject to minor amendments. The manuscript is entitled ‘Cost utility of LNG-IUS	Thank you. As the study is ‘in confidence’ it cannot be used in the guideline. If the full paper is published before the final submission of the guideline then it will be examined.

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				compared with hysterectomy and second generation endometrial ablative techniques in managing patients with menorrhagia in the UK.'[i] The abstract is attached (academic in confidence). The evaluation demonstrates LNG-IUS is a cost effective alternative to MEA, TBEA and hysterectomy, affording the NHS a less expensive treatment modality without detrimental effects on resulting health gain.	
Schering Health Care Ltd	Full version	Chapter 9 (esp p207-08)		The guideline recommends the use of endometrial ablation as first line treatment in secondary care. No consideration is given to the use of LNG-IUS in secondary care. There is evidence to show that LNG-IUS is equally as effective as second generation ablation with no difference in quality of life or the number of women requesting further intervention (hysterectomy) during follow-up. LNG-IUS has also proved to be a useful option in secondary care vs. hysterectomy and primary ablation techniques (TCRE). Patient choice is important and therefore LNG-IUS should also be considered in secondary care. This is supported by the following evidence: LNG-IUS vs. second generation ablative techniques: Barrington (2003)[ii] randomised 50 women who had been referred by their GP to secondary care with menorrhagia refractory to medical therapy to either LNG-IUS or endometrial balloon ablation. At the 6 month follow-up one of the women in the LNG-IUS opted for a hysterectomy and 5 women in the ablation group requested hysterectomy. They concluded that both LNG-IUS and ablation were equally effective in management of menorrhagia and therefore the choice of treatment should be tailored to the woman. Busfield (2006)[iii] compared LNG-IUS to thermal balloon ablation in a randomised prospective trial for the treatment of HMB. At 12 and 24 months women had significantly lower PBAC scores than women treated with thermal balloon ablation. Both treatments resulted in a significant increase in	<p>Thank you. The GDG considered all available evidence of treatments against LNG-IUS.</p> <p>The GDG has removed the location of treatment from all recommendations as this is outside the remit of the guideline (except where not including the location could result in misinterpretation of the recommendation).</p>

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				<p>overall quality of life. There was no difference between the two groups regarding quality of life, patient satisfaction or the number of women requesting an alternative treatment during 24 months of follow-up. LNG-IUS vs. first generation ablative techniques: Kittelsen & Istre (1998)[iv] reported the preliminary results of a comparative trial evaluating the efficacy of LNG-IUS and transcervical resection of the endometrium (TCRE) in the treatment of menorrhagia. Menorrhagic women who had failed conservative medical treatment, referred by their general practitioners to a gynaecological clinic specialising in operative hysterectomy, were recruited to the trial. The patients were randomised to either having a LNG-IUS fitted or a TCRE carried out. Twenty four patients in the LNG-IUS group and 29 patients in the TCRE group completed 20 months of follow up. Bleeding intensity was assessed using the PBAC score and this was reduced in both groups, from 418 to 42 in the LNG-IUS group and from 378 to 6.6 in the TCRE group. The authors concluded that although both methods have a dramatic effect on the bleeding intensity of these patients, LNG-IUS has the benefit of being reversible and has no operative hazards. Rauramo (2004)[v] conducted an open randomised 3 year trial. Patients with HMB were randomly assigned to LNG-IUS or TCRE. Pictorial blood loss decreased from baseline significantly in both groups and did not differ between them. They concluded that both treatments efficiently reduce blood loss and the high continuation rate suggests that LNG-IUS is comparable to TCRE. LNG-IUS vs. Hysterectomy: Nagrani (2002)[vi] (follow-up study to Barrington and Bowen Simpkins, 1997[vii] see below) recruited 50 women who had failed to respond to medical therapy for menorrhagia who were on the waiting list for hysterectomy. All were fitted with LNG-IUS and were followed up for 4 to 5 years. 50% of women continued to use the device and</p>	

Organisation	Doc	Page no	Line no	Comments	Response
				<p>67.4% avoided surgery. The LNG-IUS was well accepted and effective in the management of menorrhagia. Barrington & Bowen-Simpkins (1997)⁶ inserted the LNG-IUS into 50 women who had failed a trial of medical therapy and were awaiting hysterectomy or transcervical resection of the endometrium (TCRE). The menstrual blood loss was reduced to acceptable levels in 37 women at 3 months and a further 4 by 6-9 months. In all, 41 patients were taken off the waiting list for surgery, 4 of whom became amenorrhoeic. Fifty six percent of patients noticed considerable improvement or cure of their premenstrual syndrome symptoms and 80% noticed a reduction in dysmenorrhoea. The authors conclude that the LNG-IUS is an effective non-surgical treatment for the management of menorrhagia and dysmenorrhoea. Lahteenmaki (1998)^[viii] ran an open randomised study of 56 women scheduled to undergo hysterectomy for HMB. women were randomised into LNG-IUS group or to continue with their existing treatment. At 6 months 64.3% of LNG-IUS users and 14.3% in the control group had cancelled their hysterectomy. At 3 years 48% continued with the LNG-IUS. They concluded that LNG-IUS should be considered before hysterectomy or other invasive treatments. Hurskainen (2001)^[ix] randomly assigned 236 women to LNG-IUS or hysterectomy. They investigated quality of life and cost effectiveness during a 12 month follow up period. At 12 months 68% of women had continued with LNG-IUS. Health related quality of life improved significantly in both groups and costs were about 3 times higher for hysterectomy group than LNG-IUS group. Hurskainen (2004)^[x] carried out a five year follow- up study. Health related quality of life was equally good in both groups with scores on the EQ5D improving over baseline for both groups, with no substantial difference between the groups (P=0.60). Costs were about 40% lower for LNG-IUS group than</p>	

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				hysterectomy group.	
Schering Health Care Ltd	Full version	164	16	<p>In this section the results of published health economic evaluations comparing LNG-IUS to other treatments for menorrhagia are summarised. I would like to draw your attention to two further health economic evaluations that have recently been published: Brown (2006)[xi]: The analysis compares LNG-IUS to thermal balloon ablation. The expected costs of treatment were \$NZ1241 for the LNG-IUS and \$NZ2418 for the thermal balloon ablation. The LNG-IUS was associated with a greater increase in quality of life measured using the SF-36, concluding that the LNG-IUS would appear to be cost effective when compared with thermal balloon ablation for the treatment of menorrhagia. Blumenthal (2006)[xii]: The analysis compares oral contraceptive (OCs), LNG-IUS and surgery in women with dysfunctional uterine bleeding who do not desire additional children. The results show that in women responding to OCs, continuing treatment with LNG-IUS instead of OCs is more effective and less expensive. For women naïve to medical therapy, the LNG-IUS had similar effectiveness but the cost of LNG-IUS was lower (US\$2796 vs. US\$4895). In women not responding to OCs, surgical management was more effective than the LNG-IUS (95.5% vs. 92%) but at a higher cost (US\$4853 vs. US\$2796), concluding that treatment strategies employing the LNG-IUS are the most cost effective in managing dysfunctional uterine bleeding. These evaluations provide economic evidence to support the use of LNG-IUS in secondary care as an alternative to surgery. The guideline recommends that endometrial ablation may be offered to women with HMB as an initial treatment in secondary care after full discussion of outcomes and other options. The use of LNG-IUS in secondary care appears to have been ignored. On page 205, lines 2-6, it clearly states that surgery reduces menstrual bleeding at one year more than</p>	Thank you for this information. The recommendation on LNG-IUS is not restricted by location.

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				medical treatments, but LNG-IUS appears equally beneficial in improving quality of life and may control bleeding as effectively as conservative surgery over the long term. Taken together with the findings of the economic model outlined in appendix A, which show that the LNG-IUS is cheaper and more effective than surgery and the economic evaluation by Brown et al 2006, women should be offered LNG-IUS in secondary care as an alternative to endometrial ablation as initial treatment.	
Schering Health Care Ltd	Full version AND NICE version	73 & 17	38808	The guideline recommends the use of endometrial ablation as first line treatment in secondary care. No consideration is given to the use of LNG-IUS in secondary care. There is evidence to show that LNG-IUS is equally as effective as second generation ablation with no difference in quality of life or the number of women requesting further intervention (hysterectomy) during follow-up. LNG-IUS has also proved to be a useful option in secondary care vs. hysterectomy and primary ablation techniques (TCRE). Taken together with the findings of the published economic evaluations and the economic model presented in appendix A, this shows that LNG-IUS is a cost effective alternative to surgical intervention in secondary care. Patient choice is important and therefore LNG-IUS should also be considered in secondary care.	Thank you. The GDG reviewed all the available evidence on LNG-IUS. It is not NICE policy to specify location of treatment, and the recommendations have been revised accordingly.
Schering Health Care Ltd	Full version	163-166; 241		There is no mention of use of LNG-IUS for use in women with HMB related to fibroids. LNG-IUS is a treatment option for menorrhagia related to fibroids where the uterine cavity is not distorted. This is supported by the following evidence: A prospective cohort study was conducted to examine the use of LNG-IUS in the treatment of heavy menstrual bleeding related to uterine fibroids (leiomyomas) (Grigorieva, 2003[xiii]). After 12 months use, LNG-IUS was associated with a marked reduction in menstrual blood loss with the mean pictorial blood loss assessment	Thank you. A recommendation has been added that a physical examination is required prior to fitting of LNG-IUS. If this examination is satisfactory, then an LNG-IUS can be fitted.

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				chart score reduced from 97 to 16 (p<0.01).	
Schering Health Care Ltd	Full version & NICE	70-72; 15-16		When discussing uses of medical treatments for HMB, a comment should be included to say that LNG-IUS can be used to treat HMB associated with fibroids which do not distort the uterine cavity. See evidence above.	Thank you. A recommendation has been added that a physical examination is required prior to fitting of LNG-IUS. If this is satisfactory, then an LNG-IUS can be fitted.
Schering Health Care Ltd	Full version & NICE	74-75; 19		There is no mention of use of LNG-IUS for use in women with HMB related to fibroids. LNG-IUS is a treatment option for women with HMB related to fibroids where the uterine cavity is not distorted.	Thank you. A recommendation has been added that a physical examination is required prior to fitting of LNG-IUS. If this is satisfactory, then an LNG-IUS can be fitted.
Schering Health Care Ltd	Full version & NICE	70-71/163-166/195-197; 16		In a number of places in the guideline it states that if HMB coexists with dysmenorrhoea, NSAIDs are preferred to tranexamic acid. In a number of clinical trials investigating the contraceptive efficacy of LNG-IUS and/or the effectiveness of the system to manage menorrhagia a reduction in menstrual pain has been observed. Barrington & Bowen-Simpkins (1997) ⁶ prospectively studied 50 women who had all failed medical treatment for menorrhagia and were all awaiting hysterectomy or transcervical resection of the endometrium. They were all given a LNG-IUS. 80% noted a reduction in dysmenorrhoea. In a randomised study looking at the performance of LNG-IUS in comparison to Nova T (copper IUD) (Nilsson 1982) ^[xvi] , a significantly greater percentage of patients in the LNG-IUS group than in the copper coil group reported an improvement in dysmenorrhoea (35% vs. 9%; p	Thank you. This data has been considered, but the GDG does not feel that the recommendation needs to be changed – TX acid is still preferred to NSAIDs where dysmenorrhoea is present.
Schering Health Care Ltd	Full version	163	6	LNG-IUS suppresses ovulation in a small minority of women in 'some' cycles. During the first year of use of LNG-IUS some women may experience some changes in ovarian function. However, after the first year, most cycles are ovulatory (Nilsson 1984) ^[xix] . The incidence of ovulatory cycles with LNG-IUS were found to be similar to that seen in patients fitted with copper-containing intrauterine devices (IUDs) (Scholten 1989) ^[xx] .	Thank you for this information. The GDG believe this statement is correct.
Schering Health Care Ltd	Full version	163	38961	For menorrhagia and contraception LNG-IUS is licensed for 5 years. For the progestogen	Thank you. The GDG is aware of this.

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				component of HRT the licensed duration of use is 4 years.	
Schering Health Care Ltd	Full version	165	14	This is 96% on p164 line 12	Thank you. This amendment has been made.
Schering Health Care Ltd	Full version	195-197	1	The recommendations for the medical management of women with heavy menstrual bleeding are included at the end of this chapter. As the chapter is entitled 'Non-hormonal medical treatments for HMB', the recommendations may be more usefully be included in a separate chapter.	Thank you for this comment. The titles of the chapters will be reviewed.
Schering Health Care Ltd	Full version	235	4	Abdominal myomectomy versus uterine artery embolisation	Thank you. This has now been amended
Schering Health Care Ltd	Full version	253	1-10, 19-25	The text under the heading Hysterectomy versus UAE (line 18) is incorrect and is in fact a duplication of the text at the top of the same page (lines 1-10).	Thank you. This has now been amended
Schering Health Care Ltd	Full version	283	7	"....perceived risk of endometrial cancer" – surely this should be ovarian cancer?	Thank you. This has now been amended
Schering Health Care Ltd	Full version	298	23	"...except for use of myomectomy or UAE for treatment of uterine fibroids"?	Thank you. UAE is a radiological intervention, not a surgical intervention. This model compared non-hormonal against surgical treatments.
Schering Health Care Ltd	Full version	299	5	Table A.1 does not contain the probabilities used in the model.	Thank you. This has been amended.
Schering Health Care Ltd	Full version	299	7	Figure A.1 is not shown in the document.	Thank you. This was a mistake as this figure has been removed. The statement referring to this figure has now been removed.
Schering Health Care Ltd	Full version	306	Table A.2	NSAIDs (Mefenamic acid): In this section the row showing the proportion of women who have surgical treatment following failed medical treatment is missing.	Thank you. This has been amended.
Schering Health Care Ltd	Full version	311	Table A.5	Cost per model cycle of COC pill: £8.31. This cost appears to be higher than you would expect for 3 months supply of a levonorgestrel containing pill.	Thank you for this data. The figures used in the model will be reviewed, and, if necessary, updated.
Schering Health Care Ltd	Full version	312	Table A.5	The resource use associated with LNG-IUS suggests that following insertion a woman should attend a 4-6 week follow up consultation, a three month follow-up consultation and routine annual follow up thereafter. The Summary of Product	The reason for the difference is that LNG-IUS is being used for different reasons.

Organisation	Doc	Page no	Line no	Comments	Response
				Characteristics states that women should be followed up 6 weeks following insertion and annually thereafter. The recent NICE guidelines on Long Acting Reversible Contraception recommend that following the 4-6 week check, women need only to return at any time to discuss problems, or if it is time to have the IUS removed. It is not clear why the follow-up recommendations for menorrhagia and contraception should differ.	
Schering Health Care Ltd	Full version	314	Table A.6	Costs of surgical treatment: It is unclear how the costs of an initial consultation (£27.66) and a second consultation (£27.66) are calculated. The NHS reference cost for a gynaecology outpatient appointment is £128 for a first attendance and £85 for a follow-up attendance.	Thank you. This was a mistake in the table and should have read as indicated based on 2004-05 tariffs. The correct costs were used in the analysis.
Schering Health Care Ltd	NICE version	16		It would be helpful to state how long LNG-IUS can be used for. For menorrhagia and contraception LNG-IUS is licensed for 5 years. For the progestogen component of HRT the licensed duration of use is 4 years.	Thank you. This will be added to the recommendation.
Schering Health Care Ltd	NICE version	17		The recommendations state that ablation may be offered as an initial treatment in secondary care after full discussion of outcomes and other treatment options. It would be helpful to clarify the alternative treatment options (pharmaceutical, other surgical interventions).	Thank you. This recommendation has been revised to remove the location of treatment.
Schering Health Care Ltd	NICE version	19		The recommendations state that hysterectomy should only be considered where other treatment options have failed or are inappropriate. It would be helpful to clarify the treatment options that should have been considered (pharmaceutical, other surgical interventions.)	Thank you. It is difficult to outline all previous treatment options as management should be individualised. Therefore, there may be circumstances where a woman goes straight to hysterectomy and others where a woman has two medical treatments, ablation and then hysterectomy. The GDG feel that taken in the entirety the recommendations would provide a healthcare professional with information on all available treatment options.
Schering Health Care Ltd	Algorithm	General		The algorithm would benefit from being made clearer. It contains a lot of information and is not easy to follow.	Thank you. Based on a number of recommendations, the algorithm is being completely reviewed.
Schering Health Care Ltd	Algorithm		1	The last box states 'if treatment successful'. To be consistent with page 2 this should say 'Treatment	Thank you. Based on a number of recommendations, the algorithm is being

Organisation	Doc	Page no	Line no	Comments	Response
				successful no further action required'	completely reviewed.
Schering Health Care Ltd	Algorithm		2	LNG-IUS is an alternative option to surgical intervention in secondary care.	Thank you for this comment. This was considered when making recommendations.
Schering Health Care Ltd	Full and NICE version	General		The guideline recommends LNG-IUS as first line pharmaceutical treatment for HMB in women requiring hormonal treatment. The NICE Long-Acting Reversible Contraception guideline (Oct 2005) recommends that if LNG-IUS is not routinely provided then an agreed mechanism should be in place for referring women for the LNG-IUS. This should also be reflected in the HMB guideline.	Thank you. The guideline contains a chapter on competencies required to undertake procedures, this includes requirement for referral.
Schering Health Care Ltd	Full and NICE version	General		The guidelines does not make it clear whether a woman should try medical management before referral for surgery. It is extremely unlikely that a patient would be referred straight to secondary care for non-pathological HMB. The algorithm is clearer on this point but the guidelines need to be clearer about what is expected in terms of initial treatment in primary care before referral to secondary care, where indeed the first line option might be surgery after other treatments have failed in primary care.	Thank you. The GDG feel that there may be circumstances when a woman is referred straight to surgery. However, a recommendation has been added stating that oral medical treatment can be used while a woman is waiting for definitive treatment.
Schering Health Care Ltd	Full and NICE version	General		The Chapter and section headings are inconsistent and misleading. For example 'Surgery as first line treatment for HMB' could be replaced with 'Surgical treatments for HMB' to make it consistent with headings such as 'Hormonal treatment for HMB'	Thank you for this comment.
Schering Health Care Ltd	Full and NICE version	General		The LNG-IUS should be referred to as the levonorgestrel intrauterine system.	Thank you. Given the number of times that levonorgestrel intrauterine system is mentioned in the document it is standard practice to use an acronym.
Schering Health Care Ltd	Full and NICE version	General		The use of brand names and generic names should be consistent throughout the document.	The document will be amended
Schering Health Care Ltd				Please separate additional documents (files too large to include in table)	Thank you for these documents
Scottish Intercollegiate Guidelines Network				This organisation was approached but did not respond.	

Organisation	Doc	Page no	Line no	Comments	Response
(SIGN)					
Sheffield South West Primary Care Trust				This organisation was approached but did not respond.	
Sheffield Teaching Hospitals NHS Trust	All	General		I see the guideline as a positive contribution to the management of women with HMB.	Thank you.
Sheffield Teaching Hospitals NHS Trust	All	General		As with all the guidelines from NICE I want to see it avoid unnecessary generalisations that may not apply to all of a group of procedures considered that then have to be slavishly followed to prevent criticism.	Thank you for this comment.
Sheffield Teaching Hospitals NHS Trust	All	General		An example of this is the guideline to perform a hysteroscopic examination post-dilation prior to all second generation endometrial ablation procedures (10.4.5). I see this as appropriate with some of the devices, such as the MEA, but not the bipolar radio-frequency device (Novasure). The latter includes within the procedure a cavity integrity test that is far more sensitive than a hysteroscopic examination for identifying a perforation.	Thank you. This recommendation has been amended to take account of the different methods.
Sheffield Teaching Hospitals NHS Trust	Full version	195	(7.4.4)	The suggestion that the Mirena IUS should be first line treatment by GPs does not fit with the experience I have of our local GPs, few of whom fit the device. Not all fit IUCDs, never mind the IUS which is larger. I would argue against the need for referral to secondary care only after the device has been fitted and found to fail as a form of treatment. For many patients the option of 'a coil' or any hormonal treatment is unacceptable.	Thank you. The GDG is aware of a number of successful training programmes for GPs wanting to fit LNG-IUS. The guideline does not prevent other treatments or referral being made if a treatment is inappropriate or not wanted. In fact, the GDG recommend alternative treatments when hormonal ones are not appropriate or wanted.
Sheffield Teaching Hospitals NHS Trust	Full version	276	10 – 11	I am concerned that all laparoscopic hysterectomies are considered together when the types of hysterectomy are discussed, rather than divided up into laparoscopically assisted vaginal hysterectomy, laparoscopic hysterectomy and total laparoscopic hysterectomy. The first of these is little more than an extension of the vaginal procedure and carries with it less risks than when the procedure is performed completely laparoscopically. I would like to see vaginal and LAVH considered together as the first choice, with particular emphasis on LAVH when removal of	Thank you. The GDG has considered this comment and has made a separate recommendation for laparoscopic hysterectomy.

Organisation	Doc	Page no	Line no	Comments	Response
				the ovaries is to be considered as well.	
Sheffield Teaching Hospitals NHS Trust			(12.4.3)	I regard it as important that the surgeon chooses the route for hysterectomy, and not feel compelled to choose a route they are unhappy with for a given patient, just because of a guideline.	Thank you for this comment. The guideline outlines that the route of hysterectomy has to be based on individualised criteria. The recommendations are guidance based on the available evidence, but there will still be need for clinical judgement in any specific situation.
Sheffield Teaching Hospitals NHS Trust	Full version	260	(12.3.3)	I do not routinely offer patients sub-total hysterectomy as an option and in fact rarely discuss it, unless asked by the patient. I remain unconvinced that it should be routinely discussed, let alone documented on the consent form.	Thank you for this comment.
Society and College of Radiographers	Full Version	General		This is a very comprehensive and informative document.	Thank you.
Society and College of Radiographers	Full version	140	13	As the studies discussed used the trans vaginal ultrasound approach for investigations for uterine assessment, and given that the sensitivity of trans-vaginal scans (TVS) is higher than trans abdominal scans (TAS), especially in the assessment of the uterine, and endometrial pathology. Should the recommendation state that TVS should be the method of choice unless there are contra-indications.	The GDG that TVS is likely to be the most accurate and commonly used approach. However, the GDG felt that there may be situations, such as large fibroids, where a TAS would be used.
Society and College of Radiographers	Full version	137	11	Has the GDG also looked at 3D ultrasound as an emerging technology for assessment of uterine and endometrial pathology?	The GDG did not examine 3D ultrasound as it is not routinely available within the NHS. The remit of NICE guidelines is to examine investigations or treatments that are routinely used within the NHS
Society and College of Radiographers	Full version	Appendix B	19	This comment is relating to competencies for diagnostic and interpretation skills. Given that a vast percentage of Gynaecological scans are performed by Radiographers, the Society and College of Radiographers (SCoR) and the Consortium for the Accreditation of Sonographic Education (CASE) has a important and crucial role in the development, accreditation, and maintenance of education and training standards for ultrasound	Thank you. SCoR has been added to the list.
Society for Academic				This organisation was approached but did not	

Organisation	Doc	Page no	Line no	Comments	Response
Primary Care				respond.	
Society of Consultants and Lead Clinicians in Reproductive Health	NICE VERSION	Algorithm flow chart	P1 & 2	Find this difficult to understand and use. Not very clear when an examination is indicated and which direction of some of the arrows. Needs to be simplified.	Thank you. Based on a number of comments, the algorithm is being completely reviewed.
Society of Consultants and Lead Clinicians in Reproductive Health	NICE VERSION	throughout		Needs to be clarity about definitions of 'heavy menstrual bleeding', menorrhagia, DUB (DUB can occur in ovulatory and anovulatory women) apart from glossary etc. Perhaps a table with definitions may help in NICE VERSION.	Thank you. The GDG feel it is sufficient to have the definitions of the type of bleeding outlined in the glossary.
Society of Consultants and Lead Clinicians in Reproductive Health	NICE VERSION	Implementation		In view of DoH initiatives 'Care nearer to home' and the NHS plan this guidance needs to focus on management of heavy menstrual bleeding in primary care or community setting rather than secondary services.	Thank you. It is outside the remit of the guideline to specify where an intervention should occur.
Society of Consultants and Lead Clinicians in Reproductive Health	NICE VERSION	Page 6		1990s not 1990's.	Thank you. This has been amended.
Society of Consultants and Lead Clinicians in Reproductive Health	NICE VERSION	Page 13		Evidence for referral at cavity size of 12cm rather than 10cm?	Thank you for this comment.
Society of Consultants and Lead Clinicians in Reproductive Health	NICE VERSION			Little discussion of free thermal fluid endometrial ablation – this may be more appropriate for treatment in community settings.	Thank you. The recommendation on endometrial ablation has been amended, and now highlights HTA as a treatment option.
Society of Consultants and Lead Clinicians in Reproductive Health	BOTH VERSIONS			Use of NSAIDS – any evidence that different NSAIDS have differing actions on HML. If not this should be clarified with a preferred choice given eg mefenamic acid.	Thank you. There was insufficient evidence to clearly differentiate between the types of NSAIDs.
South East Sheffield Primary Care Trust				This organisation was approached but did not respond.	
Staffordshire Moorlands Primary Care Trust				This organisation was approached but did not respond.	
Stockport PCT				This organisation was approached but did not respond.	
Tameside and Glossop Acute Services NHS Trust				This organisation was approached but did not respond.	
The Daisy Network				This organisation was approached but did not respond.	

Organisation	Doc	Page no	Line no	Comments	Response
The David Lewis Centre				This organisation was approached but did not respond.	
The Hysterectomy Association				This organisation was approached but did not respond.	
The London Fibroid Clinic				This organisation was approached but did not respond.	
The National Association of Assistants in Surgical Practice				This organisation was approached but did not respond.	
The North West London Hospitals NHS Trust				This organisation was approached but did not respond.	
The Royal Society of Medicine				This organisation was approached but did not respond.	
The Royal West Sussex Trust				This organisation was approached but did not respond.	
UCLH NHS Foundation Trust				This organisation was approached but did not respond.	
UK Anaemia	NICE	General		The evident determination to get to the bottom of the problem of heavy menstrual bleeding and not to cover it up is to be applauded. However, it does not appear to recognise that anaemia and its consequences are not only a frequent companion of HMB but are often the major presenting symptom.	The GDG considered anaemia when developing the guideline. It was felt that if a treatment was effective on HMB then it would also improve anaemia.
UK Anaemia	NICE	General		The guideline recognises the difficulty of quantitatively assessing menstrual blood loss and other non-menstrual vaginal blood loss but it appears to accept that the patient presents with real not perceived problems. An assessment of iron stores could be argued to be the most direct means of distinguishing the two. It is thus a great pity that the guideline specifically precludes a measurement of the serum ferritin concentration at first presentation. This taken together with the MCH would provide a cheap, reliable and effective means of detecting diminished iron stores and hence true HMB .	Thank you. The GDG discussed in-depth the definition of HMB. The GDG decided that treatment should be based on the impact that MBL was having on a woman, rather than any objective measure.
UK Anaemia	NICE	General		HMB and anaemia should be treated as a global entity and that this should be made clear at the outset. In addition the full blood count should	Thank you for this comment. Based on the available evidence and experience, the GDG disagree with this statement.

Organisation	Doc	Page no	Line no	Comments	Response
				always be accompanied by a serum ferritin measurement. Failure to do so will simply mean that the woman has to return at a later date for a further investigation thus prolonging the rational appraisal of the situation.	
UK Specialised Services Public Health Network				This organisation was approached but did not respond.	
University College London Hospitals NHS Trust	Full	Section 4 Page 66		The draft NICE guidelines advocate an endometrial biopsy in women with persistent IMB, women over the age of 45 years, those where medical treatment has failed and prior to surgery / UAE. The guidance states that if history taking reveals HMB without the presence of pathology, then there is no need to undertake a physical examination prior to initiating first-line medical treatment. This statement is based upon grade D evidence (GPP - page 66 line 17). However, this recommendation is controversial. It is not always possible to obtain an accurate history from patients. It is important to examine patients in order to exclude pathology e.g. fibroid uterus, prolapsed fibroid polyp, cervical pathology etc.	Thank you. The GDG have discussed this point and have revised the recommendations. The GDG still believes that oral pharmaceutical treatment can be initiated without a physical examination. However, the GDG has clarified that more invasive procedures require physical examination and investigation prior to use.
University College London Hospitals NHS Trust	Full	Section 10.3 Page 210		This section bases its evidence on three systematic reviews two of which are Cochrane reviews and the other one Health Technology Assessment review. The first Cochrane review compares endometrial destruction techniques with hysterectomy, the other two include studies comparing some or all destruction techniques. These latter studies (The last Cochrane review was published in 2005) conclude that there were very few significant differences in the main clinical outcomes (Garside et al 2004) or 'some differences were also found in amenorrhoea rates and satisfaction rates, but there did not appear to be a trend over time so these results may be due to chance (Lethaby et al 2005'. Despite this the draft NICE Guidelines suggest that 'second generation ablation techniques (MEA, TBEA) should be considered ahead of first generation techniques'. This recommendation was based on the fact that the GDG felt results from a recent	The recommendation was based on the fact that after reviewing all the clinical and cost-effectiveness evidence, the GDG felt that second generation techniques should be preferred to first generation techniques in most situations. Of course, there will be situations where first generation techniques may be preferred. Therefore, the GDG has separated the recommendations on 1 st and 2 nd generation techniques, and specified under what circumstances each should be used.

Organisation	Doc	Page no	Line no	Comments	Response
				<p>study (Cooper et al 2005) were important. This study gave long term comparison of outcome of MEA and TCRE. This study was funded by the manufacturer of the MEA technique (or the authors were somehow associated with the company). Its main outcomes showed similar amenorrhoea and hypomenorrhoea rates and reduction in pain score was very similar. Despite this hysterectomy rates were higher in the TCRE group and satisfaction rates were with MEA were higher. Hence it is difficult to justify recommending second generation techniques ahead of first generation techniques with the conclusion from one single study. It appears that TCRE and REA stood their ground well in systemic reviews which included as many as 19 studies, 12 of which were funded/partially funded by the manufacturers or had authors with conflict of interest. Hence the NICE guidelines should stick with the conclusions of systemic reviews until further systemic reviews which will include new data are published. It is true that first generation techniques are more difficult to learn, but experienced practitioners should not be forced into using the second generation as the first choice. Furthermore hysteroscopic resection is a versatile skill which is still necessary for the treatment of submucosal fibroids, hence maintenance of this skill amongst gynaecologists is paramount.</p>	
University College London Hospitals NHS Trust	Full	Section 12.3 page 249 page 256 and onwards	line 6	<p>The 3 subdivisions of laparoscopic approach are correct. However on page In comparing the laparoscopic approach to vaginal hysterectomy and abdominal hysterectomy, the three modes of the laparoscopic approach are not considered separately. LAVH is closer to vaginal hysterectomy than TLH and therefore the three methods cannot be considered as the same in the conclusions. Indeed TLH can be considered as abdominal hysterectomy carried out through small holes with increased vision. Indeed in the oncology world randomised studies comparing</p>	<p>Thank you for this comment. The GDG discussed complexity surrounding route of hysterectomy, in-depth. In response, the GDG has outlined a separate recommendation on the criteria for use of laparoscopic methods.</p>

Organisation	Doc	Page no	Line no	Comments	Response
				<p>LAVH and TLH have been carried out and suggest different risks. LAVH is merely vaginal hysterectomy with laparoscopic bilateral oophorectomy. Indeed line 12 page 256 and subsequent it points out that complications from LAVH and vaginal hysterectomy are not different. If it is appropriate to do TAH when ovaries need to be removed then it follows that women admitted for laparoscopic removal of ovaries should also be encouraged to only have abdominal removal of ovaries. Also it would follow that the vaginal approach should be abandoned for hysterectomy in favour of the abdominal approach. This is again confirmed in the study reported on page 263. Cost analysis study on page 266 demonstrates that LAVH is preferential to TAH when ovaries are to be removed. Thus with regards LAVH it would suggest that in fact if vaginal hysterectomy is to be recommended over TAH then the LAVH should also be recommended when the ovaries are to be removed. Of note there are no data presented on the complication rates of vaginal oophorectomy. With regards LH the data again is conflicting but the argument is probably in favour of TAH over this approach from the data presented. However, there are no data presented assessing the longer term risks of wound hernia and it costs with the abdominal route. However the assumption in the paper on cost analysis on this aspect does not adequately assess the theatre time costs. These will vary according to staff numbers in theatres, anaesthetic time, delay in getting patients from the wards to theatre, coffee breaks etc. The effect not only on bed stay but on the number of beds that the hospital has not been fully assessed. Also with this method and others the data presented is largely six years old and there has been a vast increase in laparoscopic surgical expertise and this has not been allowed for. Throughout the review there has not been enough emphasis on surgical skills and the expertise variations and</p>	

Organisation	Doc	Page no	Line no	Comments	Response
				<p>hence how this influences the choice in different centres. With regards TLH there are no data presented and indeed there are series in the literature suggesting that in high risk women such as obesity then this approach is superior to TAH and indeed the inference with regards wound complication would suggest cost-effectiveness. Although only one reference is given there are several others revealed on a medline search. Although the data relates to endometrial cancer, the act of removing the uterus is the same. It would seem inappropriate that just because a woman does not have cancer she is denied a TLH which has been shown in overweight women to be superior. Thus it would appear that in those cases where vaginal hysterectomy is not possible and the woman is overweight, TLH is the approach of choice. In other situations there are no data available in the literature (or at least not considered in the guidelines). Finally in the comparison on subtotal and total hysterectomy the laparoscopic approach is not even commented on despite large series in literature. Thus the conclusions presented on page 276 line 10 are not valid. They should read that vaginal hysterectomy is the route of choice. Where the ovaries are to be removed then LAVH is the mode of choice. Where the patient is high risk and vaginal hysterectomy is not possible then TLH is the route of choice. Data presented on LH suggests that the role is possibly inferior to TAH.</p>	
University College London Hospitals NHS Trust	Refs			<p>Ghezzi F, Cromi A, Bergamini V, Uccella S, Beretta P, Franchi M, Bolis P. Laparoscopic-assisted vaginal hysterectomy versus total laparoscopic hysterectomy for the management of endometrial cancer: a randomized clinical trial. J Minim Invasive Gynecol. 2006 Mar-Apr;13(2):114-20. Bojahr B, Raatz D, Schonleber G, Abri C, Ohlinger R. Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique. J Minim Invasive Gynecol. 2006 May-Jun;13(3):183-9. Yu</p>	<p>Thank you for these references. They will be considered for inclusion in the guideline. The majority are retrospective case-series, and therefore would be excluded from the guideline given that RCT and large prospective cohort data is available on the same subject.</p>

Organisation	Doc	Page no	Line no	Comments	Response
				C KH, Cutner A, Mould T, Olaitan A. Total laparoscopic hysterectomy as a primary surgical treatment for endometrial cancer in morbidly obese women. BJOG. 2005;112:115-117.	
University Hospital Birmingham NHS Trust				This organisation was approached but did not respond.	
Vitaline Pharmaceuticals UK Ltd	Full			There is no direct treatment of the symptoms of fatigue etc caused by the anaemia	Thank you. Treatment of fatigue was not considered by the GDG. The GDG focused on the treatment of the MBL. The argument being that an improvement in this would reduce the effects of anaemia.
Vitaline Pharmaceuticals UK Ltd	Full	3.8.2	13	A successful treatment outcome is determined by the woman with HMB.	Thank you for this comment. This is what our recommendations state.
Vitaline Pharmaceuticals UK Ltd	Full	128	14-25	There is no mention in the draft for consultation for the routine testing of Ferritin although studies recommend this as the most accurate test for diagnosing IDA.	Thank you. After considering the available evidence and based on clinical experience, the GDG felt that routine testing of ferritin was not required in women presenting with HMB.
Vitaline Pharmaceuticals UK Ltd	General			Anaemia (usually IDA) is an associated problem, often symptomatic in patients with HMB. There is no section that treats the IDA which can be symptomatic. Although treatment for HMB may stop the problem this does not address the patients with low iron stores.	Thank you for this comment. The GDG have discussed the relationship between HMB and anaemia, and has reflected this in the recommendations.
Welsh Assembly Government				Thank you for giving the Welsh Assembly Government the opportunity to comment on the above guideline. We are content with the technical detail of the evidence supporting the provisional recommendations and have no further comments to make at this stage.	Thank you
Wirral Hospital NHS Trust	NICE	249	6	The 3 subdivisions of laparoscopic approach are correct. However on page 256 and onwards in comparing the laparoscopic approach to vaginal hysterectomy and abdominal hysterectomy, the three modes of the laparoscopic approach are not considered separately. LAVH is closer to vaginal hysterectomy than TLH and therefore the three methods cannot be considered as the same in the conclusions. Indeed TLH can be considered as abdominal hysterectomy carried out through small holes with increased vision. In the oncology world	Thank you for this comment. The GDG has now made a recommendation outlining the specific criteria for using laparoscopic surgery for HMB.

Organisation	Doc	Page no	Line no	Comments	Response
				randomised studies comparing LAVH and TLH have been carried out and suggest different risks. LAVH is merely vaginal hysterectomy with laparoscopic bilateral oophorectomy. Indeed line 12 page 256 and subsequent it points out that complications from LAVH and vaginal hysterectomy are not different. If it is appropriate to do TAH when ovaries need to be removed then it follows that women admitted for laparoscopic removal of ovaries should also be encouraged to only have abdominal removal of ovaries. Also it would follow that the vaginal approach should be abandoned for hysterectomy in favour of the abdominal approach. This is again confirmed in the study reported on page 263.	
Wirral Hospital NHS Trust	NICE	266		LAVH is preferential to TAH when ovaries are to be removed. Thus with regards LAVH it would suggest that in fact if vaginal Hysterectomy is to be recommended over TAH then the LAVH should also be recommended when the ovaries are to be removed. Of note there are no data presented on the complication rates of vaginal oophorectomy. With regards LH the data again is conflicting but the argument is probably in favour of TAH over this approach from the data presented. However, there are no data presented assessing the longer term risks Of wound hernia and it costs with the abdominal route. However, the assumption in the paper on cost analysis on this aspect does not adequately assess the theatre time costs. These will vary according to staff numbers in theatres, anaesthetic time, delay in getting patients from the wards to theatre, coffee breaks etc. The effect not only on bed stay but on the number of beds that the hospital has not been fully assessed. Also with this method and others the data presented is largely six years old and there has been a vast increase in laparoscopic surgical expertise and this has not been allowed for. Throughout the review there has not been enough emphasis on surgical skills and the expertise variations and hence how this	Thank you. A separate recommendation has been added on the use of laparoscopic surgery, For example, when undertaking oophorectomy.

Organisation	Doc	Page no	Line no	Comments	Response
				influences the choice in different centres. With regards TLH there are no data presented and indeed there are Series in the literature suggesting that in high risk women such as obesity then this approach is superior to TAH and indeed the inference with regards wound complication would suggest cost-effectiveness. Although only one reference is given there are several others revealed on a medline search. Although the data relates to endometrial cancer, the act of removing the uterus is the same. It would seem inappropriate that just because a women does not have cancer she is denied a TLH which has been shown in overweight women to be superior. Thus it would appear that in those cases where vaginal hysterectomy is not possible and the women is overweight, TLH is the approach of choice. In other situations there are no data available in the literature (or at least not considered in the guidelines).	
Wirral Hospital NHS Trust	NICE	276	10	Finally in the comparison on subtotal and total hysterectomy the laparoscopic approach is not even commented on despite large series in the literature. Thus the conclusions presented are not valid. They should read that vaginal hysterectomy is the route of choice. Where The ovaries are to be removed then LAVH is the mode of choice. Where the patient is high risk and vaginal hysterectomy is not possible then TLH is possibly the route of choice. Data presented on LH suggests that the role is possibly inferior to TAH. Ghezzi F, Cromi A, Bergamini V, Uccella S, Beretta P, Franchi M, Bolis. P.Laparoscopic-assisted vaginal hysterectomy versus total laparoscopic hysterectomy for the management of endometrial cancer: a randomized clinical trial. J Minim Invasive Gynecol. 2006 Mar-Apr;13(2):114-20. Bojahr B, Raatz D, Schonleber G, Abri C, Ohlinger R. Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique.J Minim Invasive Gynecol. 2006 May-Jun;13(3):183-9. Yu	Thank you for these references. They will be assessed for inclusion in the guideline. However, the majority are retrospective case-series, and therefore would be excluded from the guideline given that RCT and large prospective cohort data is available on the same subject.

Organisation	Doc	Page no	Line no	Comments	Response
				C KH, Cutner A, Mould T, Olaitan A. Total laparoscopic hysterectomy as a primary surgical treatment for endometrial cancer in morbidly obese women. BJOG. 2005;112:115-117.	
Wirral Hospital NHS Trust	General			What is the evidence base behind using Mirena an (interventional procedure) as a primary treatment with tranexamic acid/mefanemic acid as a secondary treatments? I found this document to be poorly referenced and It is difficult to track through the 600+ pages of evidence to establish the links. Whilst I appreciate the need to keep to timescales an 8 week consultation period including the summer is really limited as many respondents are on annual leave or covering colleagues and so unable to find time to respond.	<p>Thank you. The recommendation on pharmaceutical treatment is based on the available RCT evidence and experience of GDG members.</p> <p>The referencing to evidence tables will be examined.</p> <p>The timeline for the guideline was set by NICE.</p>
Women's Health Concern				This organisation was approached but did not respond.	
Wyeth Laboratories				This organisation was approached but did not respond.	